Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2271 (Ortega) – As Amended April 18, 2024

SUBJECT: St. Rose Hospital.

SUMMARY: Requires the Department of Health Care Access and Information (HCAI) to approve the forgiveness of two loans for the St. Rose Hospital (SRH) in the City of Hayward. Specifically, **this bill**:

1) Requires HCAI to approve the forgiveness of both of the following loans for SRH:
   a) The California Health Facility Construction Loan Insurance Law (LIL); and,
   b) The Distressed Hospital Loan Program (DHLP).

2) Requires HCAI to forgive the full amounts of the principal, interests, fees, and any other outstanding balances of the loans.

3) Finds and declares that a special statue is necessary because of the unique circumstances facing the City of Hayward and the surrounding areas of the County of Alameda with regard to the availability of a safety net hospital whose patients are overwhelmingly Medi-Cal beneficiaries.

EXISTING LAW:

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

2) Establishes the LIL within HCAI, to provide, without cost to the state, an insurance program for health facility construction, improvement, and expansion loans in order to stimulate the flow of private capital into health facilities construction, improvement, and expansion and in order to rationally meet the need for new, expanded and modernized public and nonprofit health facilities necessary to protect the health of all the people of this state. [HSC §129005]

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

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, SRH is a distressed safety net hospital that treats mostly low-income Medi-Cal and Medicare patients who often cannot find care anywhere else. It is the only emergency department (ED) in the City of Hayward. SRH's

current financial situation is dire; the hospital will face bankruptcy and possible closure in the next six months if another entity doesn't acquire the hospital. Alameda Health System (AHS), a public, state-created, hospital system, is in the bidding process to buy SRH, but requires financial assistance to do so.

The author states that this bill would forgive two of SRH's state loans to make it possible for AHS to acquire SRH and keep the hospital open: a) The LIL loan; and, b) The DHLP. If SRH were to close, the more than 150,000 residents of Hayward would be left without a safety net hospital or an ED and would be forced to drive 20 to 40 minutes to the nearest hospitals in surrounding cities. The author notes that we know that hospital closures and healthcare deserts are heavily correlated with a number of health risks, including increased maternal mortality rates. The author concludes that this bill is urgently needed to avoid a disastrous hospital closure and protect the health of the residents of Hayward and surrounding communities.

2) BACKGROUND.

a) SRH. SRH is a safety net community hospital with 117 beds and a payer mix composed primarily of Medi-Cal, Medicare and other governmentally covered vulnerable patient populations. According to information supplied by the author, late last year, it was determined by studies sponsored by a range of community stakeholders that SRH would likely not survive for much longer unless it became part of a larger and stronger health system, and the hospital issued a request for information from potential partners. As of April 15, SRH is currently in exclusive discussions with the AHS, with the goal of reaching a decision within 90 days. However, as a public hospital system itself, AHS is unable to retire or pay SRH's currently outstanding capital debt. The retirement of that debt would be required for a successful acquisition of the hospital and integration of SRH into AHS.

SRH currently has major outstanding debt in the form of a $17.2 million distressed hospital loan under DHLP. SRH also has a mortgage loan with an outstanding balance of approximately $21 million and a line of credit of $10 million, both from City National Bank and both insured by the Cal-Mortgage LIL program. While Cal-Mortgage would be obligated to assume responsibility for these loans if SRH were to default on them, there is nothing in Cal-Mortgage's enabling statute to permit Cal-Mortgage to proactively assume responsibility for repaying these loans.

This bill provides the statutory authority for HCAI to forgive the LIL loan, and requires HCAI to forgive the DHLP.

b) SRH annual reports. As part of then-Attorney General Kamala Harris' approval of SRH entering into a management services agreement with a purchase option with another entity in 2013, the Attorney General set certain conditions on the approval. One of the conditions was the submittal of annual reports to the Attorney General's office regarding compliance with the conditions. According to the 2022 report, like many community hospitals across the State of California and the United States, SRH has been adversely impacted by the COVID-19 pandemic. Since the start of the COVID-19 pandemic, SRH has experienced: i) decreasing patient volumes especially in its ED; ii) significant staffing challenges especially as it relates to nurse staffing; iii) restrictions that have affected its

ability to engage with the community and provide community benefits; and, iv) financial losses. First, due to the various stay-at-home orders and other restrictions in place due to the COVID-19 pandemic, SRH has seen a substantial decrease in its patient volumes when compared to pre-COVID-19 periods especially in its ED, labor and delivery unit, and inpatient surgical units. While some patient volumes have returned, the patient volumes have not returned to pre-COVID-19 levels.

The reduced patient volumes are described in this report as follows:

	2019	2020
ED Visits	32,572	27,797
Newborn Deliveries	503	327
Inpatient Surgeries	961	647

In addition, the AG Report indicates that SRH had the following payer mix in the last quarter of 2021:

	Discharges	Outpatient Visits
Medicare Traditional	30%	18%
Medicare Managed Care	12.5%	6.2%
Medi-Cal Traditional	12.5%	6.8%
Medi-Cal Managed Care	31%	41.2%

c) **HCAI LIL Program.** To be eligible for loan insurance, the borrower must be either a California nonprofit public benefit corporation (including a hospital) or a political subdivision. In addition, it must be organized to own and operate a health facility and assure that its services are, or will be, available to all persons residing in the facility's service area. Loans may be insured to finance or refinance the construction of new facilities; to acquire existing buildings; to expand, modernize, or renovate existing buildings; or, to finance fixed or movable equipment needed to operate the facility.

d) **DHLP.** AB 112 (Committee on Budget), Chapter 6, Statutes of 2023, established the DHLP, until January 1, 2032, which will provide interest free cashflow loans to not-for-profit hospitals and public hospitals, as defined, in significant financial distress, or to governmental entities representing closed hospitals. The DHLP is jointly administered by HCAI and the California Health Facilities Financing Authority (CHFFA). The following hospitals received a total of $300 million in financial support:

i) Beverly Hospital $5 million;
ii) Dameron Hospital Association $29 million;
iii) El Centro Regional Medical Center (El Centro) $28 million;
iv) **Hayward Sisters Hospital, dba St. Rose Hospital $17.65 million**;
v) Hazel Hawkins Memorial $10 million (subsequently declared bankruptcy and declined their loan award);
vi) John C. Fremont Healthcare District $9.35 million;
vii) Kaweah Delta Health Care District $20.75 million;
viii) Madera Community Hospital $2 million;
ix) Martin Luther King, Jr. Community Hospital $14 million;

x) Palo Verde Hospital $8.5 million;
xi) Pioneers Memorial Healthcare District $28 million;
xii) Ridgecrest Regional Hospital $5.5 million;
xiii) San Gorgonio Memorial Healthcare District $9.8 million;
xiv) Sonoma Valley Hospital $3.1 million;
xv) TriCity Medical Center $33.2 million; and,
xvi) Watsonville Community Hospital $8.3 million.

The loans are at zero-interest and are repayable over 72 months, with an initial 18-month grace period at the beginning of the loan term. The program will sunset on December 31, 2031. HCAI and CHFFA received 30 applicants for the program, however, not all hospitals were awarded funds. During the extensive loan application review process, HCAI considered a diverse set of criteria. Hospitals that demonstrated the greatest levels of financial distress, at-risk of closing in the near term, and had a well-founded plan to remain open and provide services and care, were prioritized and issued loans through the program. Hospitals that did not receive funds from the program demonstrated less financial distress when compared to other hospitals that applied.

AB 112 included language that requires HCAI, in consultation with CHFFA, and upon approval of the Department of Finance, to develop an application and approval process for loan forgiveness or modification of the terms of the loan, including a delay of the beginning of the loan repayment period or an extension of the 72-month loan repayment term, or both. The process must include, but is not limited to, eligibility criteria for an applicant for loan forgiveness or modification, including which portion of a loan may be forgiven or modified.

HCAI, in consultation with CHHSA and CHFFA, has initiated the development of loan forgiveness criteria and intends to release draft language for comment in the next few months. Awarded facilities have an initial 18-month grace period at the beginning of the loan term. As such, the forgiveness criteria will be completed well in advance of the beginning of the repayment timeframe.

e) AHS. AHS is an integrated public health care system of five hospitals and four wellness centers with over 800 beds and 1,000 physicians. AHS was founded in 1864 as Alameda County Infirmary. By the 1920s, the Fairmont Hospital emerged as the first public rehabilitation facility in the West. In 1927, Highland Hospital opened, opening its own school of nursing. The ‘60s brought an innovative network of neighborhood-based clinics for wellness and preventive care. John George Psychiatric Hospital opened in 1992, and the separate components consolidated into what is now AHS, employing over 4,500 individuals.

In 2013 AHS took over ownership of San Leandro Hospital from Sutter Health to ensure its ED remained open. Sutter Health had previously announced its intention to close the hospital. At the time, San Leandro Hospital was the sole acute care facility in San Leandro. Its ED served 26,478 people annually. The San Leandro City Council endorsed a plan proposed by Alameda County Supervisor Wilma Chan and advanced by San Leandro Mayor Stephen H. Cassidy for San Leandro to donate $1 million per year for three years. With other funding, the city's donation was intended to keep the hospital open until it could achieve profitability as part of its transfer to AHS. As part of the

transition, Sutter Health also established a $22 million fund to support the hospital's ongoing operations. Those funds were expended to fund the transition from 2013 to 2014.

3) **SUPPORT.** SRH is a sponsor of this bill and states that as a standalone community hospital which serves a disproportionate number of underinsured and uninsured patients, SRH has faced and continues to face financial challenges, questions about its sustainability, and questions about its future ability to meet the healthcare needs of the seniors and low-income patients that rely on SRH to meet their critical healthcare needs. For this reason, SRH's Board of Directors and management team have been pursuing affiliations with larger public or non-profit health systems for the past several years. SRH also participated in a study coordinated by a variety of community stakeholders which called for a well-recognized healthcare consultant to evaluate various options for SRH's long-term sustainability. This study identified an urgent need for SRH to pursue opportunities to become part of a larger health system as part of its efforts to ensure its long-term sustainability. SRH notes that opportunities to become part of a larger public or non-profit health systems are limited by SRH's long-term debt that is insured by HCAI's LIL Program and the debt under the DHLP. Larger public or non-profit health systems cannot assume this debt while at the same time fulfilling their important missions to the communities they serve and investing in the long-term sustainability of SRH. By addressing SRH's long-term debt this bill will substantially increase the likelihood that SRH will be able to join a larger public or non-profit health system and ensure its long-term sustainability. SRH concludes this will also allow SRH to continue to serve the communities especially those seniors and low-income residents of southern Alameda County that rely on SRH to meet their critical healthcare needs.

   AHS is a sponsor of this bill and states that it will make it possible for AHS to consider acquiring SRH, thereby preserving access to essential health care services for the residents of Hayward, California and the surrounding region.

   AHS is a California public hospital authority. AHS includes three acute care hospitals, a psychiatric hospital, four ambulatory care wellness centers, five post-acute facilities, and the only adult Level 1 Trauma Center and psychiatric ED in Alameda County. As the safety net health care system in Alameda County, AHS is devoted to serving the needs of all County residents, including residents of the City of Hayward, and has the requisite operational and clinical strengths to assist SRH in developing the programs, services and efficiencies necessary to become more financially viable.

   AHS notes that SRH is a critical provider of safety net services and one of three general acute disproportionate share hospitals in Alameda County. Despite protracted financial headwinds stemming from a challenging payer mix and decreasing utilization of its non-emergency services, SRH has continued to deliver services to the Hayward community. In 2023, in response to the Hospital's increasingly challenged financial situation, a group of stakeholders (including representatives of AHS) engaged a consulting firm to investigate the sustainability of SRH as a stand-alone hospital. In October 2023, the consulting firm recommended that SRH pursue an integrated affiliation with another health system. In December 2023, the SRH Board issued a Request for Information from hospital systems interested in such an affiliation.

   AHS understands and appreciates the importance of SRH as a safety net provider for the communities and patient populations it serves. At the same time, AHS also agrees with the

2023 consultant findings that SRH is unlikely to remain financially viable, or even survive, as a stand-alone community hospital in the present environment without becoming part of a stronger health system. For these reasons, in January 2024 AHS expressed a willingness to consider exploring the possibility of acquiring SRH in a way that strengthens SRH and improves its ability to continue to serve the residents of Hayward and Alameda County.

However, AHS notes that it is also an essential public safety net health system, and would be unable to acquire SRH if doing so would require AHS to assume responsibility for the SRH's outstanding debts. AHS concludes that for this reason, the enactment of this bill is essential to ongoing deliberations regarding this potential acquisition, and thus to the ability of SRH to continue providing access to essential emergency and hospital services to the residents of Hayward and the surrounding region.

4) **RELATED LEGISLATION.** AB 2098 (Garcia) extends the repayment requirements for nondesignated public hospitals participating in a CHFFA loan program. AB 2098 is pending in the Assembly Appropriations Committee.

5) **PREVIOUS LEGISLATION.**

a) AB 112 established the DHLP, until January 1, 2032, which provides interest free cashflow loans to not-for-profit hospitals and public hospitals, as defined, in significant financial distress, or to governmental entities representing closed hospitals. Requires HCAI to administer the DHLP and to enter into an interagency agreement with CHFFA to implement the DHLP.

b) AB 1131 (Garcia) of 2023 would have established the Hospitals First Revolving Fund, administered by HCAI, to offer grants and low-cost loans to hospitals in rural and medically underserved communities to prevent the closure of a hospital or facilitate the reopening of a closed hospital. AB 1131 was held in the Assembly Appropriations Committee.

c) SB 45 (Roth) would have established the California Acute Care Psychiatric Hospital Loan Fund within CHFFA and would continuously appropriate moneys in that fund to CHFFA to provide loans to qualifying county or city and county applicants for the purpose of building or renovating acute care psychiatric hospitals, psychiatric health facilities, or psychiatric units in general acute care hospitals, as defined. Would have required CHFFA to develop an application for county or city and county applicants by January 1, 2025. SB 45 was held in the Assembly Appropriations Committee.

REGISTERED SUPPORT / OPPOSITION:

Support
Alameda Health System (cosponsor)
Hayward Sisters Hospital Dba St. Rose Hospital (cosponsor)

Opposition
None on file

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Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2348 (Rodriguez) – As Amended April 1, 2024

SUBJECT: Emergency medical services.

SUMMARY: Requires a local emergency medical services authority (LEMSA) to adopt policies and procedures for calculating and reporting ambulance patient offload times. Requires the Emergency Medical Services Authority (EMSA), to develop a statewide standard methodology for the calculation and reporting by a LEMSA, of response times for emergency ambulance services, and exemptions to those required times, provided in exclusive operating areas (EOAs), as defined. Specifically, **this bill**:

1) Adds a requirement for EMSA to develop planning and implementation guidelines for response and transportation, including response times and exemptions, as well as quality improvement and disaster medical response.

2) Requires EMSA to develop, using input from stakeholders, including, but not limited to, hospitals, LEMSAs, and public and private emergency medical services (EMS) providers, and, after approval by the Emergency Medical Services Commission (Commission) described in 6) of existing law below, a statewide standard methodology for the calculation and reporting by a LEMSA of contract ambulance response time response times for emergency ambulance services provided in EOAs and ambulance patient offload time.

3) Requires a LEMSA to adopt policies and procedures for calculating and reporting response times, as defined, for emergency ambulance services providers operating under an EOA.

4) Defines, for purposes of this bill, "response time" to means the interval between the point in time when the address or location is received by the responding EMS provider's dispatch center and the point in time that the transporting ambulance unit arrives at the provided address or location.

5) Requires EMSA to ensure the EMS system planning and implementation guidelines for response times comply with all of the following requirements:
   a) Include a list of standardized terminology for LEMSAs to use when granting exemptions or when modifying original response time data for any publicly reported 911 response times required by this bill. Requires the list of standardized terminology to include the following terms and definitions:
      i) "Cancelled calls" means an EMS response in which the responding unit is notified and begins the response, but the response is terminated prior to responding to the EMS unit arrival on scene using predefined objective criteria;
      ii) "Do not count" means an EMS response generated within the computer-aided dispatch (CAD) incident data that, upon review, does not satisfy the criteria for an EMS response that is subject to compliance monitoring using predefined objective criteria;
      iii) "Exemption" means an EMS response where the incident data is administratively excluded from the CAD data used to calculate response interval compliance using predefined objective criteria; and,

iv) "Time correction" means an EMS response where defined points in time in the CAD incident data are administratively modified from the original CAD incident data using predefined objective criteria.

b) Requires the list of standardized terminology described in a) above to include common reasons for granting exemptions from 911 response times in the various emergency medical services areas of the state.

6) Requires a LEMSA to adopt policies and procedures for calculating and reporting ambulance patient offload time (APOT).

7) Requires a LEMSA to use the statewide standard methodology for calculating and reporting response interval performance developed by EMSA pursuant to 2) above.

8) Requires a LEMSA, when establishing response time compliance requirements, to weigh the risk to the safety of the responding crew and public against the severity of the medical emergency when determining what level of response and time allotment to require from an emergency ambulance services provider.

9) Requires LEMSA response times reporting to include data from all emergency ambulance services providers operating in EOAs where the annual transport volume of all emergency ambulance transports within an exclusive operating area exceeds 10,000 transports per calendar year within their jurisdiction.

10) Requires a LEMSA to report emergency ambulance services provider response times to EMSA in a data dispatch form that is consistent with the California Emergency Medical Services Information System (CEMSIS) and the National Emergency Medical Services Information System (NEMSIS) standards, as specified by EMSA, including with the following:
    a) The point in time that the public safety agency dispatch center receives the EMS call;
    b) The point in time that the EMS provider's dispatch center that is responsible for directly dispatching the ambulance unit receives EMS caller data from a public agency dispatch center;
    c) The point in time that the responding ambulance unit is notified of EMS caller data by dispatch;
    d) The point in time that the ambulance unit is en route; and,
    e) The point in time that the ambulance unit arrives on scene.

11) Requires a LEMSA to make response times publicly available monthly on the LEMSA internet website both in raw form and on a 90th percentile fractal compliance scale. Defines for purposes of this provision, "raw form" to mean the response time prior to administrative exemptions or modification.

12) Requires the LEMSA to include on the LEMSA's internet website the response times provided to the LEMSA by an emergency ambulance services provider.

13) Defines, for purposes of 10) above, "EMS caller data" to mean the address or location of the emergency.

14) Requires an emergency ambulance services provider to report response times to the LEMSA that has jurisdiction over the provider.

15) Specifies that this bill does not apply to calls not originating in the 911 system and does not prohibit a LEMSA from reporting response interval compliance from emergency ambulance services providers that are not in an EOA.

16) Specifies that this bill does not prohibit LEMSAs from granting exemptions that do not use the terminology established by EMSA when the reason for granting the exemption does not meet the definition of a term established by EMSA, and does not prohibit a LEMSA, when utilizing standardized terminology to grant exemptions from 911 response times, from including additional information or rationales when granting exemptions.

17) Requires a LEMSA annual EMS plan to include the LEMSAs annual budget.

18) Requires EMSA to approve or request changes to a LEMSAs proposed plans within 90 calendar days of receipt.

19) Requires a LEMSA to make the plan accessible on the agency's internet website within 30 calendar days of approval by EMSA.

20) Requires EMSA to make each LEMSAs plan submitted to EMSA accessible on the EMSA's internet website within 30 calendar days of approval by EMSA.

21) Requires a LEMSA to include in the annual EMS plan all of the following:
    a) The list of administrative exemptions approved by the local EMS agency, if any, relating to 911 response time performance standards;
    b) The list of administrative modifications relating to reported response time performance standards approved by the LEMSA, if any; and,
    c) Any exemptions from meeting 911 response times granted by the LEMSA in the previous calendar year.

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) §179.100]

2) Requires EMSA, utilizing regional and local information, to assess each EMS area or the system's service area for the purpose of determining the need for additional emergency services, and the coordination and effectiveness of EMS. Requires EMSA to develop planning and implementation guidelines for EMS systems which address specified components, including communications, system organization and management, and data collection and evaluation. [HSC §179.102]

3) 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]

4) Requires, upon the request of a city or fire district that contracted for or provided, as of June 1, 1980, prehospital EMS, a county to enter into a written agreement with the city or fire district regarding the provision of prehospital EMS for that city or fire district. Requires, until such time that an agreement is reached, prehospital EMS to be continued at not less than the existing level, and the administration of prehospital EMS by cities and fire districts presently providing such services to be retained by those cities and fire districts, except the level of prehospital EMS may be reduced where the city council, or the governing body of a fire district, pursuant to a public hearing, determines that the reduction is necessary. [HSC § 1797.201]

5) Authorizes a LEMSA to create one or more exclusive operating areas (EOAs) in the development of a local plan, if a competitive process is utilized to select the provider or providers of the services pursuant to the plan. Specifies that no competitive process is required if the LEMSA develops or implements a local plan that continues the use of existing providers operating within a local EMS area in the manner and scope in which the services have been provided without interruption since January 1, 1981. Requires a LEMSA which elects to create one or more EOAs in the development of a local plan to develop and submit for approval to EMSA, as part of the local EMS plan, its competitive process for selecting providers and determining the scope of their operations. Requires this plan to include provisions for a competitive process held at periodic intervals. [HSC §1797.224.]

6) Establishes the 18-member Commission, within the California Health and Human Services Agency. Defines the duties of the Commission to include reviewing regulations, standards, and guidelines developed by EMSA; advising EMSA on a data collection system; advising on emergency facilities and services, emergency communications, medical equipment, personnel training, and various aspects of the EMS system; and, to make recommendations for further development of the EMS system. [HSC §1799 and 1799.2]

7) Requires EMSA, by no later than December 31, 2024, to develop and implement a CEMSIS requirement for an electronic signature for use between the emergency department (ED) medical personnel at a receiving hospital and the Emergency Medical Technician, Advanced Emergency Medical Technician, or Emergency Medical Technician-Paramedic that captures the points in time when the ambulance arrives at the hospital ED bay and when transfer of care is executed for documentation of APOT, as defined. Requires the signature to be collected when physical transfer of the patient occurs and the report is given to hospital staff and to note ambulance arrival time at the hospital. Requires, by no later than July 1, 2024, every LEMSA to develop a standard not to exceed 30 minutes, 90% of the time, for APOT and report the adopted time to the authority. [HSC § 1797.120.5.(a)]

8) Defines APOT as the interval between the arrival of an ambulance patient at an ED and the time that the patient is transferred to an ED gurney, bed, chair, or other acceptable location and the ED assumes responsibility for care of the patient. [HSC § 1797.120.]

9) Defines “response time” to mean the interval between the point in time when the address or location is received by the responding EMS provider’s dispatch center and the point in time that the transporting ambulance unit arrives at the provided address or location. [*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, LEMSAs are responsible for planning, coordinating, and improving local emergency and medical response systems. LEMSAs primarily work to organize prehospital services. Their plans provide policies for system organization and management, staffing and training, communication, response and transportation for emergency services, facilities and critical care, data collection and system evaluation, public information and education, disaster medical response, and more. The author states that by requiring LEMSAs and EMSA to post approved plans on their websites, we can increase transparency for policymakers, stakeholders, and residents who want to see how emergency management officials are planning for response and care. Additionally, requiring ambulance providers to report publicly and to EMSA their 911 response times, and having LEMSAs make public their budgets and exemptions for not meeting 911 response time standards, we can see what may be hindering emergency response, either in planning, response, or simply unpredictable circumstances. The author concludes that this transparency and additional data will help EMSA and LEMSAs in their EMS planning and quality improvement efforts.

2) **BACKGROUND.** EMSA is the lead agency and centralized resource to oversee emergency and disaster medical services. Day-to-day EMS system management is the responsibility of the local and regional LEMSAs. California has 34 LEMSA systems that provide EMS for California's 58 counties. Regional systems are usually comprised of small, more rural, less-populated counties and single-county systems generally exist in the larger and more urban counties. There are seven regional EMS agencies comprised of 32 counties and 26 single-county LEMSAs. Both single and multi-county LEMSAs develop and submit five-year EMS plans and annual updates to EMSA for a local EMS system according to the state system standards and guidelines. The purpose of the local EMS plans is to meet community EMS needs through the effective utilization of local resources. Between 2019 and June 2022, there were 33 LEMSAs. In July 2022, Stanislaus County separated from Mountain-Valley EMS (a multi-county LEMSA) bringing the total number of LEMSAs to 34.

   The EMS Act comprehensively regulates emergency medical care in California. Enacted in 1980, the Act provides for the creation of emergency medical procedures and protocols, certification of emergency medical personnel, and coordination of emergency responses by fire departments, ambulance services, hospitals, specialty care centers, and other providers within the local EMS system. HSC §1797.201 (Section 201), generally known as "201 rights," was added late in the legislative process that led to the passage of the EMS Act. Section 201 was included to address concerns some cities expressed about the EMS Act's potential impact on their authority to continue providing EMS programs they had previously started in their cities.

   a) **Creation of EOAs**. Health and Safety Code §1797.224 permits a local EMS agency to create one or more EOAs for emergency services, including ambulance transport, when developing an EMS plan, if a competitive process is utilized to select the provider or providers of the services pursuant to the plan (although no competitive process is required if the plan continues the use of existing providers operating without interruption since January 1, 1981). When a LEMSA elects to create an exclusive operating area, it is required to submit for approval to EMSA, as part of the local EMS plan, its competitive process for selecting providers and determining the scope of their operations. The plan is

also required to include provisions for a competitive process to be held at periodic intervals.

This bill requires response time reporting by EMS providers operating in an EOA.

b) Annual reports. EMSA is mandated to annually report on the effectiveness of EMS systems and related impact on death and disability. State law further identifies that one of the required elements of an EMS system is data collection and evaluation. EMSA meets these mandates by collecting data from the LEMSAs.

According to EMSA, "data collected serves to provide an image of the EMS system, the number and types of patients being cared for, and the EMS and hospital institutions and individuals who are providing that care. As more data becomes available to the EMSA, that image will sharpen. As the reliability of the data improves, answers to questions about the quality of the care provided to EMS patients will be possible. And finally, EMSA's concurrent effort to integrate EMS data with existing data streams drawn from the spectrum of medical care using Health Information Exchange promises to answer questions about the impact of EMS care on patient outcomes. EMSA's converging data objectives will, together, allow California to at last measure the value that EMS adds to the health care system."

c) Emergency Medical Directors Association of California (EMDAC) Recommended Response Time Intervals. Some LEMSAs use the following Response Call Intervals, as recommended by EMDAC, as benchmarks:

i) Basic Life Support with AED on scene – 5 minutes from time of first ring at primary Public Safety Answering Point (PSAP) to vehicle arrival at the scene with the wheels stopped;

ii) Advanced Life Support – 10 minutes from time of first ring at primary PSAP to vehicle arrival at the scene with the wheels stopped; and,

iii) Patient Transport Vehicle – 12 minutes from time of first ring at primary PSAP to vehicle arrival at the scene with the wheels stopped.

Across EMS, response times are used as a process indicator to assess emergency medical services provider's performance across the country. Response times are objective, quantifiable, and easily understood by the public and policy makers.

d) Quality Improvement (QI). QI in EMS is the intentional process of making system-level changes in clinical processes with a continuous reassessment to improve the delivery of high-quality prehospital care. Effective QI programs are transparent; both administration and clinical staff understand the goals and methods of any ongoing quality improvement project. QI programs often use Key Performance Indicators (KPIs) to measure ongoing clinical performance, identify areas for improvement, and assess the impact of process changes. EMS systems generally build their KPIs on clinical evidence, a perceived system deficit, or an operational need. The goal of QI is to develop a high-reliability organization that operates in a relatively error-free state over a long period of time.

e) NEMSIS and CEMSIS. NEMSIS was formed in 2001 by the National Association of State EMS Directors, in conjunction with the National Highway Traffic Safety

Administration and the Trauma/EMS Systems program of the Health Resources and Services Administration's Maternal and Child Health Bureau, in order to develop a national EMS database. NEMSIS is the national repository that will be used to potentially store EMS data from every state in the nation, and was developed to help states collect more standardized elements to allow submission to the national database.

CEMSIS is a demonstration project for improving EMS data analysis across California. CEMSIS offers a secure, centralized data system for collecting data about individual EMS requests, patients treated at hospitals, and EMS provider organizations. CEMSIS uses the NEMSIS standard for how patient care information resulting from a 911 call for emergency assistance is collected. Thirty-three of California's 34 LEMSAs currently send a variety of local data collections to CEMSIS on a voluntary basis, and in return, these local agencies gain access to digital tools for running comprehensive reports on their own data at no cost.

f) Importance of Response Times. Emergency medical services (EMS) provide critical prehospital care, and disparities in response times to time-sensitive conditions, such as cardiac arrest, may contribute to disparities in patient outcomes. A 2018 *Journal of the American Medical Association* study, "Association Between Income and Ambulance Response Time in Cardiac Arrest," demonstrates that total EMS time for cardiac arrest incidents is longer and that a lower proportion of 911 calls meets national ambulance response time benchmarks in low-income compared with high-income neighborhoods. The study found a persistent and significant time difference between high-income and low-income zip codes, even after controlling for common EMS system demand indicators, such as weekday and time of day to account for traffic. The findings are particularly concerning given the time sensitivity of conditions like cardiac arrest in which the heart has ceased functioning and immediate medical care is required to restore function and circulation. Patients with cardiac arrest from the poorest neighborhoods had longer EMS times that were less likely to meet national benchmarks compared with those from the wealthiest neighborhoods, which may lead to increased disparities in the delivery of prehospital care over time.

The author states that the data generated by this bill should contribute to LEMSA and EMSA QI programs.

3) **SUPPORT.** The California Fire Chiefs Association (CalChiefs) and the Fire Districts Association of California (FDAC), support this bill and state that it would require EMSA and LEMSAs to engage in a number of planning and reporting actions to increase transparency and improve emergency response. EMSA would be required to develop a standardized list of exemptions that LEMSAs give to their contracted ambulance providers and LEMSAs would be required to report any such granted exemptions as part of their annual plans. This bill would also require that both EMSA and LEMSAs publish annual plans on their websites, an already commonplace practice that ensures transparency for the public. CalChiefs and FDAC conclude that this bill would also require ambulance providers to report their 911 response times so that the public and policymakers have a clear picture of emergency response in the state.

4) **RELATED LEGISLATION.** AB 2973 (Hart) authorizes a county board of supervisors or the governing body of an entity or a LEMSA to provide or support the provision of EMS to

persons located within the county. Requires a county board of supervisors or a LEMSA to adopt a written policy setting forth requirements for an emergency ambulance services provider in order to enter into a contract with a provider for emergency ambulance services. AB 2973 is pending in the Assembly Health Committee.

5) **PREVIOUS LEGISLATION.** AB 379 (Rodriguez) of 2023 was substantially similar to this bill. AB 379 was held in Senate Appropriations.

6) **DOUBLE REFERRAL.** This bill is double referred, it passed the Assembly Committee on Emergency Management with a vote of 7-0 on April 8, 2024.

7) **SUGGESTED AMENDMENT.** As currently drafted this bill only requires reporting of response times in EOAs. The Committee may wish to amend this bill to apply to all EMS service providers, whether they are in an EOA or not.

REGISTERED SUPPORT / OPPOSITION:

Support

California Fire Chiefs Association (cosponsor)
Fire Districts Association of California (cosponsor)
Global Medical Response

Opposition

None on file

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2352 (Irwin) – As Amended April 10, 2024

SUBJECT: Behavioral health and psychiatric advance directives.

SUMMARY: Specifies the requirements for formation of a written or digital psychiatric advance directive (PAD) and specifies how a PAD may be used in numerous healthcare and legal settings. Specifically, **this bill**:

Creates PAD Requirements

1) Defines "PAD" as a legal written or digital document, executed on a voluntary basis in accordance with the requirements for advance health care directives (AHCD) by a person who has the capacity to make physical and behavioral health decisions, that allows a person with behavioral health illness to protect their autonomy and ability to direct their own care by documenting their preferences for treatment, as specified, and identifying a health care advocate, if chosen, in advance of a behavioral health crisis. Specifies a PAD does not include power of attorney for health care and allows a PAD to be a standalone document.

2) Provides that a PAD is legally sufficient if all of the following requirements are satisfied:
   a) The PAD contains the date of its execution;

   b) The PAD is signed by the individual and, if a health care advocate is chosen, signed by the health care advocate acknowledging and accepting appointment, or, if a health care advocate is not identified, signed by one additional adult in the individual's presence and at the individual's direction; and,

   c) The PAD is signed by one additional witness who is not related to the individual. Specifies the witness may be an employee or contractor of a behavioral health plan.

3) Defines "health care advocate" to mean an individual chosen by the person creating the PAD who is in agreement to uphold the person's preferences for treatment in the case of a behavioral health crisis. Prohibits the health care advocate's acceptance of appointment from allowing for power of attorney for health care decisions. The health care advocate's appointment is considered valid with a legal signature on the written or digital PAD.

4) Includes the following statutory language for a witness to a PAD to sign:

   "I declare under penalty of perjury under the laws of California (1) that the individual who signed or acknowledged this AHCD or PAD is personally known to me, or that the individual's identity was proven to me by convincing evidence (2) that the individual signed or acknowledged this AHCD or PAD in my presence (3) that the individual appears to be of sound mind and under no duress, fraud, or undue influence (4) that I am not a person appointed as surrogate by this AHCD or PAD, and (5) that I am not the individual's health care provider, an employee of the individual's health care provider, the operator of a community care facility, an employee of an operator of a community care facility, the

operator of a residential care facility for the elderly, nor an employee of an operator of a residential care facility for the elderly."

5) Includes the following additional statutory language for a witness who is a non-family member to sign:

   "I further declare under penalty of perjury under the laws of California that I am not related to the individual executing this AHCD or PAD by blood, marriage, or adoption, and, to the best of my knowledge, I am not entitled to any part of the individual's estate upon his or her death under a will now existing or by operation of law."

Adds PAD to Existing AHCD Laws

6) Clarifies that a valid and effective PAD, like an AHCD, applies to the treatment of a person who is placed in a mental health treatment facility.

7) Clarifies that a valid and effective PAD, like an AHCD, applies to the treatment of a person who is a ward or conservatee.

8) Clarifies that a written or digital PAD may include the individual's nomination of a health care advocate.

9) Clarifies that unlike an AHCD, a PAD is not required to be notarized and, like an AHCD, can be signed with a digital signature that meets specified criteria.

10) Allows an appeal to be taken with respect to a PAD, like an appeal respecting an AHCD, from either of the following:
    a) Any final order under Probate Code Section (PROB) § 4766, determining among other things, whether or not a patient has capacity to make health care decisions; or,
    b) An order dismissing the petition or denying a motion to dismiss under § PROB 4768 (which allows a court to dismiss a petition if it appears that the proceeding is not reasonably necessary for the protection of the interests of the patient).

11) Provides that a written AHCD, written or digital PAD, or similar instrument executed in another state or jurisdiction in compliance with the laws of that state or jurisdiction or of this state, is valid and enforceable in this state to the same extent as a written AHCD or PAD validly executed in this state; and in the absence of knowledge to the contrary, a physician or other health care provider may presume that a written AHCD, written or digital PAD or similar instrument, whether executed in another state or jurisdiction or in this state, is valid.

12) Provides that a health care provider, health care service plan, health care institution, disability insurer, self-insured employee welfare plan, or nonprofit hospital plan or a similar insurance plan may not require or prohibit the execution or revocation of an AHCD or PAD as a condition for providing health care, admission to a facility, or furnishing insurance.

13) Clarifies that nothing prohibits the execution of a voluntary standalone PAD.

14) Prohibits a health care provider or plan of any kind from requiring or prohibiting an AHCD or PAD as a condition for providing care.

15) Provides that a patient having capacity can revoke a PAD, just as they can revoke an agent or an AHCD.

16) Requires a provider, agent, or conservator to promptly communicate any revocation of a PAD, like an AHCD.

17) Provides that, like an AHCD, a PAD that conflicts with an earlier PAD revokes the earlier PAD to the extent of the conflict.

18) Adds PADs to the existing statutory AHCD form and explanation.

19) Requires health care providers to record the existence of a PAD, like an AHCD, and to request a copy of the PAD.

20) Provides that a PAD, like an AHCD, is exercisable free of judicial intervention and effective without judicial approval.

21) Requires the registry system for AHCDs established by the Secretary of State (SOS) to include a registry for PADs and for the SOS to establish and make available upon request, provide a registry card, and to provide privacy protections.

22) Requires the SOS to establish procedures to advise registrants that a standalone digital PAD may be accessed in a cloud-based setting or provided as a printed document.

23) Provides that failure to register with the SOS does not affect the validity of a PAD; provide superiority of a PAD, or affect the ability to revoke a PAD.

24) Clarifies that 21) through 23) above do not affect the duty of a behavioral health care provider from providing information to a patient regarding AHCDs or PADs pursuant to any provision of federal law.

25) Requires the SOS and State Department of Health Services to develop information regarding PADs with links available on internet sites.

Integrates PADs into Various Programs and Processes

26) Requires a court, in determining whether a conservatorship is the least restrictive alternative available, and whether to grant or deny a conservatorship petition, to consider the person's abilities and capacities with current and possible supports, including, but not limited to, supported decision making agreements, and PADs.

27) Requires that for purposes of the conservatorship alternatives program in court self-help centers, the centers are required to provide information relating to PADs as one of the less restrictive alternatives to conservatorship.

28) Requires at the last hearing before a minor or non-minor dependent ages out of foster care that a PAD form is provided to the minor or non-minor dependent.

29) Requires the 90-day transition plan prepared for a minor or non-minor dependent who is transitioning out of foster care to include information about creating a PAD and choosing a health care advocate, as well as a PAD written or digital form.

30) Modifies the definition of "crisis intervention" for purposes of the Lanterman-Petris-Short Act (LPS Act) to include a "health care advocate" in the list of persons who may be interviewed by qualified professionals that is designed to "alleviate personal or family situations that present a serious and imminent threat to the health or stability of the person or the family" and includes a PAD as one of the services that may be sought for the stability of the person or the family.

31) Modifies the definition of "pre-petition screening" for purposes of the LPS Act to include a PAD in the list of interventions that a person should be persuaded to receive on a voluntary basis.

32) Adds "health care advocate" to the list of persons on the statutory form who should be advised when a person is detained for a 72-hour evaluation.

33) Requires the designated facility to keep, for each patient evaluated, a record of the advisement given pursuant to 29) above which must include, among other requirements, whether the person detained has an AHCD or a PAD.

34) Requires a supporter in a Community Assistance, Recovery, and Empowerment (CARE) Act process to, among other requirements of existing law, provide information to the respondent about AHCDs and PADs.

35) Provides that a respondent in a CARE proceeding may have a supporter present in any meeting, judicial proceeding, status hearing, or communication related to interacting or communicating with the chosen health care advocate.

36) Prohibits that unless explicitly authorized by the respondent with capacity to make that authorization, a supporter in a CARE proceeding from creating a PAD.

37) Provides that a CARE plan may include a PAD.

Updates Terminology and Definitions

38) Provides that a behavioral health care provider, like a physical health care provider, who is acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for any actions in compliance with this division, including, but not limited to, any of the following conduct:

    a) Complying with a health care decision of a person that the health care provider or health care institution believes in good faith has the authority to make a health care decision for a patient, including a decision to withhold or withdraw health care;
    b) Declining to comply with a health care decision of a person based on a belief that the person then lacked authority;

c) Complying with an AHCD and assuming that the directive was valid when made and has not been revoked or terminated; and,
d) Declining to comply with an individual health care instruction or health care decision.

39) Provides that any behavioral health care provider, like a physical health care provider, who intentionally violates this part is subject to liability to the aggrieved individual for damages of two thousand five hundred dollars ($2,500) or actual damages resulting from the violation, whichever is greater, plus reasonable attorney's fees; and any person who falsifies, forges, or revokes a PAD without consent is liable for damages of ten thousand dollars ($10,000) or actual damages resulting from the action, whichever is greater, plus reasonable attorney's fees.

40) Makes the definition of PAD in 1) above applicable to all code sections in which the term "psychiatric advance directive" is used.

41) Changes "mental health" to "behavioral health" throughout the codes.

42) Makes numerous other minor, conforming, and non-substantive changes.

EXISTING LAW:

1) Provides that an AHCD is either an individual health care instruction or a power of attorney for health care. [PROB §4605]

2) Defines "health care" as any care, treatment, services, or procedure to maintain, diagnose, or otherwise affect a patient's physical or mental condition. [PROB §4615]

3) Defines "individual health care instruction" as an individual's authorized written or oral direction concerning a health care decision for the individual. [PROB §4623]

4) Defines "health care decision" as a decision made by an individual or an individual's agent, conservator, or surrogate, regarding that individual's health care, including selection and discharge of health care providers and institutions, approval or disapproval of diagnostic tests, surgical procedures, and programs of medication, and directions to provide, withhold, or withdraw artificial nutrition and hydration and all other forms of health care, including cardiopulmonary resuscitation. [PROB §4617 (a)]

5) Clarifies that "health care decision" does not include a decision made by a patient's agent, conservator, or surrogate to consent to treatments identified in 7), below. [PROB §4617 (b)]

6) Provides that an adult having capacity may execute a power of attorney for health care, which may authorize the agent to make health care decisions. [PROB §4671]

7) States that consent to any of the following on behalf of a patient is not authorized:

a) Commitment to or placement in a mental health treatment facility;
b) Convulsive treatment;
c) Psychosurgery;
d) Sterilization; and,
e) Abortion. [PROB § 4652]

8) States that it is the intent of the Legislature to promote the use of a PAD, subject to the requirements of this bill, by a person who wants to make sure their health care providers know their treatment preferences in the event of a future mental health crisis. [PROB §4679 (b)]

9) States legislative findings and declarations that:
   a) Research has demonstrated that the use of PADs improves collaboration, which improves outcomes, increases empowerment, and improves medication adherence;
   b) A PAD is most helpful when it includes reasons for preferring or opposing specific types of treatment; and,
   c) Mental health preferences that do not constitute health care instructions or decisions as defined in this bill may provide valuable information to improve an individual's mental health care. [PROB §4679 (c)]

10) Defines "PAD" to mean a legal document, executed on a voluntary basis by a person who has the capacity to make medical decisions that allows a person with mental illness to protect their autonomy and ability to self-direct care by documenting their preferences for treatment in advance of a mental health crisis. [PROB §4679 (a)(2) & Welfare & Institutions Code (WIC) §5971 (n)]

11) Establishes the LPS Act 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. Permits involuntary detention of a person deemed to be a danger to self or others, or "gravely disabled," as defined, for periods of up to 72 hours for evaluation and treatment, or for up-to 14 days and up-to 30 days for additional intensive treatment in county-designated facilities. [WIC §5000, *et seq*.]

12) Establishes the CARE Court Program which facilitates a court-ordered plan for individuals facing mental health or substance use disorders, initiated by family, county and community-based social services, behavioral health providers, or first responders [WIC §5970, *et seq*.]

13) Defines "Graduation plan" (from CARE program) to mean "a voluntary agreement entered into by the parties at the end of the CARE program that includes a strategy to support a successful transition out of court jurisdiction and that may include a PAD. A graduation plan includes the same elements as a CARE plan to support the respondent in accessing community-based services and supports." Prohibits the graduation plan from placing additional requirements on the local government entities and states that it is not enforceable by the court. [WIC §5971 (h)]

14) Provides that in CARE proceedings, when the respondent elects to be graduated from the program, the graduation plan may, at respondent's election, include a PAD, which shall have the force of law. Specifies that upon completion of the hearing, the respondent is officially graduated from the program. [WIC §5977.3 (a)(3)(A)]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, a behavioral health crisis is one of the most challenging experiences anyone can face and without a roadmap the situation can snowball for the individual in crisis, the first responders and health care professionals providing treatment, and the family and friends advocating for their loved one. The author continues that PADs are a tool meant to empower an individual with behavioral health challenges to support their decision making, communicate how to appropriately provide them care, and help de-escalate potential crisis situations. The author argues that PADs are woefully underutilized since many individuals are unaware of their existence, and most first responders and health care professionals lack access to them. The author concludes that this bill seeks to build out a legal framework for PADs in California, which will work in tandem with a pilot project already underway in seven counties across the state to expand use of PADs, and ensure access to first responders and health care professionals.

2) **BACKGROUND.**

   a) **ACHDs.** An AHCD is a document providing guidance or instructions for making health care decisions that contains either an individual health care instruction, or a power of attorney for health care, or both. The AHCD may assist in guiding inpatient treatment decisions, and is recommended for all adults, regardless of their health status. The advantage of an AHCD is that it can articulate in detail the wishes of the individual for numerous circumstances related to health care treatment, including mental health treatment, and allows the individual to designate an appointed agent to make health care decisions on that person's behalf, should that person ever become incapacitated. An AHCD is generally only applicable when the individual no longer has the capacity to make their own health care decisions**.**

      Existing law establishes the process, and provides a statutory form, for an individual to give instructions for health care decisions. The AHCD form allows an individual, with capacity to make decisions and to select an agent to make health care decisions if the individual is not able to do so. The directive also allows the individual to make end-of-life health care choices, including the choice to prolong, or not prolong, life and to seek relief from pain. Providers also have some discretion in following an AHCD. They may decline to follow an AHCD if it would violate their professional standards of care or for "reasons of conscience." Existing law also allows individuals to use AHCDs for mental health and treatment.

   b) **PADs.** Twenty-seven states, excluding California, have implemented standalone mental-health specific directives known as PADs. PADs memorialize a person's preferences for future mental health treatment and allow for a proxy in the event of a mental health crisis. Though PADs vary by state, they may contain questions prompting an individual to specify whether, in the event they are incapable of consenting to mental health treatment, they consent to the use of specific psychotropic medications; the administration of electroconvulsive treatment; admission to a facility for mental health treatment; preferences for seclusion and restraint; and, preferences for pre-emergency mental health interventions.

According to the Substance Abuse and Mental Health Services Administration (SAMHSA) 2019 report, "A practical Guide to PADS," these forms offer several advantages. For example, similar to an AHCD, a PAD may allow an individual to retain autonomy over treatment choices in psychiatric emergencies, and, in the event of a psychiatric crisis resulting in hospitalization, a PAD may facilitate a conversation with the patient about their treatment.

SAMHSA reports that people who complete a PAD tend to experience significant improvement in working alongside their clinicians, fewer coercive crisis interventions, better correspondence between preferred and prescribed medications over time, and increased perception that their personal needs for mental health services are being met. Given that people of color are hospitalized for psychiatric reasons at a higher rate than whites, PADs have the potential to help address inequities in mental health care by reducing the likelihood of unnecessary involuntary treatment and helping to ensure that any treatment provided aligns with the patient's preferences.

c) Pilot program for PAD development. Six counties (Contra Costa, Fresno, Mariposa, Monterey, Orange, Shasta), as well as the Tri-City Mental Health Authority (cities of Pomona, Claremont, and La Verne), are involved in an ongoing project, the Multi-County PADs Innovations Project, that began in July of 2021 and is scheduled to end on June 30, 2025. The project is funded by the Mental Health Service Act (MHSA) and seeks to expand and facilitate the use of PADs in California. It has received approval from the Mental Health Services Oversight and Accountability Commission (MHSOAC) to "use Innovation Funds to develop the infrastructure for sustainable PADs usage in the state of California."

One key goal of the counties is to have a standardized written and digital PAD. California looks to be the first state to have a standardized template, training "toolkit," and a PADs technology platform for consumer-identified and first responder or hospital access in the event of a mental health crisis.

3) OPPOSED UNLESS AMENDED. Disability Rights California (DRC) and Mental Health America California (MHAC) are opposed unless this bill is amended. Both DRC and MHAC state that they have been working with the pilot project team, support PADS, and have proudly sponsored legislation to promote their use. However they argue that this bill goes far beyond what is needed to test a digital platform for PADs and pushes mental health policy away from the original intent of PADs. DRC and MHAC detail thorough concerns with his language, some of which are covered in the policy comments below. DRC and MHAC suggest the bill be substantially amended to focus exclusively on what they understand to be the bill's intent: create a legal framework to facilitate the testing and use of a digital platform which, in turn, will hopefully further promote the use of PADs.

4) PREVIOUS LEGISLATION.

a) AB 1029 (Pellerin), Chapter 171, Statutes of 2023, makes a number of clarifications in the law related to mental health care decisions, specifically decisions that can be made by a third party on behalf of another individual.

b) SB 326 (Eggman), Chapter 790, Statutes of 2023, recasts the MHSA as the Behavioral Health Services Act (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 mental health 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 disorder (SUD) regardless of whether they have additional mental health diagnoses or needs. Most provisions were 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). SB 326 will go into effect January 1, 2025.

c) AB 2288 (Choi), Chapter 21, Statutes of 2022, adds language to advance health care AHCDs to clarify that the document may also include instructions relating to mental health treatment.

d) SB 1338 (Umberg), Chapter 319, Statutes of 2022, establishes the CARE Act, which must be implemented by Glenn, Orange, Riverside, San Diego, San Francisco, Stanislaus, and Tuolumne Counties by October 1, 2023, and the remaining counties by December 1, 2024, subject to delays based on a state or local emergency, or discretionary approval by the Department of Health Care Services (DHCS), up until December 1, 2025. Provides that the CARE Act only becomes operative upon DHCS, in consultation with county stakeholders, developing a CARE Act allocation to provide state financial assistance to counties to implement the CARE process.

5) POLICY COMMENTS.

a) Significant implications changing "mental" to "behavioral" health. While this may seem like a relatively minor update, it may have significant repercussions. Mental health and behavioral health are not interchangeable terms. Behavioral health is a broad term with varying definitions, generally referring to substance use and mental health disorders of any severity. Despite the recent passage of Proposition 1, which among other things updates the MHSA to the BHSA, swaths of state laws and programs currently apply to mental health, mental health with a co-occurring SUD, or SUD alone.

For example – this bill changes terms throughout the LPS Act which outlines mandatory treatment options for those with mental illness**.** Under the LPS Act, an individual may be involuntary committed for varying lengths of time for the purpose of treatment and evaluation, provided that certain requirements are met. This bill also replaces "mental health" with "behavioral health" throughout Laura's Law, which provides for court-ordered assisted outpatient treatment (AOT). In participating counties, the court may order a person into an AOT program if the person is found to meet existing involuntary commitment requirements under the LPS Act or meets non-involuntary commitment requirements, including that the person has refused treatment, their mental health condition is substantially deteriorating, and AOT would be the least restrictive level of care necessary to ensure the person's recovery and stability in the community. By replacing terminology throughout these code sections this bill would make significant

changes to current law, including expanding involuntary treatment laws to include those with SUD.

b) Are CARE Court proceedings an appropriate place to institute a PAD? SB 1338 (Umberg) enacted the CARE Court Program. CARE Court was intended to "provide a vital solution to ensure access to comprehensive services and supports for some of the most ill and most vulnerable Californians." SB 1338 codified the term PAD for the first time, and uses it at several points in its language. In addition to defining PAD, SB 1338:

i) Permits a PAD to be part of a "graduation plan," a voluntary agreement at the end of a CARE program to support a successful transition out of court jurisdiction;

ii) Allows a supporter to be present in any "meeting, judicial proceeding, status hearing, or communication related to . . .[e]stablishing a [PAD];"

iii) Requires DHCS to provide training and technical assistance to county behavioral health agencies regarding PADs;

iv) Requires annual CARE Act data from the trial courts to include the number, rates, and trends of PADs created for participants with active CARE plans; and,

v) Included the number of PADs in the annual metrics to determine the effectiveness of the CARE Act model.

This bill expands the presence of PADS in the CARE process including:

i) Provides that a CARE plan, which is executed once an individual is determined to be eligible for involuntary treatment and services, may include a PAD.

ii) Requires a CARE supporter to provide information to the respondent about AHCDs and PADs.

iii) Provides that unless explicitly authorized by the respondent with capacity to make that authorization, a supporter in a CARE proceeding cannot create a PAD.

Groups such as DRC and MHAC object to the use of PADs in CARE Court as they believe CARE Court is coercive. PADS are already part of the voluntary CARE graduation plan but this bill goes further by putting PADs into the mandated CARE plan. That arguably is very early in the CARE Court process and therefore could be coercive.

This bill also creates a "health care advocate" who can be chosen by the person creating the PAD. The bill as drafted further requires the health care advocate to be an individuals designated "supporter" throughout the CARE process. DRC and MHAC argue that this expansion of the health care advocate's duties into CARE Court dramatically changes the duties of the advocate and risks changing the advocate's role from neutral to coercive.

c) Should PADs be structurally different than AHCDs? This bill creates different standards and processes for PADs compared to AHCDs. For example, an AHCD contains either an individual health care instruction, or a power of attorney for health care, or both. Whereas this bill explicitly states that a PAD does not include power of attorney.

SAMSHA reports that PADs in other states contain options for power of attorney, allowing someone to appoint an individual to serve as a health care agent with decision making authority in medical or psychiatric emergencies, incapacitation, and end of life care instructions. Additionally, under existing law AHCDs and PADs have the same witness signature requirements, two witnesses or a notary public. The bill eliminates the ability to use a notary for a PAD and requires only two witnesses.

The author's office argues that the process of appointing a power of attorney or identifying a notary presents obstacles that the participants in the multi-county behavioral health innovation project believe are unnecessary for a preference document.

Under current law, granting power of attorney and executing an AHCD or PAD with a notary are options– not mandates. The opponents have a shared goal of ensuring PADs are accessible and easy to complete, but question why this bill is limiting PADs as a preference document instead of leaving individuals with the option of creating a true directive.

Going forward, the author should work with stakeholders and advocates representing peers with lived experience to ensure that the state's PADs framework meets the needs of every individual who wishes to create one.

d) Lack of statutory framework. The author's stated intent is to "build out a legal framework for PADs in California," yet this bill leaves many questions unanswered about how PADs will be created, stored, and accessed. There is a statutory form for an AHCD, but this bill does not propose a statutory form for a PAD. Should there be some sort of standard form for PADs? This bill introduces a brand new digital format for PADs, which is being built and tested by the pilot project. Will the platform built by the pilot be the standard? Or will competitors be allowed to introduce different platforms? How will hospitals, law enforcement, and other relevant parties access a digital PAD? Will they need to purchase a platform? Are there any privacy concerns?

The author's office has indicated they are working with the California Department of Justice to work through some of these questions. It is imperative that discussions on these important questions involve all relevant stakeholders with an interest in this process.

e) Ongoing pilot project. Phase one of the multi-county pilot project began in 2021 and is scheduled to end in 2025. In their most recent annual report covering fiscal years (FY) 2021-22 through 2022-23, the project notes that "moving into the FY 2023-2024, the project will train identified PADs teams, or priority population peers and professionals, in the facilitation of a PAD and continue beta testing and fine-tuning the technology platform. The Fresno pilot will sunset June 2024, and new opportunities for additional counties to identify priority populations, be trained in the technology platform and continue testing the project will become an option. In addition, FY 2023-24 will begin a collaborative effort to address the legislation needs to move PADs forward in California, both in use and, most importantly, in consent and autonomy of the individualized PAD." Phase 2, which includes the rollout of the live digital platform won't begin until July 1, 2025.

This digital PAD pilot is still ongoing, meaning there are many lessons to be learned and details to be fine-tuned. While statutory authority may be needed to allow this project to fully test digital PADs, the Legislature should ponder if this bill should include a sunset date or reporting requirements for ongoing evaluation of this new format.

6) **PROPOSED AMENDMENTS.**

a) Terminology throughout mental health and treatment laws have been carefully crafted and subject to extensive public debate. Due to the sensitivities and potential impact, these changes are usually considered in standalone bills. The Committee may wish to remove all of the changes from "mental" to "behavioral" health throughout this bill to ensure these changes are thoroughly considered to avoid unintentional consequences.

b) This bill goes beyond what is needed to build a framework for written and digital PADs, including inserting PADs and the consideration of PADs into various mental health programs and processes ranging from conservatorship, transitional hearings for foster youth, to CARE Court proceedings. The author's intention is to ensure there is adequate awareness and accessibility to PADs, which is an important goal. However, some of the language in this bill goes beyond awareness as it pertains to CARE Court. The Committee may wish to review and amend these provisions of the bill to ensure we are promoting awareness while carefully balancing protections from coercion.

c) Phase one of the multi-county pilot project began in 2021 and is scheduled to end in 2025. Phase 2, which includes the rollout of the live digital platform won't begin until July 1, 2025. The Committee may wish to require MHSOAC to assess the pilot project as it continues and report updates and recommendations to the Legislature to ensure we have sufficient oversight as this new program is implemented.

7) **DOUBLE REFERRAL**. This bill has been double referred. It passed the Assembly Judiciary Committee with a vote of 10 - 0 on April 9, 2024.

REGISTERED SUPPORT / OPPOSITION:

Support

One individual

Opposition

None on file.

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2383 (Wendy Carrillo) – As Amended April 15, 2024

SUBJECT: State Department of Developmental Services: services for children with developmental disabilities: training programs.

SUMMARY: Requires the State Department of Developmental Services (DDS), in consultation with the State Department of Health Care Services (DHCS), to develop or contract for the development of, and to implement by July 1, 2025, required training programs for specified hospital and regional center care management professionals. The training must provide those care management professionals with an understanding of Medi-Cal home- and community-based (HCBS) waivers, and information on how to identify a newborn who is likely to qualify for any of those waivers. Specifically, **this bill**:

1) Applies to case managers, social workers, Early Start liaisons, coordinators, navigators, and, in the hospital setting, medical discharge planners. Requires the training program to include an initial training and an annual refresher course.

2) Requires the training program to provide those care management professionals with an understanding of Medi-Cal HCBS waivers under Section 1915(c) of the federal Social Security Act, including:

    a) The HCBS Alternatives Waiver;
    b) The HCBS Waiver for Californians with Developmental Disabilities,
    c) The Self-Determination Program Waiver for Individuals with Developmental Disabilities; and,
    d) The Medi-Cal Waiver Program.

3) Requires the training program to provide care management professionals with information on how to identify a newborn who is likely to qualify for any of those waivers.

4) Requires, consistent with the training required by 2) above, a care management professional to provide the family of a child with a developmental disability information and a navigation plan on Medi-Cal HCBS waiver programs when the care management professional has reason to believe that it is more likely than not that the child would qualify under one or more waivers.

5) Requires DDS to solicit and consider stakeholder input when developing the training program. Authorizes DDS to consult or collaborate with DHCS, the Department of Public Health (DPH), or both, for purposes of developing the training program, as necessary.

6) Requires a care management professional to receive the initial training described in 2) above within 60 days from the date the training program is implemented, and a care management professional employed after the date the program is implemented to receive the initial training within 60 days of their employment.

EXISTING LAW:

1) Establishes an entitlement to services for individuals with developmental disabilities under the Lanterman Developmental Disabilities Services Act (Lanterman Act). [Welfare and Institutions Code Section (WIC) § 4500, *et seq*.]

2) Establishes a system of nonprofit regional centers throughout the state to identify needs and coordinate services for eligible individuals with developmental disabilities and requires DDS to contract with regional centers to provide case management services and arrange for or purchase services that meet the needs of individuals with developmental disabilities, as defined. [WIC § 4620 *et seq.*]

3) Requires the development of an Individual Program Plan (IPP) for each regional center consumer, which specifies services to be provided to the consumer, based on his or her individualized needs determination and preferences, and defines that planning process as the vehicle to ensure that services and supports are customized to meet the needs of consumers who are served by regional centers. [WIC § 4646]

4) Grants all individuals with developmental disabilities, among all other rights and responsibilities established for any individual by the United States Constitution and laws and the California Constitution and laws, the right to treatment and rehabilitation services and supports in the least restrictive environment. [WIC § 4502]

5) Defines "developmental disability" to mean a disability that originates before an individual attains 18 years of age, continues, or can be expected to continue, indefinitely, and constitutes a substantial disability for that individual. As defined by the Director of DDS, in consultation with the Superintendent of Public Instruction, this term shall include intellectual disability, cerebral palsy, epilepsy, and autism. This term shall also include disabling conditions found to be closely related to intellectual disability or to require treatment similar to that required for individuals with an intellectual disability, but shall not include other handicapping conditions that are solely physical in nature. [WIC § 4512]

6) Establishes DPH, which, among other functions, licenses and regulates health facilities, including hospitals, as specified. [Health and Safety Code §1250, *et seq*.]

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

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

9) Permits, under federal law, a state Medicaid program to pay for part or all of the cost of HCBS services (other than room and board) that are federally approved, and which are provided pursuant to a written plan of care to individuals with respect to whom there has been a determination that, but for the provision of such services, the individuals would require the level of care provided in a hospital or a nursing facility or intermediate care facility for the [developmentally disabled,] the cost of which could be otherwise be reimbursed by the state's Medicaid program. [42 United States Code § 1396n, or § 1915(c) of the Social Security Act (SSA)]

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 ensure that state programs to support middle income families with medically fragile children are utilized to the maximum extent possible. These waiver programs allow for a child to receive services and care through Medi-Cal, without the parent's income taken into consideration. The author concludes that by training hospital and regional center staff to recognize when a family would likely benefit from a waiver program and requiring that they be informed, loved ones can save the expense and planning time required to coordinate care, allowing them to spend more time being a family.

2) **BACKGROUND.**

   a) **Regional Centers**. Pursuant to the Lanterman Act, some individuals with developmental disabilities or related risk factors qualify for services offered through regional centers contracted with the state DDS. Regional centers provide each consumer with a service coordinator, who coordinates the activities necessary to develop and implement the consumer's IPP. Regional centers serve as fixed points of contact in the community for consumers and their families to access services and supports. Regional center staff participate in the individual program planning process, assist consumers to obtain necessary services and supports from "generic agencies," like state agencies that offer health benefits, and purchase other services as necessary. The regional center conducts a variety of activities to achieve the stated objectives of a consumer's IPP.

   b) **Medicaid Waivers and Demonstrations**. Medicaid (Medi-Cal in California) is administered as a state-federal partnership. States are subject to federal law and strict federal rules that guide the provision of Medicaid services. However, federal law also authorizes the Centers for Medicare and Medicaid Services (CMS), which oversees state Medicaid programs, to approve various demonstrations and waivers. Under these authorities, states are granted flexibility to design, deliver and receive federal financial participation (or federal matching funds) for Medicaid services in ways that are not otherwise authorized under Medicaid rules. The demonstrations and waivers are categorized according to the section of the federal SSA that describes the particular demonstration or waiver authority and requirements.

   c) **1915(c) HCBS Waivers.** Under Section 1915(c) of the federal SSA, CMS may waive certain provisions of Medicaid law to give states additional flexibility to design and improve their HCBS programs. HCBS, or 1915(c) waivers, allow state Medicaid programs to develop creative alternatives for individuals who would otherwise require care in a nursing facility or hospital. Medi-Cal has an agreement with the federal government that allows for waiver services to be offered in either a home or community setting. The services offered under the waiver must cost no more than the alternative institutional level of care. Recipients of HCBS waivers must have full-scope Medi-Cal eligibility.

      HCBS waivers offer a variety of services designed to support individuals with intensive needs to live in the community, including case management, community transition

services, private duty nursing, family training, home health aides, life-sustaining utility reimbursement, habilitation services, respite care, and other services required to maintain the health and safety of eligible participants in the community setting of their choice. Depending on the waiver, services are provided by licensed and certified Home Health Agencies; individually licensed HCBS Waiver Providers; and/or unlicensed caregivers.

HCBS waivers included in the training required by this bill include the following:

i) **HCBS-DD Waiver**. The HCBS for the Developmentally Disabled (HCBS-DD) Waiver is administered by DDS, which authorizes HCBS for developmentally disabled persons who are regional center consumers. The waiver services make it possible for consumers to live in the community instead of a facility, such as an Intermediate Care Facility for the Developmentally Disabled (ICF-DD). The HCBS-DD Waiver is currently California largest HCBS waiver.
ii) **Self-Determination Waiver**. The Self Determination Program (SDP) waiver is designed for individuals who meet the diagnostic and level-of-care criteria for services provided in an ICF-DD. The SDP waiver allows participants the opportunity to accept greater control and responsibility regarding the delivery of needed services. An individual budget is determined by the individual program planning team based on the expected cost of an individual's service needs, and the individual or their family decides on the particular services and providers.
iii) **Home and Community-Based Alternatives (HCBA) Waiver**. The HCBA waiver provides care management services to persons at risk of nursing home or institutional placement. Care is managed by a team comprised of a nurse and social worker. The team coordinates waiver and other Medi-Cal health care and long-term services and supports. Care management and services are provided in the participant's community-based residence.
iv) **The Medi-Cal Waiver Program (MCWP).** Under the MCWP, local agencies under contract with DPH, Office of AIDS provide HCBS as an alternative to nursing facility care or hospitalization, to persons living with HIV/AIDS. The waiver aims to assist participants with disease management, preventing HIV transmission, stabilizing overall health, improving quality of life, avoiding costly institutional care; increase coordination among service providers and eliminate duplication of services; and transition participants to more appropriate programs as their medical and psychosocial status improves.

d) Institutional Deeming. Institutional deeming is a Medi-Cal eligibility rule that considers only the personal income and resources of a person under the age of 18 or a married adult who is otherwise eligible for a waiver. This allows a person who meets the criteria above to be determined as eligible for Medi-Cal regardless of his or her parent's or spouse's income and resources. Through institutional deeming, a family may obtain Medi-Cal benefits for needed services, regardless of income. This also allows the person who is "institutionally deemed" to be eligible for all Medi-Cal services, including waiver services and other health care services. This eligibility applies as long as the person is enrolled in the waiver, and is particularly important for individuals who may have intensive care needs but who may not otherwise qualify for Medi-Cal based on household income.

e) Training Mandates. Current law establishes training mandates for hospital and other health facility staff on a variety of topics. For hospitals, some of these topics include infection control, reducing bias and discrimination, and safety and violence prevention. Licensure statute governing licensed health professions also mandates training on certain topics. For instance, licensed clinical social workers are required to earn 36 hours of Continuing Education Units per 2-year renewal period. Required topics include one-time or annual training on suicide risk assessment, HIV/AIDS, telehealth, and law and ethics.

This bill would require training of care management professionals, as specified, within hospitals and regional centers to assist these professionals to identify children, including newborns, who may be eligible for one of California's HCBS programs. These HCBS waiver programs are not broadly well-known, and may be difficult to navigate. This is particularly true for families who may not think they are eligible for supports like Medi-Cal based on their income, but whose children may be able to qualify for Medi-Cal and be enrolled in a waiver program through institutional deeming, as explained above.

3) **SUPPORT.** The Arc & United Cerebral Palsy California Collaboration, the state's largest intellectual and developmental disability organization and sponsor of this bill, writes in support that there is definitive need for training on pathways to the Medi-Cal medical waivers in the stressful period when a family has been told their child is medically fragile or determined to have a developmental disability. The sponsor indicates the training program will equip care professionals with the tools to support families struggling to navigate the complex array of intensive services their children may need.

4) **PREVIOUS LEGISLATION.** AB 1152 (Hernández), Chapter 981, Statutes of 2018, requires each hospital to include, as part of its discharge policy, a written homeless patient discharge planning policy and process. Prohibits a hospital from discharging a homeless patient to a location other than where the patient identifies as his or her residence unless to another licensed facility, or a social services agency or provider that has agreed to accept the patient, and requires certain conditions to be met prior to discharging the homeless patient.

5) **DOUBLE REFERRAL.** This bill is double referred. It passed the Assembly Committee on Human Services with a 6-0 vote.

6) **AMENDMENT.** The author and Committee have agreed to amend the bill to narrow the hospital staff training requirement to general acute care hospitals only.

REGISTERED SUPPORT / OPPOSITION:

Support
The Arc & United Cerebral Palsy California Collaboration (sponsor)

Opposition
None on file.

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2467 (Bauer-Kahan) – As Amended March 4, 2024

SUBJECT: Health care coverage for menopause.

SUMMARY: Requires health plan contract or insurance policy coverage for the treatment of perimenopause and menopause, as specified. Specifically, **this bill** requires a health plan contract or insurance policy, as specified, to include coverage for treatment of perimenopause and menopause that includes, but is not limited to, all of the following:

1) Hormone therapy, including, but not limited to, combination estrogen and hormone medicines, combination estrogen and progestin medicines, and estrogen-only medicines;

2) Low-dose antidepressants;

3) Anticonvulsants;

4) Vaginal estrogen;

5) Medications to prevent or treat osteoporosis;

6) Fezolinetant (Veozah) or other hormone-free options;

7) Topical hormone therapy; and,

8) Bioidentical hormones.

EXISTING LAW:

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

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

3) Prohibits, with respect to an individual or group health plan contract or health insurance policy that covers EHBs, the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days from exceeding $250; for a product with an actuarial value at or equivalent to a Bronze level, limits cost sharing to not more than $500 for a supply of up to 30 days; and for a high deductible health plan the $250 or $500 limits apply only after an enrollee’s deductible is met. [HSC §1342.73 and INS §10123.1932]

4) Defines "basic health care services" as all of the following:
   a) Physician services, including consultation and referral;
   b) Hospital inpatient services and ambulatory care services;
   c) Diagnostic laboratory and therapeutic radiologic services;
   d) Home health services;
   e) Preventive health services;
   f) Emergency health care services, including ambulance and ambulance transport services and out-of-area coverage; and,
   g) Hospice care, as specified. [HSC §1345]

5) Requires the criteria or guidelines used by health plans and insurers, or any entities with which plans or insurers contract for utilization review or utilization management functions, to determine whether to authorize, modify, or deny health care services to:
   a) Be developed with involvement from actively practicing health care providers;
   b) Be consistent with sound clinical principles and processes;
   c) Be evaluated, and updated if necessary, at least annually;
   d) If used as the basis of a decision to modify, delay, or deny services in a specified case under review, be disclosed to the provider and the enrollee or insured in that specified case; and,
   e) Be available to the public upon request. [HSC §1363.5 and INS §10123.135]

6) 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]

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

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, this bill mandates coverage for healthcare treatment plans for people experiencing perimenopause and menopause related symptoms. Treatment for menopause has changed over the years. Eighty four percent of those experiencing menopause are not using the same treatment that their mother or grandmother used, yet the array of treatments available are not widely publicized. It is time for treatments to be made accessible and cost efficient for those that experience

perimenopause and menopause. The author concludes that menopause is not just a personal experience; it's a public health issue that deserves our attention and action.

2) **BACKGROUND.** According to the California Health Benefits Review Program (CHBRP), menopause is part of the normal aging process in which menstruation has ceased for 12 consecutive months. This transition to a new stage of life (rather than a condition or disease) is experienced by every woman and most often occurs naturally between ages 45 and 55 years but may occur between ages 40 and 64 years (median age 51 years). There are three clinical stages of the menopause transition:

   a) Perimenopause is when menstruation becomes irregular in frequency, duration, and bleeding intensity for an average of one to three years before periods stop completely; and,

   b) Menopause is the complete cessation of menstruation for 12 consecutive months; average at menopause: 51 years.

   c) Postmenopause is defined as the point after which no menstruation has occurred for one year. Physiologically, during the menopause transition (whether naturally or clinically induced), the ovaries produce less estrogen and progesterone as they stop releasing eggs. Once a woman achieves menopause, she can no longer become pregnant without significant medical intervention. The decrease in the hormonal levels may lead to bothersome symptoms prompting requests for treatment.

   This bill addresses one particular drug and multiple bill-identified therapeutic categories of drugs. CHBRP considered some subcategories and some additional drugs. CHBRP approached the bill-identified therapeutic category “bioidentical hormones” as two subcategories: compounded bioidenticals and manufactured bioidenticals. CHBRP did so because manufactured bioidenticals have approval from the Food and Drug Administration (FDA), though compounded bioidenticals do not, and clinical recommendations are very different for the two subcategories. Within the bill-identified therapeutic category “vaginal estrogen,” CHBRP included multiple particular drugs because one example, estradiol ring (Femring), is a high-dose vaginal estrogen. As a treatment, it is not interchangeable with the other examples of vaginal estrogen, which are low-dose estrogen. Although it does not fit into a bill-defined therapeutic category, CHBRP has included a focus on ospemifene because it is the only nonhormonal, oral alternative to low-dose vaginal estrogen for the treatment of genitourinary syndrome of menopause (GSM). The bill-identified therapeutic category “hormone therapy” specifies combination estrogen and progestin as a treatment as well as estrogen-only drugs. Estrogen-only drugs are often accompanied by a progestin-only prescription (separate pills that are, effectively, the combination treatment) and so CHBRP has included progestin-only drugs as a focus in this analysis. The table below describes the treatment mandated in this bill and includes the CHBRP assigned therapeutic drug categories, administration, and symptoms:

AB 2467-Specified Language for Drug Treatments of Menopause Symptoms	Therapeutic Categories Assigned by CHBRP for Analysis	Routes of Administration & Dosage Form	Menopause Symptoms Treated	Notes
Hormonal Drug Therapy				
Hormone therapy (e.g., combination estrogen and hormone drugs, combination estrogen and progestin, and estrogen only)	• Oral systemic ○ Estrogen only ○ Progesterone only (co-prescribed with estrogen) ○ Combination estrogen and hormone	Oral tablet or capsule	VMS, GSM	Systemic treatment. Estrogen-only drugs recommended only for women who have had a hysterectomy because of the marked increased risk of uterine cancer when estrogen is taken alone. Progesterone-only drugs are co- prescribed with estrogen-only drugs to reduce risk of uterine cancer. Combination hormone can have significant negative side effects; can have side benefit of reducing bone loss.
Topical estrogen	• Transdermal systemic	Transdermal patch, spray, cream/gel/ lotion	VMS, GSM	Systemic treatment.
Vaginal estrogen	• Vaginal estrogen ○ High dose ○ Low dose	 Vaginal silicone ring only Vaginal silicone ring, suppository, or cream	 VMS, GMS GSM only	 Only one vaginal ring product uses high-dose estrogen that absorbs systemically to treat VMS. Most vaginal estrogens are locally applied and have a lower dose that has local effects.
Bioidentical hormones[a]	• Compounded bioidentical hormones	Oral tablet/capsule, spray, cream/gel, lotion	VMS, GSM	Custom compounded at a compounding pharmacy that are plant-derived natural hormones (not FDA regulated); may vary in doses across and between pharmacies.
Nonhormonal Drug Therapy				
Other hormone-free options	Ospemifene	Oral tablet	GSM	Systemic treatment. May increase risk of blood clots.
Fezolinetant	Fezolinetant	Oral tablet	VMS only	Appropriate for women wanting treatment for VMS who have contraindication to hormone therapy due to high risk of or have/had hormone-sensitive cancers.
Low-dose antidepressants	Antidepressants (SSRI and SNRI)	Oral tablet/capsule	VMS only	Appropriate for women wanting treatment for VMS who have contraindications to hormone therapy (high risk due to hormone-sensitive cancers).
Anticonvulsants	Anticonvulsants	Oral tablet/capsule	VMS only	Appropriate for women wanting treatment for VMS who have contraindications to hormone therapy (high risk due to hormone- sensitive cancers).
Medications to prevent or treat osteoporosis	Medications to prevent or treat osteoporosis	Oral tablet/capsule, injection, intravenous, subcutaneous	Bone loss	Slow bone loss or encourage bone regrowth by improving bone density and strength. Side effects may include stomach upset, heart burn, and other serious outcomes.

d) CHBRP analysis. AB 1996 (Thomson), Chapter 795, Statutes of 2002, requests the University of California to assess legislation proposing a mandated benefit or service and prepare a written analysis with relevant data on the medical, economic, and public health impacts of proposed health plan and health insurance benefit mandate legislation. CHBRP was created in response to AB 1996. SB 125 (Hernandez), Chapter 9, Statutes of 2015, added an impact assessment on EHBs, and legislation that impacts health insurance benefit designs, cost sharing, premiums, and other health insurance topics. CHBRP's analysis of this bill includes the following:

i) **Impact on expenditures.** For enrollees in DMHC-regulated plans and CDI-regulated policies, this bill would increase total premiums paid (by employers and enrollees) and cost sharing, though it would decrease expenses for noncovered benefits. This would result in an increase of total net annual expenditures for enrollees with DMHC-regulated plans and CDI-regulated policies of $3,993,000 (0.0025%). CHBRP projects no change to copayments or coinsurance rates but does project increases in utilization of some drugs and therefore an increase in enrollee cost sharing. Increases in utilization of covered benefits are a combination of reductions in utilization that was paid for out of pocket at baseline that would be covered under this bill postmandate and new utilization due to increased take-up with increases in coverage.

ii) **EHBs.** This bill does not appear to exceed the EHB definition.

iii) **Medical effectiveness.** Commonly referenced guidelines indicate that hormone therapy remains the most effective treatment for vasomotor symptoms (VMS) and GSM, and has been shown to prevent bone loss and fractures. Hormone therapy risks depend on type, dose, duration of use, route of administration, timing of initiation, and whether a progestogen is used. There is clear and convincing evidence that low-dose vaginal estrogen for the treatment of GSM is effective. There is limited evidence that compounded bioidentical hormones are effective treatment for menopause symptoms. Use of compounded bioidentical hormones is only recommended for patients with an allergy to an active pharmaceutical ingredient or inactive ingredient of a drug product approved by the FDA or documented requirement for a different dosage form than available. This is due to serious concerns about the safety, efficacy, and standardization of these drugs, which are not regulated by the FDA. There is a preponderance of evidence that fezolinetant is effective for treatment of VMS. There is a preponderance of evidence that ospemifene improved symptoms of GSM.

iv) **Utilization.** At baseline, 13.2 million enrollees have an outpatient pharmacy benefit regulated by DMHC or CDI. Among the specific drugs that CHBRP identified as treatments for menopause symptoms, an estimated 7% of enrollees in DMHC-regulated plans and CDI-regulated policies have coverage for fezolinetant and 15% have coverage for ospemifene at baseline. For other drugs and categories, baseline coverage ranges from 92% to 100%, and would increase to or remain at 100% for all if this bill were enacted. Because CHBRP is concerned with estimating the marginal impact of this bill, the utilization analyses focus on drugs and treatments for which enrollees in DMHC-regulated plans and CDI-regulated policies did not have 100% coverage at baseline. As current utilization for both is nearly entirely as a non-covered benefit, the increase in benefit coverage would be expected to increase utilization for fezolinetant (231%) and ospemifene (187%). Utilization of other drugs and treatments would be expected to increase in proportion to the increase in benefit coverage.

v) **Public health.** Within the first year postmandate, CHBRP finds that this bill would reduce or abate menopause symptoms for women receiving the additional 15,400 (30-day) prescriptions (which might translate to ~1,250 women, assuming each received one prescription for 12 consecutive months).

vi) **Long-term impacts**. CHBRP does not anticipate any additional changes postmandate that are different from the new levels of coverage established under this bill. If a lower-cost drug option were to become available, DMHC-regulated plans and CDI-regulated policies could shift to covering those options, which would potentially reduce overall costs. The long-term public health impacts of this bill are expected to be similar to those described in the short-term impact section. Most bill-specified drug categories (where most prescriptions are concentrated) are already covered at baseline. Therefore, CHBRP anticipates that a limited number of women (especially those with hormone-sensitive cancer experience) will continue to access the newly covered categories.

3) **SUPPORT.** The National Women's Political Caucus of California (NWPC-CA) writes that this bill helps to eliminate sex and gender-based inequity. Reproductive freedom is far more than the choice to end a pregnancy; it is access to the entire range of health care services that girls and women need throughout their lives. Neither menstruation nor menopause -the beginning and end of the reproductive cycle in women—have had the health care focus they need. Coverage of medical appointments, medications, and other health care support for issues related directly to menopause is not a given in health care plans, but it should be for any person who can experience menopause. NWPC-CA concludes that this bill would do much to prevent that care being overlooked and not accessible to all who need it.

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) oppose mandates for health plans and insurers to cover specific services, as well as bills that eliminate cost sharing and limit utilization management, which have similar cost impacts as coverage mandates. Moreover, they will increase costs, reduce choice and competition, and further incent some employers and individuals to avoid state regulation by seeking alternative coverage options. These bills will lead to higher premiums, harming affordability and access for small businesses and individual market consumers. CAHP, ACLHIC, and AHIP write that state mandates increase costs of coverage, especially for families who buy coverage without subsidies, small business owners who cannot or do not wish to self-insure, and California taxpayers who foot the bill for the state's share of those mandates.

5) **RELATED LEGISLATION.** AB 2914 (Bonta) and SB 1290 (Roth) state the intent of the Legislature to review California's EHB benchmark plan. AB 2914 is pending in Assembly Health Committee. SB 1290 is pending in Senate Appropriations Committee.

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

7) **AUTHOR'S AMENDMENTS.** The author wishes to amend this bill to delete references to brand name prescription drugs.

REGISTERED SUPPORT / OPPOSITION:

Support

Astellas Pharma US, INC.
Bayer US LLC
California Life Sciences
National Women's Political Caucus of California

Opposition

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

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2563 (Essayli) – As Introduced February 14, 2024

SUBJECT: Newborn screening program.

SUMMARY: Requires the State Department of Public Health (DPH) to expand statewide screening of newborns to include screening for Duchenne Muscular Dystrophy (DMD). Expands the purposes for which moneys from the Genetic Disease Testing Fund are expended.

EXISTING LAW:

1) Establishes the policy of the state to make every effort to detect, as early as possible, phenylketonuria (PKU) and other preventable heritable or congenital disorders leading to intellectual disability or physical defects. [Health and Safety Code (HSC) § 125000]

2) Requires DPH to establish a genetic disease unit to coordinate all programs in the area of genetic disease and to promote a statewide program of information, testing, and counseling services. Requires the unit to designate tests and regulations to be used in executing this program. [HSC § 125000]

3) Requires DPH to establish a program for the development, provision, and evaluation of genetic disease testing. [HSC § 125001]

4) Requires DPH to expand statewide screening of newborns to include tandem mass spectrometry screening for fatty acid oxidation, amino acid, organic acid disorders, and congenital adrenal hyperplasia as soon as possible. Requires DPH to provide information with respect to these disorders and available testing resources to all women receiving prenatal care and to all women admitted to a hospital for delivery. [HSC § 125001]

5) Requires DPH expand statewide screening of newborns to include screening for severe combined immunodeficiency (SCID) as soon as possible. In implementing the SCID screening test, requires DPH to also screen for other T-cell lymphopenias that are detectable as a result of screening for SCID, insofar as it does not require additional costs or equipment beyond that needed to test for SCID. [HSC § 125001]

6) Requires DPH to expand statewide screening of newborns to include screening for adrenoleukodystrophy (ALD) and any other disease that is detectable in blood samples as soon as practicable, but no later than two years after the disease is adopted by the federal Recommended Uniform Screening Panel (RUSP), or enrollment of the act amending this subdivision, whichever is later. [HSC § 125001]

7) Establishes the continuously appropriated Genetic Disease Testing Fund (GDTF), consisting of fees paid for newborn screening (NBS) tests, and states the intent of the Legislature that all costs of the genetic disease testing program be fully supported by fees paid for NBS tests, which are deposited in the GDTF. [HSC § 124977]

8) Authorizes moneys in the GDTF to be used for the expansion of the Genetic Disease Branch Screening Information System to include cystic fibrosis, biotinidase, SCID, and ALD and exempts the expansion of contracts for this purpose from certain provisions of the Public Contract Code, the Government Code, and the State Administrative Manual, as specified. [HSC § 124977]

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 add DMD to the statewide NBS panel. The author states that DMD is a debilitating and often fatal disorder that causes progressive muscle deterioration and weakness, affecting approximately one in 3,600 male infants worldwide. The author further notes that early intervention and treatment can make a critical difference in the life of a DMD patient, and further investment into understanding this disorder will bring us closer to more effective treatments and a cure. The author continues that this bill will bring California in line with the policies already enacted in states like Ohio and New York, along with many others currently considering similar proposals. The author concludes California can and should be a leader in this space, as NBSs for DMD will save and improve lives.

2) **BACKGROUND.**

   a) **DMD.** According to the Muscular Dystrophy Association, DMD is a genetic disorder characterized by progressive muscle degeneration and weakness due to the alterations of a protein called *dystrophin* that helps keep muscle cells intact. DMD symptom onset is in early childhood, usually between ages two and three. The disease primarily affects boys, but in rare cases it can affect girls. In Europe and North America, the prevalence of DMD is approximately six per 100,000 individuals. Muscle weakness is the principal symptom of DMD. It can begin as early as age two or three, first affecting the proximal muscles (those close to the core of the body) and later affecting the distal limb muscles (those close to the extremities). Usually, the lower external muscles are affected before the upper external muscles. The affected child might have difficulty jumping, running, and walking. Other symptoms include enlargement of the calves, a waddling gait, and lumbar lordosis (an inward curve of the spine). Later on, the heart and respiratory muscles are affected as well. Progressive weakness and scoliosis result in impaired pulmonary function, which can eventually cause acute respiratory failure. Life expectancy for those with DMD has increased over the years, with some patients surviving beyond 30 years. A 2015 study published in Pediatrics found that the prevalence of DMD has been estimated to be lower in Black individuals and higher in Latino individuals compared to white individuals. In terms of prevalence of DMD in California, there are five certified Duchenne Care Centers. The sponsor indicates these centers serve over 500 patients. It should be noted that this figure does not reflect all patients in California living with DMD, as there are patients who do not receive services from these centers.

   b) **Treatment of DMD.** In March 2024, U.S. Food and Drug Administration (FDA) approved Duvyzat (givinostat) oral medication for the treatment of DMD in patients six years of age and older. Duvyzat is the first nonsteroidal drug approved to treat patients with all genetic variants of DMD. It is a histone deacetylase (HDAC) inhibitor that works by targeting pathogenic processes to reduce inflammation and loss of muscle.

c) **Benefits of NBS.** NBS for DMD has been performed, primarily as pilot studies, in various parts of the world since the 1970s as early detection was believed to be beneficial. The benefits include early treatments such as physical therapy, allowing families to prepare for supporting a child with DMD by accessing appropriate resources and considering family planning options for future children. In 2023, Ohio became the first state to mandate universal NBS for DMD, with New York following shortly thereafter.

d) **Role of the federal government in NBS.** In the United States, screening of newborns is under the purview of state public health departments. Each state decides which disorders to screen, and expansion of each state's panel of screened conditions occurs on a state-by-state basis. The federal government also plays a role in NBS through the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) of the Secretary of the Department of Health and Human Services (DHHS). The ACHDNC is charged with evaluating conditions for screening newborns and children for heritable disorders recommending to the Secretary of DHHS the conditions for which newborns and children should be screened. If accepted by the Secretary, these conditions become part of the Secretary's RUSP which is made up of core and secondary conditions. Currently, there are 36 core and 25 secondary conditions on the Secretary's RUSP. ACHDNC also established a system of nomination and evidence review to evaluate conditions that are candidates for screening.

e) **California Newborn Screening Program (CNSP).** NBS began in California in 1966 with screening for one disorder, called PKU. The CNSP has expanded and now includes 80 different disorders, both genetic (passed down in families) and congenital (present at birth). To ensure the health of all its newborns, state law requires that all babies born in California have NBS soon after birth. The goal of the program is to identify babies with these disorders early, so that treatment can be started right away. A parent or guardian of the newborn child may only decline NBS based on the objection that it conflicts with his or her religious beliefs or practices. The CNSP takes a blood sample from a newborn's heel from 12 to 48 hours after birth to check for genetic disorders. At the same time, the newborn receives a hearing and congenital heart disease screening.

f) **Adding DMD to CNSP.** DMD screening is currently undergoing evidentiary review by ACHDNC. This bill would add DMD to California's Newborn Screening Panel. SB 1095 (Pan), Chapter 393, Statutes of 2016, requires DPH to expand statewide screening of newborns to include screening for any disease that is detectable in blood samples as soon as the disease as practicable, but no later than two years after the disease is adopted by the RUSP.

g) **Genetic disease testing.** In August 2023, the ACDHNC voted to move DMD screening to evidence-based review. The process is ongoing. For conditions that have been added to the RUSP using this process, the time from when a nomination is *first* presented to the Committee, to when the DHHS Secretary adds the condition to the RUSP has ranged from one year and nine months (21 months) to 10 years (120 months). Most have been around three to four years. According to information provided by the author's office, DMD screening may face an uphill battle for inclusion in RUSP because testing technology is nascent and evidence of success is limited. According to a review published in Nature in 2021, neonatal screening is considered for neonatal-onset disorders for

which early treatment shows strong evidence of improved outcome. The review further states that Although DMD does not fully meet these criteria, advocacy groups are in favour of an early diagnosis to enable early management and interventions. The review continues Emerging therapies that might be more effective when used in an early stage of the disease before irreversible muscle damage has occurred strengthen their request to include DMD in NBS.

3) **SUPPORT.** This bill is supported by various groups, including Cure Duchenne (CD)**,** who states that this bill would significantly reduce the diagnostic journey for families facing this devastating disease and enable them to access impactful treatments sooner. CCD continues that DMD is a devastating muscle disease. While rare, it is one of the most common forms of muscular dystrophy, occurring in approximately 1:5,000 male births. Those living with DMD lose their ability to walk, feed themselves, breathe independently and succumb to heart failure. CD further states that there is hope through new pharmacological and gene- based therapies, as there are now eight FDA approved treatments and more than 25 companies investing in finding a cure for this devastating disease. CD contends that while science is moving forward, diagnosis has not. Researchers and clinicians have been working for more than 20 years toward a genetic screening for DMD and yet the average age of diagnosis has remained at approximately five years old. This diagnostic delay is one too many families face—taking away precious time from patients and delaying access to the necessary medical guidance parents need to make informed decisions to give their child the best chance at a healthier, longer life. DMD can be detected at birth with the same drops of blood already used for the state's NBS panel. CD concludes that this bill will ensure California families will not be faced with the same diagnostic delays and give California children timely access to much needed care to provide their best chance at a healthier and longer life.

4) **PREVIOUS LEGISLATION.**

a) SB 643 (Pan) of 2017 would have added DMD to the list of medical conditions eligible for coverage under the Genetically Handicapped Persons Program. SB 643 was vetoed.

b) SB 1095 (Pan), Chapter 393, Statutes of 2016, requires the DPH to expand statewide screening of newborns to include screening for any disease that is detectable in blood samples as soon as the disease as practicable, but no later than two years after the disease is adopted by RUSP or enrollment of SB 1095, whichever is later.

c) AB 1559 (Pan), Chapter 565, Statutes of 2014, requires DPH to expand statewide screening of newborns to include screening for ALD as soon as ALD is adopted by RUSP.

d) AB 395 (Pan), Chapter 395, Statutes of 2011, requires DPH to expand statewide screening of newborns to include screening for SCID and, insofar as it does not require additional costs, other T-cell lymphopenias detectable as a result of screening for SCID, and would make related changes.

REGISTERED SUPPORT / OPPOSITION:

Support

Butte County SELPA
California Children's Hospital Assn
California Life Sciences
Capricor Therapeutics, INC.
CureDuchenne
National Association of Pediatric Nurse Practitioners (NAPNAP)
North Santa Cruz County SELPA
Satellos Bioscience INC.
SELPA Administrators of California
Solano County SELPA
Solid Biosciences
The Akari Foundation
Yolo County SELPA

Opposition

None on file.

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2574 (Valencia) – As Introduced February 14, 2024

SUBJECT: Alcoholism or drug abuse recovery or treatment facilities.

SUMMARY: Exempts sober living homes (SLHs) from being considered a residential use of property when evidence demonstrates that the SLH is an integral part of a licensed drug treatment facility located elsewhere. Specifically, **this bill**:

1) Exempts SLHs from being considered a residential use of property when evidence demonstrates that the SLH is an integral part of a licensed drug treatment facility located elsewhere. Allows evidence to include, but not be limited to:
   a) Transportation provided by the licensed facility to and from the SLH;
   b) Advertising connecting the facility to the SLH; or,
   c) Employees of the licensed facilities providing services or supervision at the SLH.

2) Defines "SLH" as an unlicensed home for persons recovering from alcoholism or drug abuse.

EXISTING LAW:

1) Grants the Department of Health Care Services (DHCS) the sole authority in state government to license alcoholism or drug abuse recovery or treatment facilities (RTFs). [Health and Safety Code (HSC) §11834.01]

2) Defines "alcoholism or drug abuse RTF" as any, place or building that provides 24-hour residential nonmedical services to adults who are recovering from problems related to alcohol, drug, or alcohol and drug misuse or abuse, and who need alcohol, drug, or alcohol and drug recovery treatment or detoxification services. [HSC §11834.02]

3) Defines a "recovery residence" (RR) as a residential dwelling that provides primary housing for individuals who seek a cooperative living arrangement that supports personal recovery from a substance use disorder (SUD) and that does not require licensure by DHCS or does not provide licensable services, as specified, including residential dwellings commonly referred to as "sober living homes," "sober living environments," or "unlicensed alcohol and drug free residences." [HSC §11833.05]

4) Prohibits any person, firm, partnership, association, corporation, or local governmental entity from operating, establishing, managing, conducting, or maintaining an alcoholism or drug abuse RTF to provide recovery, treatment, or detoxification services without first obtaining a current valid license from DHCS. [HSC §11834.30]

5) Requires all licensed RTFs and programs certified by DHCS to disclose any ownership, control of, or financial interest in, a RR to DHCS. Additionally requires disclosure of any contractual relationship with an entity that regularly provides professional services or addiction treatment or recovery services to clients of programs certified or RTFs licensed by DHCS, if the entity is not part of the certified program or licensed RTF. [HSC §11833.05]

6) Requires an RTF that serves six or fewer persons, for purposes of local regulation, to be considered a residential use of property. Prohibits the application of any term to an RTF that implies the treatment home is a business run for profit or differs in any other way from a single-family residence. [HSC §11834.23]

7) Requires DHCS to conduct a site visit to investigate an allegation of an entity operating without a valid RTF license. Requires an employee or agent of DHCS to take the following actions if evidence substantiates that the entity is providing RTF services without a license:

   a) Submit the findings of the investigation;

   b) Issue a written notice to the entity stating that it is operating in violation DHCS's licensing law and inform them of the date by which it ceases providing services and notice that DHCS will assess a civil penalty of $2,000 per day for every day they continue to provide services beyond the date specified in the notice;

   c) Notice that the case will be referred for civil proceedings in the event the entity continues to provide services beyond the date specified in the notice; and,

   d) Inform the entity of the licensing requirements. [HSC §11834.31]

8) Prohibits, under the Fair Employment and Housing Act (FEHA), discrimination against any person in any housing accommodation on the basis of race, color, religion, sex, marital status, national origin, ancestry, familial status, or disability. Specifies that discriminatory land use regulations, zoning laws, and restrictive covenants are unlawful acts. [Government Code §12900 et seq.]

FISCAL EFFECT: None.

COMMENTS:

1) PURPOSE OF THIS BILL. According to the author, this bill will protect communities and residents of SLHs by ensuring they are regulated by the state. The author continues that licensed RTFs provide necessary recovery services to those suffering from SUD, but some licensed RTFs have been found to be operating unlicensed SLHs for individuals in recovery who transition out of the treatment facility. The author argues that these SLHs are not covered under the licensure of the RTF, and are being considered a residential use of property despite providing services offered by the RTF to the residents of the sober living home. The author concludes that by requiring unlicensed SLHs to be covered under the RTF's licensure, DHCS can provide the necessary oversight of these homes.

2) BACKGROUND.

a) Prevalence of SUD in California. A 2022 publication from the California Health Care Foundation, entitled "Substance Use in California: Prevalence and Treatment" reported that substance use in California is widespread with over half of Californians over age 12 reporting using alcohol in the past month and 20% reporting using marijuana in the past year. According to the 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. The California Department of Public Health'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.

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

As part of their licensing function, DHCS conducts reviews of RTF operations every two years, or as necessary. DHCS's Substance Use Disorder Compliance Division checks for compliance with statute and regulations to ensure the health and safety of RTF residents and investigates all complaints related to RTFs, including deaths, complaints against staff, and allegations of operating without a license. DHCS has the authority to suspend or revoke a license for conduct in the operation of an RTF that is inimical to the health, morals, welfare, or safety of either an individual in, or receiving services from, the facility or to the people of the State of California.

AB 118 (Committee on Budget), Chapter 42, Statutes of 2023, requires other non-residential, outpatient alcohol or other drug programs be certified by DHCS. Certification is required when at least one of the following is provided: outpatient treatment services; recovery services; detoxification; or, medications for addiction treatment. DHCS does not license alcohol and drug RRs with six or less beds that don't provide licensable services, known as RRs.

c) RRs. A RR, sometimes called a SLH, is a residence for people in recovery from substance abuse. It may serve as support for individuals undergoing treatment but it does not provide treatment or care, whether medical or nonmedical. The state laws and licensing requirements that govern treatment and care facilities do not currently include RRs. Therefore, the state does not keep any list of registered RRs, conduct inspections of RRs, or perform any of the other activities associated with licensing facilities. An RR may be completely self-governed or have formal on-site management, but in the latter case, the managers' duties relate to the administration of the house rather than the tenants or their recovery (as in "case management.") The tenants of an RR pay rent and abide by house rules, which always include maintenance of sobriety and participation in a self-help program. Multiple studies have shown the effectiveness of this kind of environment as a support for people transitioning out of drug or alcohol treatment. The effectiveness of sober living as one component of a person's successful recovery program is not controversial. The California Research Bureau estimates that there are at least 12,000 sober living beds in the state to serve an eligible population of between 25,000 and 35,000 individuals. If an RR is providing any licensable services then it must obtain a valid RTF license from DHCS.

DHCS's Drug Medi-Cal-Organized Delivery System waiver permits counties to use RRs in their continuum of services if they adhere to the following guidelines: the RR does not provide SUD services that would require licensure by DHCS; all residents of a RR are actively engaged in medically necessary recovery support services to be provided off-site; each county develops guidelines for contracted RR entities; and, the county provides monitoring and oversight of the RR.

d) Fair Housing Act (FHA) and Americans with Disabilities Act (ADA). The FHA makes it illegal to engage in various discriminatory practices relating to the sale and rental of housing based on race, color, religion, sex, marital status, national origin, ancestry, familial status, or disability. FHA also prohibits land use regulations, zoning ordinances, and restrictive covenants from discriminating in housing on the basis of the aforementioned categories. FHA also states that groups of people with disabilities living together in a single dwelling unit are considered a family.

In addition, the ADA affords civil rights protection to individuals with disabilities, similar to the protections provided to individuals on the basis of race, sex, national origin, and religion. Under the ADA, an individual with a "disability" is someone who has a current "physical or mental impairment" that "substantially limits" one or more of that person's "major life activities," such as caring for one's self, working, etc., or has a record of such a substantially limiting impairment, or is regarded as having such an impairment. The protections of the ADA apply to those who have successfully completed a drug rehabilitation program, or who are currently enrolled in such programs.

In a joint statement issued in November 2016 by the federal Department of Justice (DOJ) and Department of Housing and Urban Development (HUD), which together are responsible for enforcing the FHA, DOJ and HUD declare that the term "group home" does not have a specific legal meaning, though land use and zoning officials and the courts have referred to some residences for persons with disabilities as group homes, including homes occupied by persons in recovery from alcohol or substance abuse. DOJ and HUD contend that persons with disabilities have the same FHA protections whether or not their housing is considered a group home, and that a household where two or more persons with disabilities choose to live together, as a matter of association, may not be subject to requirements or conditions that are not imposed on households consisting of persons without disabilities.

DOJ and HUD further state that the provision of services (medical, supervisory, supportive, etc.) is not required for a group home to be protected under the FHA. Group homes can also be opened by individuals or organizations, both for-profit ("commercially operated") and nonprofit, and still be protected by the FHA. Further, the FHA does not require a person who resides in an RR to have participated in or be currently participating in a substance abuse treatment program to be considered a person with a disability. The fact that a resident of an RR may currently be illegally using a controlled substance does not deprive the other residents of the RR of the protection of the FHA. The DOJ and HUD statement also says that localities and states must ensure that actions to enforce criminal and other laws against RRs are not taken to target RRs and are applied equally, regardless of whether the residents of housing are persons with disabilities.

e) California Department of Housing and Community Development's (HCD) Group Home Technical Advisory (GHTA). In response to numerous local governments amending their zoning ordinances to add discriminatory regulations for group homes, particularly RRs, HCD's Division of Housing Policy Development issued the GHTA in December 2022. The GHTA provides guidance about how discriminatory ordinances interact with obligations under state planning and zoning laws to promote more inclusive communities and affirmatively further fair housing. HCD states that group homes are an especially important type of housing for persons with disabilities, yet local land use policies and practices can block new group homes from opening, force existing ones to close, and impose costs, legal fees, and administrative burdens that make it difficult for group homes to operate. These concerns arise in the context of a shortage of adequate housing for persons with disabilities, which is a particularly acute problem within California's broader housing crisis and the overlapping SUD epidemic. The GHTA provides guidance to assist local governments in identifying and correcting discriminatory land use policies, including the following:

i) Intentional Discrimination and Discriminatory Effects. Land use policies and practices must not discriminate on the basis of disability or other characteristics protected by state and federal law, including SUD. Intentional discrimination includes "an act or failure to act" in which any protected characteristic is a motivating factor, even when other factors may have also motivated the practice. Even if a locality did not act with intentional discriminatory purpose, land use policies or practices can be found unlawful if they have a discriminate effect. Lastly, discrimination can arise from a jurisdiction failing to make reasonable accommodations in rules, policies, practices, or services when accommodations may be necessary to afford a disabled person equal opportunity to use and enjoy a dwelling.

ii) Supportive and Transitional Housing Protections. If a group home operates in ways that fall within the statutory definitions of supportive housing or transitional housing, jurisdictions must comply with Housing Element Law's specific protections of these types of housing. This includes the requirement that supportive and transitional housing be permitted in all zones allowing residential uses and are not subject to any restrictions not imposed on similar dwellings (like single-family homes) in the same zone in which the transitional housing and supportive housing is located.

iii) State and Federal Law Distinctions. Localities must confirm that a policy or practice complies with state housing laws even if it complies with federal law, because California law provides broader and different protections than federal law.

iv) Restrictive Definitions of Single-Family Residence. Zoning ordinances sometimes attempt to restrict or limit group homes in single-family residential zones through definitions of single housekeeping units or single-family homes that impermissibly constrain group homes from locating in single-family zones. This includes, for example, definitions that equate group homes with boardinghouses, require all residents to share a common deed or lease, overly scrutinize residents' living arrangements, or automatically exclude group homes that are owned by for-profit businesses or pay staff to help manage a home's operations. These definitions not

only violate state housing laws, but the California Constitution's protections of the rights of unrelated persons to live together in communal housing.

v) **Conditional Use Permits or Special Approvals.** Some local zoning ordinances require group homes to apply for conditional use permits or obtain other special approvals to locate in single-family zones. Unlicensed group homes that operate as single-family residences and do not provide licensable services must be allowed in single-family neighborhoods, subject only to the generally applicable, nondiscriminatory health, safety, and zoning laws that apply to all single-family residences. Licensed group homes that operate as single-family residences and provide licensable services should be subject to the same. Group homes operating as single-family residences that provide licensable services to more than six residents may be subject to conditional use or other discretionary approval processes, but local governments must still provide flexible and reasonable accommodations in these permitting processes.

vi) **Spacing Requirements.** Spacing requirements restrict group homes from locating within a specific distance of other group homes. The Legislature has crafted careful limitations on spacing requirements, yet some local governments have imposed spacing requirements on RRs. These spacing requirements are very unlikely to withstand scrutiny under state housing and fair housing laws, HCD notes it would require substantial and detailed statistical evidence to establish that a spacing requirement would be of benefit to the residents of an RR. The Legislature has repeatedly rejected attempts to impose spacing requirements on RRs, citing concerns that they would discriminate on the basis of disability, impede opening new RRs, reduce access to much needed recovery services, and stigmatize RRs and their occupants.

3) **SUPPORT.** The League of California Cities (The League) are sponsors of this bill, stating that residential recovery housing provides a wide range of benefits to some of California's most vulnerable residents and it is critical that their needs are prioritized over profits. The League continues that compliance with state licensing laws administered through DHCS is essential to safeguarding residents' well-being and maintaining quality care. The League states that there have been cases where a licensed RTF provides services to the residents of a SLH but does not include the SLH in the facility's licensure. The League argues that this bill would provide much-needed clarity to ensure that if a recovery residence is operated as a business with a licensed treatment facility, it is regulated like a business, not a residential home.

4) **RELATED LEGISLATION.**

a) AB 2081 (Davies) requires an operator of a licensed RTF or certified alcohol or other drug program to disclose on its internet website and intake form paperwork a disclosure that an individual may check the DHCS website to confirm whether the facility's license or program's certification has been placed in probationary status, been subject to a temporary suspension order, been revoked, or the operator has been given a notice of operation in violation of law. AB 2081 is currently pending in the Assembly Appropriations Committee.

b) AB 2121 (Dixon) requires RTFs licensed by DHCS to be located more than 300 feet from another RTF or community care facility. Requires DHCS to notify the city or county in which the facility is located of the issuance of a license. AB 2121 is currently pending in the Assembly Health Committee.

c) AB 2893 (Ward) requires DHCS to establish a certification process for recovery homes and adds a standard for recovery homes that meets the state's Housing First requirements. AB 2893 is currently pending in the Assembly Health Committee.

d) SB 913 (Umberg) permits a city attorney of a city in which housing units are located or a district attorney, if the units are located in the unincorporated area of the county, to enforce parts of DHCS licensing laws, as specified. Requires DHCS to adopt a process that permits a city or county to conduct announced and/or unannounced site visits to facilities licensed by DHCS and to SLHs/RRs that do not require DHCS licensure. SB 913 is currently pending in the Senate Judiciary Committee.

e) SB 1334 (Newman) defines an RR, for purposes of licensing RTFs, as a residential dwelling that provides primary housing for individuals who seek a cooperative living arrangement that supports personal recovery from a substance use disorder, does not require DHCS licensure, and does not provide licensable services, and clarifies that an unlicensed RR may provide services to its residents, including, but not limited to, dining, housekeeping, security, transportation, and recreation. Exempts RRs from being required to be licensed RTFs if the facility does not offer recovery services, as defined, and would allow residents of an RR to actively participate in recovery services outside of the home. Requires RRs to be operated as a separate business from a licensed RTF and require RRs to maintain separate agreements with each resident for the housing and services it provides. SB 1334 is currently pending in the Senate Health Committee.

5) PREVIOUS LEGISLATION.

a) AB 1696 (Sanchez) of 2021 would have required any government entity that contracts with a privately owned RR to provide recovery services to require the RR to comply with specified requirements. AB 1696 was vetoed by the Governor.

b) SB 349 (Umberg), Chapter 15, Statutes of 2022, creates the California Ethical Treatment for Persons with Addiction Act to provide protection for SUD treatment clients and their families. Imposes requirements and proscribed unlawful acts relating to marketing and advertising with respect to treatment provide. Requires treatment providers to adopt a client bill of rights for persons seeking treatment for SUD, and to make the bill of rights available to all-clients and prospective clients; a treatment provider to maintain records of referrals to or from a RR, as specified and, provides that acts made unlawful by the bill be subject to a civil fine of up to $20,000 per violation.

c) AB 1158 (Petrie Norris), Chapter 443, Statutes of 2021, requires an RFT licensed by DHCS serving more than six residents to maintain specified insurance coverages, including commercial general liability insurance and employer's liability insurance. Required a licensee serving six or fewer residents to maintain general liability insurance coverage. Requires any government entity that contract with privately owned RR or RTF

serving more than six residents to require the contractors to, at all times, maintain specific insurance coverage.

d) AB 1098 (Daly) of 2021 would have created the Excellence in Recovery Residence Housing Act. Would have required the Secretary of California Health and Human Services to develop and publish on the DHCS internet website consensus-based guidelines and nationally recognized standards for counties to use to promote the availability of high-quality RR housing for individuals with a SUD and to dissuade the use of contracting with, or referral to, RRs that do not meet these guidelines and standards. AB 1098 was held on the Assembly Appropriations Committee suspense file.

e) SB 589 (Bates) of 2020 would have prohibited an operator of a licensed RTF, an alcohol or other drug program (AOD), a RR, or a third party from engaging in specified marketing activities including make a false or misleading statements or providing false or misleading information about the entity's products, goods, services, or geographical locations in its marketing, advertising materials, or media, or on its internet website or on a third-party internet AB 589 was vetoed by the Governor with the following message:

> "This bill would establish several prohibitions related to the advertisement of SUD services by the operator of a RTF, an AOD, a RR, or a third party that provides any advertising or marketing services or directory listings to any of those entities. While it is important to protect vulnerable patients and their families from unethical marketing practices, I am concerned that as crafted, this measure creates a false promise. DHCS has no jurisdiction or licensing oversight over RRs or third parties. As such, it cannot take enforcement against those entities for violations of advertisement requirements."

6) PROPOSED AMENDMENTS. The author's stated intent is to ensure that SLHs are "regulated by the state," but this bill as drafted erects barriers to RRs that are not aligned with state and federal laws that protect this type of housing. Furthermore RRs, including SLHs, are already prohibited from providing licensable services without a license. Licensable services do not include the parameters of transportation, advertising, and staffing that are included in this bill. Lastly, there are no prohibitions on a licensed RTF owning or having a financial interest in an unlicensed RR or other facility. In fact, this practice is common given the ample evidence that RRs improve odds of successful recovery and are an important pillar in the SUD continuum of care.

Existing statute aims to bolster DHCS's oversight of the relationships between licensed RTFs and unlicensed RRs by requiring all DHCS licensed facilities and certified programs to report ownership, control or financial interest in a RR. The sponsors of this legislation argue that current law allows some financial relationships to fall through the cracks as it only requires the licensed facility to report a relationship. Licensed RTFs are required to report less than others, such as licensed skill nursing facilities who are required to report the financial relationships of "the licensee, or the general partner, director, or officer of the licensee."

To ensure that DHCS is able to thoroughly oversee and investigate relationships between licensed and unlicensed facilities, the Committee may wish to amend this bill to align the reporting requirements for DHCS licensed facilities and certified programs with those of skilled nursing facilities.

REGISTERED SUPPORT / OPPOSITION:

Support

League of California Cities (sponsor)
Sue Kempf, Mayor, City of Laguna Beach
City of Cypress
City of Fountain Valley
City of Placentia
County of Orange

Opposition

None on file.

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2613 (Zbur) – As Introduced February 14, 2024

SUBJECT: Jaqueline Marie Zbur Rare Disease Advisory Council.

SUMMARY: Establishes within the California Health and Human Services Agency (CHHSA), until January 1, 2029, the Jacqueline Marie Zbur Rare Disease Advisory Council (advisory council), composed of a minimum of 17 members. Specifically, **this bill**:

1) Establishes the advisory council, a Rare Disease Advisory Council (RDAC), within CHHSA.

2) Requires the Governor, on or before February 1, 2025, to appoint the first chair of the advisory council.

3) Requires the chair of the advisory council, on or before January 1, 2025, to appoint the minimum membership of the advisory council composed of the following 17 members:
   a) Two physicians and surgeons licensed to practice in this state who have expertise in treating patients with rare diseases, at least one of whom shall also treat children with rare diseases;
   b) One registered professional nurse licensed to practice in this state who has expertise in providing care to patients with rare diseases;
   c) One representative of the administration of a hospital located in this state and treats rare disease patients;
   d) One representative of the administration of an outpatient health care facility located in this state and treats rare disease patients;
   e) One representative of the health care coverage industry;
   f) One representative of the biopharmaceutical industry;
   g) One representative of the scientific community who is engaged in rare disease research;
   h) One rare disease geneticist or genetic counselor;
   i) Five individuals who are either a rare disease patient or a caregiver to a rare disease patient. Prohibits more than three individuals from each category;
   j) One medical social worker or mental health provider who works with rare disease patients; and,
   k) Two representatives of patient advocacy organizations that operate within this state.

4) Permits the advisory council to advise the CHHSA on additional at-large appointments to the advisory council that may be necessary to carry out its duties. Authorizes at-large appointments to the advisory council to serve on an ad hoc basis.

5) Requires all members of the advisory council to serve without compensation, but allows the members appointed pursuant to 2) above to be reimbursed for travel and other miscellaneous expenses necessary to perform their duties within the limits of funds made available to the advisory council for its purposes.

6) Prohibits a single rare disease population from having more than two representatives on the advisory council.

7) Requires members of the advisory council appointed pursuant to 2) above to serve January 1, 2029. Requires any vacancy in the membership of the advisory council to be filled in the same manner as provided for in the original appointment.

8) Requires each member of the advisory council to annually sign a conflict of interest statement disclosing any economic or other relationship with an entity that could influence the member's decisions. Prohibits at least 20% of the advisory council's members from having a conflict of interest with respect to an insurer, pharmaceutical benefits manager, or pharmaceutical manufacturer above.

9) Requires the advisory council to hold an initial organizational meeting within 60 days after the date of the last appointment made pursuant to 2).

10) Requires, at the initial organizational meeting, the advisory council to select its vice chair from among its members.

11) Requires, at the initial organizational meeting, the chair to appoint a secretary at their discretion.

12) Authorizes the chair to appoint a secretary who is also a member of the advisory council or an employee of the DPH.

13) Requires the advisory council to meet periodically, but at least six times annually.

14) Authorizes the advisory council to call to its assistance, and avail itself of the services of, the employees of any state, county, or municipal department, board, bureau, commission, or agency as it requires and as are available to it for its purposes, if those employees elect to participate.

15) Requires the advisory council to perform all of the following duties:
    a) Act as the advisory body on rare diseases to the Legislature, and state departments, agencies, commissions, and authorities, and private agencies, that provide services to, or that are charged with the care of, persons with rare diseases;
    b) Evaluate and make recommendations to improve Medi-Cal and state-regulated private health insurance coverage of drugs and biological products for rare disease patients;
    c) Engage with the Medi-Cal Drug Use Review Board, also known as Medi-Cal DUR, and serve as an expert advisory committee to the board, when the board makes recommendations or determinations regarding beneficiary access to drugs or biological products for rare diseases;
    d) Defines for purposes of this bill, "beneficiary access" means developing prior authorization and reauthorization criteria for a rare disease drug, including placement on a preferred drug list or a formulary, as well as payment, cost sharing, drug utilization review, or medication therapy management;
    e) Prepare a first-year landscape survey of the needs of rare disease patients, caregivers, and providers in the state. Requires the advisory council to convene public hearings, make inquiries, and solicit comments from the general public in the state to assist the advisory council in fulfilling this duty;

f) Consult with experts on rare diseases to develop policy recommendations to improve patient access to, and quality of, rare disease specialists, affordable and comprehensive health care coverage, relevant diagnostics, timely treatment, and other needed services;
g) Create and maintain an internet website;
h) Identify, consolidate, and publish on the advisory council's internet website a list of existing, publicly accessible resources on research, diagnosis, treatment, and education relating to rare diseases in California to foster recognition and access to treatment; and,
i) Identify areas of unmet need for research and opportunities for collaboration with stakeholders and rare disease advisory councils in other states that can inform future studies and work done by the advisory council.

16) Requires the advisory council to apply for, and accept, any grant of funds from the federal government, private foundations, or other sources that are available for programs related to rare diseases.

17) Prohibits the advisory council from accepting any funds from the employer of a currently seated council member.

18) Requires the advisory council to report to the CHHSA and the Legislature on the activities of the advisory council and its findings and recommendations on issues relating to the quality and cost-effectiveness of, and access to, treatment and services provided to persons with rare diseases in this state, as follows:
a) An interim report, submitted on or before July 1, 2026; and,
b) A final report, submitted on or before December 31, 2028.

19) Requires the advisory council to submit reports to the Legislature in compliance with existing law.

20) Requires the advisory council to post the reports required by this bill on its internet website.

21) Repeals the provisions of this bill on January 1, 2029.

EXISTING LAW:

1) Establishes in state government the CHHSA and within CHHSA, among other departments, offices and councils, the Department of Health Care Services (DHCS) and the California Department of Public Health (DPH). [Government Code §12800, 12803]

2) Establishes in state government the State Public Health Officer, who serves as the director of DPH. [Health & Safety Code (HSC) §131005]

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 create a RDAC in California. The author's sister, Jacqueline Marie Zbur, endured a three-year battle with ALS (amyotrophic lateral sclerosis), also known as Lou Gehrig's disease. The author states that the RDAC will serve as a vital platform to amplify the voices of millions of Californians grappling with rare diseases and will guide the Legislature in supporting the rare disease

community. The author notes that rare disease patients face unique challenges every day, including obtaining an accurate diagnosis, accessing medical specialists with knowledge of their condition, battling for access for quality care and therapies, and obtaining fair insurance coverage of their treatment and care. The author contends that this bill makes important progress towards addressing challenges for the rare disease community by fostering recommendations on – and understanding of – disease representation, specialist physician directories, financial impacts to patients and the State, and what private and public resources may be available to patients and their families. The author also notes that this bill gives rare disease patients a much needed voice to advocate and strategically plan for the future of rare diseases. The author contends that it is time for California to join 27 other states in adopting a RDAC, through which a diverse group of experts will be able to develop recommendations for the State on how best to address the challenges faced by the nearly three million Californians with rare diseases, their families, and their caregivers.

2) BACKGROUND.

a) Background on Rare Diseases. According to the National Human Genome Institute, a rare disease is a condition that affects fewer than 200,000 people in the United States. There are more than 6,800 rare diseases. Altogether, rare diseases affect an estimated 25 million to 30 million Americans. Examples of rare diseases include life-threatening and physically or mentally disabling conditions such as ALS; Huntington disease, spina bifida, fragile X syndrome, Guillain-Barré syndrome, Crohn disease, cystic fibrosis, and Duchenne muscular dystrophy.

According to a 2016 essay published in Preventing Chronic Disease: Public Health Research, Practice, and Policy, rare disease patients are few and scattered across populations and many rare diseases have a long list of characteristics that present serious challenges for public health practitioners. Among rare diseases it is common to find that: i) diagnoses are difficult and delayed; ii) case definitions for surveillance are usually lacking; iii) International Classification of Diseases codes for record keeping are poorly defined or not assigned; iv) underlying molecular or physiologic mechanisms are unknown; v) specialized and coordinated medical care is in short supply, and treatments can be complex; g standards of care for treatment and rehabilitation are not evidence-based because health research is necessarily done at small scale; vi) longitudinal data collections are scarce; vii) the development of new medications and treatments can be fragmented and slow; viii) screening strategies lack efficiency; and, ix) scope and capacity of most registries and databases are limited.

The knowledge of most rare diseases is so insufficient that they are also known as orphan diseases (and their treatments known as orphan drugs) because of their failure to attract the interest of researchers, medical specialists, drug makers, and policy makers. The essay recommends five goals for a comprehensive public health approach to rare diseases and its potential impact on affected populations. The goals include: i) defining and examining the impact of the disease; ii) developing common surveillance practices; iii) improving knowledge about the disease; iv) support health care systems in treating the diseases; and, v) reducing the impact of the diseases on patients, their relatives and caregivers, and society in general.

b) Office of Rare Diseases. In 2002, Congress enacted the Rare Diseases Act (RDA) which established within the Office of Rare Diseases within National Institutes of Health (NIH) to recommend an agenda for conducting and supporting research on rare diseases through the national research institutes and centers. Under the RDA, the NIH can enter into cooperative agreements with and make grants for regional centers of excellence on rare diseases.

c) State Programs Addressing Rare Diseases. DHCS and DPH operate state programs that provide services and screenings for individuals with certain diseases and health problems, which include some rare diseases. These programs include the California Children's Services Program (CCS), Genetically Handicapped Persons Program (GHPP), and Genetic Disease Screening Program (GDSP).

d) RDAC. This bill creates the advisory council which will be tasked with: i) evaluating and making recommendations to improve Medi-Cal and state-regulated private insurance coverage of medications that treat rare disease, as well as engaging the Medi-Cal DUR Board; ii) preparing a survey of the rare disease landscape in California, and convening public hearings to assist the advisory council in fulfilling its duties; iii) consulting with experts in rare diseases to develop policy recommendations; iv) creating and maintaining a website for the advisory council; v) identifying and publishing a list of resources on said website; and, vi) identifying areas of unmet need for research and opportunities for collaboration with stakeholders and RDACs in other states that can inform future studies and work done by the advisory council to increase awareness of rare diseases and provide a forum for stakeholders knowledgeable about the needs of rare disease patients to help shape policies to improve health outcomes for rare disease patients. There have been several legislative attempts in State of California to create a RDAC.

In 2015, the first RDAC was created in North Carolina by patients, caregivers, families and providers. Since then, an additional 26 states have established RDACs. With the support of the National Association for Rare Disorders (NARD), the sponsor of this bill, and other patient organizations and stakeholders in the rare disease community, RDACs work to strategically identify and address barriers that prevent individuals living with rare diseases from obtaining proper treatment and care for their condition. In 2023, three states signed RDAC legislation into law.

3) **SUPPORT**. A coalition of organizations representing individuals with rare diseases including NARD, the California Center for Rare Diseases at the University of California, Las Angeles, Hemophilia Council of California, and the California Chronic Care Coalition state, for patients living with one of the over 10,000 known rare conditions, it can take several years to receive an accurate diagnosis and effective treatment. Further, only a handful of rare diseases are well understood, with most not receiving sufficient attention or funding for research. This lack of awareness often contributes to the obstacles to timely treatment and care faced by many rare disease patients. The coalition states that creating an RDAC in California will give rare disease patients a unified voice in state government to help address challenges that are faced by the rare disease community by serving as the advisory body on rare diseases to the Legislature and state departments, and relieve some of the burden on the state by expeditiously delivering direct feedback, solutions, and resources to California.

4) **RELATED LEGISLATION.** AB 2680 (Aguiar-Curry) of 2024 renames the Alzheimer's Disease and Related Disorders Committee to the Alzheimer's Disease and Related Conditions Advisory Committee, expands the number of members serving on the committee from 14 to at least 21, but not more than 25 and prescribes the qualifications of certain members on the committee. AB 2680 passed the Assembly Health Committee 16-0.

5) **PREVIOUS LEGISLATION.**

   a) SB 247 (Eggman) of 2021 would have established the RDAC within the California Health and Human Services Agency and would have specified the purposes of the RDAC, including coordinating statewide efforts for the study of the incidence of rare diseases within the state, and acting as the advisory body on rare diseases to the Legislature and state and private agencies that provide services to persons with rare diseases, adopting implementing regulations, and researching and determining the most appropriate method to collect data on rare diseases, and identifying best practices for rare disease care. SB 247 was vetoed by the Governor, who stated, in part: "While it is important for the public, providers, state agencies, and private partners to have access to information on rare diseases, the purpose and duties of the Advisory Council as would be required by SB 247 are extensive and costly. Bills with a significant fiscal impact, such as this measure, should be considered in the annual budget process. For this reason, I cannot sign this bill".

   b) AB 2283 (Eggman) of 2020 was identical to SB 247. AB 2283 was not heard by the Assembly Health Committee.

   c) AB 1016 (Maienschein) of 2019 would have established a RDAC. AB 1016 was held on the Assembly Appropriations suspense file.

   d) ACR 28 (Gipson) of 2019 would have recognized September 2020 as Sickle Cell Disease Awareness Month and encouraged the Legislature to appropriate funds for research, treatment, monitoring, education, and outreach related to the disease. ACR 28 was not heard by the Senate Health Committee.

6) **SUGGESTED AMENDMENT.** To clarify language related to the appointment of the secretary of the RDAC, the author may wish to amend this bill as follows:

124965.4. The advisory council shall hold an initial organizational meeting within 60 days after the date of the last appointment made pursuant to subdivision (c) of Section 124965.2. At that initial organizational meeting, the advisory council shall select its vice chair from among its members, and the chair shall appoint, at their discretion, a secretary. ~~The chair may appoint, but is not required to appoint, a secretary who is also a member of the advisory council or an employee of the State Department of Public Health.~~ The secretary shall be an employee of the Department or a member of the advisory council.

REGISTERED SUPPORT / OPPOSITION:

Support

Acadia Pharmaceuticals
ALS Association
Axis Advocacy
CA Action Link for Rare Diseases
California Chronic Care Coalition
California Coalition for PKU and Allied Disorders
California Hepatitis C Task Force
California Life Sciences
Chronic Care Policy Alliance
Cystic Fibrosis Research Institute
Dravet Syndrome Foundation
Epilepsy Foundation of San Diego County
Fair Time for Women
Family Voices of Ca
Hemophilia Council of California
Liver Coalition of San Diego
Lupus Foundation of Southern California
National Organization for Rare Disorders
National Organization for Rare Disorders (NORD)
National Pku Alliance
Neuropathy Action Foundation
NMDP
Parkinson's Association of San Diego
Rasopathies Network
Santa Monica Democratic Club
TSC Alliance

Opposition

None on file.

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2637 (Schiavo) – As Introduced February 14, 2024

SUBJECT: Health Facilities Financing Authority Act.

SUMMARY: Changes the definition of "working capital" in the Health Facilities Financing Act to remove the two year cap on interest on any loan for working capital. Deletes the provision of law requiring a private nonprofit corporation or association to repay and discharge a loan for working capital within 24 months.

EXISTING LAW:

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

2) Defines "Health facility," for purposes of CHFFA eligibility, to mean a facility, place, or building that is licensed, accredited, or certified and organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, or physical, mental, or developmental disability, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, including, but not limited to, a general acute care hospital that is 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. [GOV § 15432]

3) Defines "working capital" to mean moneys to be used by, or on behalf of, a participating health institution to pay or prepay maintenance or operation expenses or any other costs that would be treated as an expense item, under generally accepted accounting principles, in connection with the ownership or operation of a health facility, including, but not limited to, reserves for maintenance or operation expenses, interest for not to exceed two years on any loan for working capital made pursuant to this part, and reserves for debt service with respect to, and any costs necessary or incidental to, that financing. [GOV § 15432]

4) Authorizes CHFFA to make secured or unsecured loans to, or purchase secured or unsecured loans of, any participating health institution in accordance with an agreement between CHFFA and the participating health institution to refinance indebtedness incurred by that participating health institution or a participating health institution that controls or manages, is controlled or managed by, is under common control or management with, or is affiliated with that participating health institution, in connection with projects undertaken or for health facilities acquired or for working capital. [GOV § 15438 (j)]

5) Requires a participating health institution that is a private nonprofit corporation or association that borrows money to finance working capital, other than as part of the cost of a

project, to repay and discharge the loan within 24 months of the loan date. [GOV §15451.5]

6) Establishes the Distressed Hospital Loan Program (DHLP), until January 1, 2032, which will provide interest free cash-flow loans to not-for-profit hospitals and public hospitals, as defined, in significant financial distress, or to governmental entities representing closed hospitals. Requires the Department of Health Care Access and Information (HCAI) to administer the DHLP and to enter into an interagency agreement with CHFFA to implement the DHLP. [Health and Safety Code 129380-129387]

7) Defines working capital for the purposes of the California Educational Facilities Authority Act without a 24 month limitation. [Education Code §94110]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, currently CHFFA acts as a conduit for hospitals to secure bond financing for things such as wages, leases, and other operational costs. Under federal tax law, the State can issue long-term tax-exempt bonds to finance working capital, including funding to address a temporary cash flow or operating deficit, such as those arising because of the COVID-19 pandemic. However, state law limits bonds offered through CHFFA for these uses to only two years, much shorter than similar financing offered to educational facilities or distressed hospitals. This has resulted in some hospitals seeking financing being turned away. The author states that this bill remedies this by extending the bond terms as allowed in federal law and aligning CHFFA with other financing programs, enabling more hospitals to secure the funds they need to navigate difficult times.

2) **BACKGROUND.** Fixed capital refers to the assets or investments required to establish and run a firm, such as property or equipment. Working capital is the cash or other liquid assets that a company utilizes to finance day-to-day activities such as payroll and bill payment.

   a) **CHFFA.** CHFFA was created to be the state's vehicle for providing financial assistance to public and nonprofit health care providers primarily through loans funded by the issuance of tax-exempt bonds. To this end, CHFFA administers the Bond Financing Program (Program) and the Tax-Exempt Equipment Financing Program. CHFFA also provides direct loans to small and rural health facilities through the Healthcare Expansion Loan Program II Financing Program.

      In September of 2021, the Governor signed into law the Non-designated Public Hospital Bridge Loan Program to enable CHFFA to issue up to $40 million in working capital loans at zero interest rate to certain hospitals that are affected by financial delays associated with the transition to the Quality Incentive Program. These Non-designated Public Hospital Bridge Loans are required to be paid back in two years, and are secured by Medi-Cal reimbursements.

      By borrowing through CHFFA’s tax-exempt bond financing program, health facilities can likely obtain rates that are 20% lower than they would through taxable financing options. Generally, non-profit, licensed health facilities in California, including adult day health centers, community clinics, skilled nursing facilities, developmentally disabled

centers, hospitals, and drug and alcohol rehabilitation centers are eligible for CHFFA financing. Proceeds from CHFFA financings may be used primarily for capital improvements such as project-related costs, including: construction; remodeling and renovation; land acquisition (as part of the proposed project); acquisition of existing health facilities; purchase or lease of equipment; refinancing or refunding of prior debt; working capital for start-up facilities; costs of bond issuance; feasibility studies; and, reimbursement of prior expenses. Not for working capital expenses, such as salaries and benefits.

Under statute, savings resulting from issuance of tax-exempt bonds for borrowers must be transferred to the consuming public through lower or contained costs for delivery of health services. CHFFA states that to enforce this requirement, applicants are required to complete a pass-through savings certification as part of its loan application that demonstrates significant community service.

Since its first bond issuance in 1981, CHFFA's Program has issued 646 bonds for an aggregate total of approximately $47.5 billion, with 275 health facilities availing themselves of this financing.

b) Long-Term Bond Financings. CHFFA serves as a conduit of tax-exempt and taxable bonds under the Program. According to CHFFA, bonds issued by CHFFA are not a debt, liability, or a pledge of the full faith and credit of the taxing power of the state, or any of its political subdivisions, but are payable solely by qualified health facility borrowers ("Borrower" or "Health Facility"). The funding received under the Program is private funding from investors, who are typically sophisticated, and who financially analyze a Borrower's financial positon prior to buying bonds and therefore investing in the Health Facility/Borrower. Borrowers are typically rated by Standard & Poor's Financial Services, Moody's Investor Services, or Fitch Ratings, and based on the credit rating of a Health Facility, an investor would require the terms (including the interest rate) to be paid on the bond funds borrowed by the Borrower (similar to how an individual's interest rate on a loan is determined by their credit score). This Program typically provides funds to hospitals who are creditworthy.

c) CHFFA "Competitors." There are other organizations in California that provide bond financing to health facilities. The California Municipal Finance Authority (CMFA) provides tax-exempt bonds similar to CHFFA. The CMFA provide access to this market for qualified borrowers by acting as the conduit issuer, much the same way CHFFA does. Eligible costs for a CMFA financing may include the purchase of land, project design costs, construction, rehabilitation, improvement, equipment purchase and installation and legal fees. Up to 2% of the proceeds of a CMFA bond offering may be used to pay the cost of issuing bonds, such as for underwriter's and legal fees. Also, the CMFA can issue taxable bonds to cover any additional costs of issuance or for additional undertakings that are not tax-exempt.

The California Infrastructure and Economic Development Bank (I-Bank) was created in 1994 to finance public infrastructure and private development that promote a healthy climate for jobs, contribute to a strong economy and improve the quality of life in California communities. I-Bank has broad authority to issue tax-exempt and taxable revenue bonds, provide financing to public agencies, provide credit enhancements,

acquire or lease facilities, and leverage State and Federal funds. Both of these organizations can and do provide financing to health facilities, only at a higher cost than CHFFA.

d) DHLP. The DHLP provides hospitals who are financially struggling with loans beyond two years (payments are required to begin after 18 months and the loan to be discharged within 72 months of the date of the loan) and does not limit the loans to capital improvements. Under existing law, CHFFA is only allowed to provide long-term funding to credit worthy health facilities for capital improvements. This bill would allow all health facilities to finance working capital expenditures for the long-term as allowed by federal tax law on a tax-exempt basis.

e) AB 1888 (Bronzan), Chapter 1426, Statutes of 1987. AB 1888, among other provisions permitted non-profit private institutions access to CHFFA working capital loans and requires such institutions to repay working capital loans within 15 months. The Department of Finance analysis in opposition to AB 1888 noted that, "Incurring long-term, tax-exempt debt to finance everyday operating (non-capital) expenses is not desirable. Operating expenses should be financed on a "pay-as-you-go" basis. Otherwise, tomorrow's clients' end up paying costs associated with services provided today."

3) SUPPORT. The California Hospital Association (CHA) supports this bill and states that every day, hospitals throughout California care for the state's most vulnerable populations, who often have no place else to turn for help. However, many of those same hospitals are on the edge of a financial cliff and facing the difficult choice of service reductions, bankruptcy, or closure, and for this reason, CHA, on behalf of its more than 400 hospital and health system members, supports this bill, which would allow CHFFA to issue long-term working capital financings by removing the limitation that loans be repaid within 24 months. CHA states that reimbursement has remained largely stagnant, yet labor expenses have spiked 16% since 2019, pharmaceutical costs have grown by 41%, and the cost of medical supplies has jumped 19%. CHA notes that this bill does not resolve these issues, but by allowing for longer CHFFA working capital loan periods, hospitals will have more options to address increased costs. During the pandemic, CHFFA was limited in its ability to provide working capital loan assistance to health facilities due to the 24-month maturity restriction and the persistent financial impacts on hospitals from the pandemic. CHA concludes that the financial condition that led to the closure of Madera Community Hospital is not an isolated circumstance, as evidenced by the appropriation and awarding of roughly $300 million from the DHLP. Hospital closures and service reductions are immediate and clear threats to health care in communities throughout California. Without relief, the reality of the hospital closure in Madera County will, without question, be replicated in other parts of California.

4) RELATED LEGISLATION. AB 2098 (Garcia) extends repayment requirements for non-designated public hospitals that received cash-flow loans from the CHFFA Fund due to the financial impacts of the COVID -19 public health emergency.

5) PREVIOUS LEGISLATION.

a) AB 112 (Committee on Budget), Chapter 6, Statutes of 2023, establishes DHLP, until January 1, 2032, which will provide interest free cash-flow loans to not-for-profit hospitals and public hospitals, as defined, in significant financial distress, or to

governmental entities representing closed hospitals. Requires HCAI to administer the DHLP and to enter into an interagency agreement with CHFFA to implement the DHLP.

b) AB 839 (Addis) Chapter 667, Statutes of 2023, adds residential care facilities for the elderly to the list of facilities eligible to participate in financing and funding programs offered by CHFFA.

6) POLICY COMMENT. This bill will allow CHFFA to provide long-term financing to health facilities for working capital. As this bill moves forward, the author may wish to consider whether allowing hospitals to finance everyday operations over the long term is financially prudent.

REGISTERED SUPPORT / OPPOSITION:

Support

California State Treasurer, Fiona Ma
California Hospital Association
District Hospital Leadership Forum

Opposition

None on file.

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2668 (Berman) – As Introduced February 14, 2024

SUBJECT: Coverage for cranial prostheses.

SUMMARY: Requires health plan, insurer, and Medi-Cal coverage of cranial prosthesis for individuals experiencing permanent or temporary medical hair loss. Limits coverage to $750. Specifically, **this bill**:

1) Requires a health, insurer, or Medi-Cal to cover cranial prostheses for individuals experiencing permanent or temporary medical hair loss, in accordance with 2) below.

2) Requires coverage to meet all of the following requirements:

   a) A licensed provider prescribes the cranial prosthesis for an enrollee, insured, or beneficiary's course of treatment for the diagnosed health condition, chronic illness, or injury, including, but not limited to, alopecia areata, alopecia medicamentosa, scarring alopecia, and lupus. Defines cranial prosthesis as a wig or hairpiece;

   b) The contract or policy provides coverage for a cranial prosthesis to an individual enrollee, insured, or beneficiary no more frequently than once every 12 months; and,

   c) The coverage is limited to seven hundred fifty dollars ($750) for each instance of coverage, and subject to any cost-sharing requirements that are otherwise applicable under the health plan contract or insurance policy.

3) Exempts specialized health plans or insurers 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 the California Department of Insurance (CDI) to regulate health insurers. [Health and Safety Code (HSC) § 1340, *et seq*., and (Insurance Code (INS) § 106, *et seq*.]

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

3) Includes, in regulations, durable medical equipment (DME) for home use as other health benefits that EHBs must cover. [Title 28 Code of Regulations §1300.67.005]

4) Defines "basic health care services" as all of the following:
   a) Physician services, including consultation and referral;
   b) Hospital inpatient services and ambulatory care services;
   c) Diagnostic laboratory and therapeutic radiologic services;
   d) Home health services;

e) Preventive health services;
f) Emergency health care services, including ambulance and ambulance transport services and out-of-area coverage; and,
g) Hospice care, as specified. [HSC § 1345]

5) 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*.] Establishes a schedule of benefits under the Medi-Cal program, which includes benefits required under federal law and benefits provided at state option but for which federal financial participation is available. [WIC §14132]

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 lack of health insurance coverage for wigs means that Californians with alopecia and other health conditions are forced to pay out of their own pockets. The cost of wigs depends on a number of factors including length and the average cost is approximately $1,500. If patients cannot afford this cost, then they do not have access to a wig, which plays a crucial role in one's mental health. To remove this barrier, this bill would provide coverage for a wig if a licensed provider prescribes the wig for treatment for a diagnosed health condition, chronic illness, or injury, including but not limited to alopecia areata (an autoimmune disease of hair follicles that causes nonscarring patches of hair loss). Importantly, the author concludes, this bill includes parameters, which would limit coverage to no more than one wig in a year and cap the amount of coverage for a wig to $750.

2) **BACKGROUND.** According to the California Health Benefits Review Program (CHBRP), patients going through medical hair loss may use medical wigs or hairpieces to help restore their physical appearance. Depending on the needs of the person and the type and degree of hair loss, many different styles of medical wigs exist. The wigs or hairpieces may cover the whole scalp or only a portion, be made of synthetic or natural hair, and have many different methods of fixation. All these features factor into the cost of the medical wigs, with some costing upwards of $5,000. Maintenance of the medical wig is required for longevity. Medical wigs are maintained in the same manner as a head of hair, where they are cleaned with shampoo and warm water, conditioned, air-dried, and then brushed into the style or position.

   a) **Barriers.** The costs of wigs can be a large barrier to their purchase and use. More broadly, patients with alopecia may experience high financial burdens related to their disease that negatively impact their well-being, including but not limited to the costs of wigs. In a survey of 675 members of the National Alopecia Areata Foundation, 31.7% and 25.2% of respondents reported that their financial burden due to alopecia areata was moderately or seriously burdensome. Median out-of-pocket expenditures among respondents was $1,354 for disease-related expenses; headwear and cosmetic options including wigs, makeup, or scarves accounted for the largest single sector expense. Respondents reported spending a median of $450 annually on this category. Another survey found that the average cost of wigs was $1,530. To address the financial burden associated with medical wigs, several organizations may offer free or discounted medical

wigs for patients with medical conditions, including nonprofit entities such as the American Cancer Society. Several organizations also provide medical wigs to patients with alopecia areata and other medical hair loss, such as Children With Hair Loss, which provides medical wigs to children and young adults at no charge. Access to medical wigs may vary on a variety of factors, including location, availability, access to vendors supplying free or discounted products, knowledge of such resources, and affordability of discounted prices. Beyond wigs, individuals with alopecia can experience costs related to their disease, such as lost income from work absenteeism and transportation costs related to medical appointments. Patients may also dedicate substantial time related to concealment of their hair loss. Additionally, there is some cross-sectional, survey-based evidence that indicates higher financial burdens among women than men.

b) CHBRP analysis. AB 1996 (Thomson), Chapter 795, Statutes of 2002, requests the University of California to assess legislation proposing a mandated benefit or service and prepare a written analysis with relevant data on the medical, economic, and public health impacts of proposed health plan and health insurance benefit mandate legislation. CHBRP was created in response to AB 1996. SB 125 (Hernandez), Chapter 9, Statutes of 2015, added an impact assessment on EHBs, and legislation that impacts health insurance benefit designs, cost sharing, premiums, and other health insurance topics. CHBRP's analysis of this bill includes the following:

i) Assumptions. CHBRP indicates that a vast majority of baseline utilization is happening outside of insurance. There are external organizations that provide medical wigs to patients experiencing medical hair loss, often at no cost or at a discounted rate. Additionally, enrollees may be unaware of existing benefit coverage and therefore do not seek coverage for medical wigs they are purchasing out of pocket. It is also possible that medical wigs that are covered under the DME benefit are not being correctly recorded within claims data. Therefore, this analysis likely overestimates the proportion of utilization that is covered by an enrollee's health insurance at baseline. Should claims data accurately reflect baseline utilization, premium impacts due to this bill would be approximately twice as high.

(1) Impact on expenditures. This bill would result in an increase of total net annual expenditures of $26,503,000 (0.02%) for enrollees with state-regulated health insurance. Total premiums paid by employers and enrollees would increase by $29,513,000. Increases in employer premiums would range between $0.004 per member per month (PMPM) for CDI-regulated large-group policies to $0.10 PMPM for DMHC-regulated large-group plans. Enrollee premiums would increase between $0.001 PMPM for CDI-regulated large-group policies and $0.06 PMPM for DMHC-regulated individual plans. At baseline, enrollee expenses for noncovered benefits are approximately $22 million. Postmandate, these expenses would be partially paid for by an increase in premiums as well as by an increase in cost sharing for covered benefits. Cost sharing would increase by $19 million and includes an enrollee's cost share of the $750 benefit amount, as well as additional expenses should an enrollee purchase a medical wig that is more expensive than $750. On average, enrollee cost sharing would increase between $0.006 PMPM for enrollees in CDI-regulated large-group policies and $0.14 PMPM for enrollees in DMHC-regulated large-group plans. Expenses for noncovered benefits would decrease by $0.007 PMPM for enrollees in CDI-

regulated large-group policies and $0.17 PMPM for enrollees in DMHC-regulated large-group plans.

(a) Medi-Cal. According to DHCS, medical wigs may be covered for Medi-Cal beneficiaries under age 21 through the Early and Periodic Screening, Detection, and Treatment benefit when determined to be medically necessary, which could include cancer treatment. Additionally, for all other Medi-Cal members, if a Medi-Cal provider believes that medical wigs may be appropriate for a Medi-Cal member for a specific condition, which could include cancer treatment, then the provider may submit an authorization request to determine if medical necessity is established. However, CHBRP notes based on responses from the Medi-Cal managed care plans, there is a discrepancy in whether managed care plans provide coverage even for beneficiaries under aged 21. For Medi-Cal beneficiaries enrolled in DMHC-regulated plans and County Organized Health Systems, premiums would increase by $0.11 PMPM.

(b) California Public Employees' Retirement System (CalPERS). For enrollees associated with CalPERS in DMHC-regulated plans, employer premiums would increase by $0.09 PMPM and enrollee premiums would increase by $0.02 PMPM. Enrollee cost sharing for CalPERS enrollees would increase by $0.12 PMPM and expenses for noncovered benefits would decrease by $0.13 PMPM.

(c) Number of Uninsured in California. CHBRP estimates this bill would have no measurable impact on the number of uninsured persons.

ii) EHBs. This bill requires coverage for a new state benefit mandate that appears to exceed the definition of EHBs in California. CHBRP estimates that the state would potentially be required to defray the following amounts due to this bill:

(1) $0.13 PMPM for each qualified health plan (QHP – products offered on Covered California) enrollee in a small-group DMHC-regulated plans;

(2) $0.11 PMPM for each QHP enrollee in an individual DMHC-regulated plan; and,

(3) $0.11 PMPM for each QHP enrollee in a small-group CDI-regulated policy.

CHBRP estimates that this translates to a state responsibility of $6,264,000 total, which includes:

(a) $6,186,000 in payments to DMHC-regulated small-group and individual plans; and,

(b) $78,000 in payments to CDI-regulated small-group policies

iii) Utilization. For patients with alopecia areata and scarring alopecia, CHBRP relied on a 2022 survey of patients with alopecia areata, which found that 85.7% obtained a medical wig and 93.1% of respondents considered getting a medical wig. Of those who did not obtain a medical wig, the reason most commonly cited was cost. CHBRP assumed that 76% of enrollees with alopecia areata and scarring alopecia without insurance coverage obtain medical wigs at baseline and 93.1% of enrollees with alopecia areata and scarring alopecia would obtain a wig postmandate.

(1) For enrollees experiencing alopecia medicamentosa (widespread hair loss commonly as a result of chemotherapy), CHBRP used a study that examined wig use among patients with cancer. This study found that among patients experiencing hair loss, 77% purchased a wig and 97% purchased a head covering (including a medical wig). CHBRP assumed that at baseline 77% of enrollees experiencing alopecia medicamentosa use medical wigs. Postmandate, 97% of enrollees with alopecia medicamentosa would obtain medical wigs.

(2) Based on responses to CHBRP's survey of California insurers, 29% of enrollees have coverage for medical wigs at baseline. The terms of benefit coverage vary among those with existing coverage. Most enrollees have baseline benefit coverage with no limit on cost per medical wig, while a small portion of enrollees have coverage with a benefit cap of $350 or $1,000 per medical wig. Some enrollees are required to obtain medical wigs through specific vendors. Additionally, how the benefit is structured varies; most coverage of medical wigs is through the DME benefit, although some enrollees have coverage under other benefit categories. Baseline benefit coverage is not limited to enrollees with certain conditions, diagnoses, or treatments. Postmandate, all enrollees would have benefit coverage for medical wigs for $750 per medical wig.

iv) Public health. Medical hair loss can lead to a reduction in quality of life and personal well-being. Specifically, it has been documented that people with alopecia areata experience more emotional distress and mental health challenges such as anxiety, depression, self-esteem issues, and lack of confidence. Similarly, patients undergoing chemotherapy have reported hair loss as one of the most distressing side effects of chemotherapy, impacting psychological well-being and overall quality of life. There is some evidence to suggest that use of well-fitting, high-quality wigs can improve quality of life and social well-being for patients experiencing distress from alopecia areata or chemotherapy-induced alopecia.

v) Long-term impacts. For enrollees with alopecia medicamentosa, some enrollees will seek a new medical wig each year, while others will use one total. A 2019 study found that the mean period of wig use among patients with cancer was 12.5 months. Approximately half of the patients who used wigs bought one wig, 25% bought two wigs, and 14% bought three or more wigs. The overall population of patients experiencing hair loss due to cancer treatment or other drug-induced hair loss is likely to remain similar over time. For enrollees with permanent or long-term hair loss due to alopecia areata or scarring alopecia, utilization of medical wigs may be greater than in the first year postmandate. The number of enrollees with these conditions at baseline will likely remain similar over time; however, this population will grow as new enrollees experience these medical conditions and associated hair loss. As a result of the increase in utilization in the long term, long-term cost impacts of this bill would likely be higher than the first year postmandate. It is possible that unit cost of medical wigs would be impacted due to the increase in insurance coverage:

(1) Insurers may negotiate the unit cost of medical wigs, potentially driving down unit cost. One way that insurers may drive down unit cost is through requiring enrollees to obtain medical wigs through specified vendors. If these vendors provide a selection of medical wigs that are lower than the $750 benefit limit, unit cost would be lower than the first year postmandate estimate provided above;

(2) Alternately, if no vendor requirements exist or the vendors offer medical wigs up to and above the benefit coverage limit, enrollees may choose wigs with prices close to the benefit coverage limit of $750, which would contribute to long-term expenditures meeting the high-end estimates of the first year postmandate. Over time, as inflation grows, $750 per medical wig may no longer be adequate to purchase a product that meets the enrollee's satisfaction, thereby limiting the value of benefit coverage for enrollees seeking a medical wig for medical hair loss.

There are disparities in the underlying conditions that cause medical hair loss. It is therefore possible that there are disparities in need for medical wigs. Black

women, in particular, have higher rates of some of the underlying conditions that lead to medical hair loss. While this bill would be expected to expand access to medical wigs, it is not clear if this expanded access would specifically address the needs of Black women, especially as it has been reported that Black women are less likely to find medical wigs with the appropriate hair texture and hair styles. Therefore, it is unknown to what extent this bill would reduce these disparities either in the short or long term.

c) **Other states.** According to CHBRP, a number of states require coverage of medical wigs for enrollees in state-regulated individual and group health plans. Connecticut, Maryland, Massachusetts, Oklahoma, and Rhode Island require coverage for medical wigs for enrollees experiencing hair loss due to cancer, leukemia, and/or chemotherapy and radiation therapy. Meanwhile, New Hampshire's requirements are similar to this bill in that coverage for medical wigs is applicable to enrollees experiencing hair loss due to medical conditions including but not limited to chemotherapy-induced hair loss. New Hampshire requires coverage for patients with hair loss resulting from cancer or leukemia treatment as well as for patients experiencing alopecia areata, alopecia totalis, or permanent loss of scalp hair due to injury. Minnesota and Delaware require coverage of medical wigs for patients with alopecia areata. Coverage in most of these states is generally subject to certain terms and conditions, such as one prosthesis per year per enrollee, often up to a certain dollar amount.

3) **SUPPORT.** The National Alopecia Areata Foundation, cosponsor of this bill, writes that the lack of health insurance coverage for wigs means that Californians with alopecia and other health conditions are forced to pay out of their own pockets. The cost of wigs depend on a number of factors including length and the average cost is approximately $1,500. If patients cannot afford this cost, then they do not have access to a wig, which plays a crucial role in one's mental health. Stanford Medicine Children's Health (Stanford) writes that alopecia areata has two peaks of onset- one in childhood and one in adulthood- but it has been reported in all ages. As with other autoimmune conditions, there is likely a genetic basis to alopecia areata with unknown triggers that result in the loss of hair. For children or young adults, this can be a difficult time and although there is medication to treat, there is no cure. Stanford believes that individuals with alopecia areata, including children and youth should be given every resource to reclaim their confidence and identity.

4) **SUPPORT IF AMENDED.** The California Society of Dermatology and Dermatologic Surgery writes that what needs further analyzing is whether there are certain conditions or patients for whom the benefit is primarily physical and/or psychological (that is, "medically necessary" and warranting coverage), as compared to cases where a wig would be mainly cosmetic or elective (with the benefit perhaps being less warranted).

5) **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) oppose mandates for health plans and insurers to cover specific services, as well as bills that eliminate cost sharing and limit utilization management, which have similar cost impacts as coverage mandates. Moreover, they will increase costs, reduce choice and competition, and further incent some employers and individuals to avoid state regulation by seeking alternative coverage options. These bills will lead to higher premiums, harming affordability and access for small businesses and individual market consumers.

CAHP, ACLHIC, and AHIP write that state mandates increase costs of coverage, especially for families who buy coverage without subsidies, small business owners who cannot or do not wish to self-insure, and California taxpayers who foot the bill for the state's share of those mandates.

6) RELATED LEGISLATION.

a) AB 2753 (Ortega) includes DME, as specified, under EHBs coverage of rehabilitative and habilitative services and devices. AB 2753 is pending in Assembly Appropriations Committee.

b) AB 2914 (Bonta) expresses the intent of the Legislature to review California's EHB benchmark plan and establish a new benchmark plan for the 2027 plan year. Limits the applicability of the current benchmark plan benefits to plan years on or before the 2027 plan year. AB 2914 is pending in Assembly Health Committee.

c) SB 1290 (Roth) is substantially similar to AB 2914. SB 1290 is pending in Senate Appropriations Committee.

7) POLICY COMMENT. EHBs. According to CHBRP, a number of ACA provisions have the potential to or do interact with state benefit mandates. In California, nongrandfathered individual and small-group health insurance are generally required to cover EHBs. States may require state-regulated health insurance to offer benefits that exceed EHBs. The state's benchmark plan, which determines which services are included as a part of California's EHBs, does not include coverage for wigs. Coverage for wigs appears to exceed EHBs, and therefore may trigger the ACA requirement that the state defray the cost of additional benefit coverage for enrollees in QHPs in Covered California (individual and small group products sold on the Exchange). If this bill were enacted, this bill could trigger this requirement, and would require the state to defray related costs as described above. It should be noted that the state has not yet triggered this ACA requirement.

REGISTERED SUPPORT / OPPOSITION:

Support

California Advocates for Alopecia (cosponsor)
National Alopecia Areata Foundation (cosponsor)
California Agents & Health Insurance Professionals (CAHIP)
San Francisco Women's Political Committee
Scarring Alopecia Foundation
Stanford Medicine Children's Health

Opposition

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

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2670 (Schiavo and Holden) – As Amended April 10, 2024

SUBJECT: Awareness campaign: abortion services.

SUMMARY: Requires the Department of Public Health (DPH) to develop an awareness campaign to publicize the internet website "abortion.ca.gov" to the general public, health care providers, health care professional associations and societies, health care employers, and local public health officers and health departments to combat the delays and impairments to timely abortion and reproductive services that individuals face when they are misled by certain pregnancy clinics.

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 and licensing of health facilities, 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) Establishes the Reproductive Privacy Act, which prohibits the state from denying or interfering with a woman's right to choose or obtain an abortion prior to viability of the fetus, or when the abortion is necessary to protect the life or health of the woman. [HSC § 123460, *et seq*.]

3) Requires the California Health and Human Services Agency (CHHSA) to establish an internet website where the public can access information on abortion services in the state. [HSC § 123430]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, crisis pregnancy centers (CPC's) intentionally mislead, and lie to people about their reproductive healthcare options to block them from accessing abortion care in a timely manner and from making choices that are best suited to them. CPC's are so widespread that they outnumber abortion clinics in California by 20%. This bill will prompt the launch of a public awareness campaign regarding abortion.ca.gov where the public can find facilities that actually provide abortions.

2) **BACKGROUND.** Under the Reproductive Privacy Act, California law prohibits the State from denying or interfering with a woman's right to choose or obtain an abortion prior to viability of the fetus, or when medically necessary. The state defines viability as the point in a pregnancy when, in the good faith medical judgment of a physician, there is a reasonable likelihood that a fetus will survive outside the uterus without "extraordinary medical measures." Abortion is considered a basic health care service in California and, therefore, is required to be covered by commercial health insurance plans and policies and the California

Public Employees' Retirement System. Medically necessary follow-up services to abortions that constitute basic health care services must also be covered. However, the state does not mandate which types of abortion methods (i.e., procedural or medication) must be covered, nor does it mandate cost-sharing requirements specific to these services. California's Medi-Cal program is one of 16 state Medicaid programs that use their own funds to cover abortion services and follow-up services for beneficiaries. The Medi-Cal program covers abortions as a physician service without cost sharing for all enrollees. California law prohibits family planning grants distributed by the Department of Health Care Services (DHCS) from funding abortions or associated services, including post-abortion examinations.

a) Restriction on Abortion. On December 1, 2021, the United States (US) Supreme Court heard oral arguments in *Dobbs v. Jackson Women's Health Organization*, a case about a Mississippi law that would ban abortion after 15 weeks of pregnancy. This case is a direct challenge to *Roe v. Wade*, the 1973 Supreme Court decision that affirmed the constitutional right to abortion and demanding that the Supreme Court ignore established legal precedent and completely overturn Roe v. Wade.

On June 24, 2022, the US Supreme Court held that the U.S. does not confer a right to abortion. The court's decision overruled both *Roe v. Wade and Planned Parenthood v. Casey* (1992), returning to individual states the power to regulate any aspect of abortion not protected by federal law. This ruling had the effect of deferring issues of abortion rights and access to the state level, allowing states to impose restrictions on abortion rights. Consequently, abortion access in the US now diverges starkly at the state level, with some states protecting the right to abortion, some having passed laws to ban abortion, and other states imposing gestational time limits or other restrictions. Although a landmark decision nationally, the ruling did not directly affect abortion coverage in California.

b) California Future of Abortion Council (Council). In September 2021, more than 40 organizations joined together to form the Council. Sexual and reproductive health care providers, reproductive rights and reproductive justice advocacy organizations, legal and policy experts, researchers, and advocates, as well as representatives from the Office of Governor Newsom and legislative leaders, convened to identify barriers to abortion services and recommend policy proposals supporting equitable and affordable access to abortion care for Californians and all who seek care in the state.

c) 2023 Budget. A number of budget items were approved in 2023 to support aspects of the reproductive health care safety net in California. California allocated over $200 million in 2022-23 to support people seeking abortion care and abortion providers over several fiscal years. Specifically, the 2022-23 Budget Act appropriated $120 million to the California Department of Health Care Access and Information (HCAI) to establish and administer five programs designed to support and expand abortion-related care and reproductive health services across the State, including funding for capital infrastructure, uncompensated care, workforce, and practical support. The 2022-23 Budget Act also allocated $20 million to DHCS for the Los Angeles County Abortion Access Safe Haven Pilot Program for the purpose of expanding and improving access to the full spectrum of sexual and reproductive health care, including abortion, in the County of Los Angeles.

d) **Abortion.ca.gov**. One of the provisions of SB 1142 (Caballero), Chapter 566, Statutes of 2022, requires CHHSA, or an entity designated by the agency, to establish an internet website where the public can find information on abortion services in the state. Recently, the internet website abortion.ca.gov was launched and includes information about abortion steps, types of abortion, abortion provider finder, telehealth-only options, fake abortion information that includes information on clinics that do not perform abortions and may provide "false, medically inaccurate information online or in person about abortion to convince you not to have an abortion. They are sometimes called crisis pregnancy centers." The website also includes a link to the consumer alert published by the California Department of Justice entitled: "Know the Difference: Crisis Pregnancy Centers v. Reproductive HealthCare Facilities."

3) SUPPORT. Reproductive Freedom for All California (formerly NARAL Pro-Choice California) supports this bill and states that California must ensure that all communities, including immigrants, LGBTQIA+, limited English speakers, BIPOC, foster youth, and people experiencing homelessness and other extreme barriers to information and care, have access to medically accurate, honest, inclusive, and comprehensive information about their options, including regarding abortion services available in our state.

4) OPPOSITION. The California Catholic Conference (CCC) is opposed to this bill and states that CCC is always opposed to the violence of abortion. However, reducing the healthcare needs of women to abortion at the expense of every other kind of reproductive healthcare will only worsen gender biases and the outcomes for women's and maternal health. Comprehensive reproductive and sexual health understands the totality of the person, including the physiological, nutritional, endocrine, cardiovascular, and psychological needs of women across the lifespan. CCC encourages the Legislature to instead use funds to address the healthcare shortage by incentivizing solutions to OBGYN training, lowering C-section rates, maternal mortality, increasing prenatal care options, or addressing social determinants of health.

5) RELATED LEGISLATION. AB 2490 (Petrie-Norris) establishes the Reproductive Health Emergency Preparedness Program (RHEPP), upon appropriation by the Legislature, to expand and improve access to reproductive and sexual health care in emergency departments. Requires the Department of Health Care Access and Information to award grants and administer the RHEPP in collaboration with a California-based organization to serve as the grant administrator, trainer, and technical assistance provider. AB 2490 is pending in the Assembly Appropriations Committee.

6) PREVIOUS LEGISLATION.

a) AB 1918 (Petrie-Norris), Chapter 561, Statutes of 2022, establishes the California Reproductive Health Service Corps within HCAI for the purposes of recruiting, training, and retaining a diverse workforce of reproductive health care professionals who will be part of reproductive health care teams to work in underserved areas.

b) AB 2091 (M. Bonta), Chapter 628, Statutes of 2022, prohibits compelling a person to identify or provide information that would identify an individual who has sought or obtained an abortion in a state, county, city, or other local criminal, administrative, legislative, or other proceeding.

c) AB 2134 (Weber), Chapter 562, Statutes of 2022, establishes the California Reproductive Health Equity Program within HCAI to ensure abortion and contraception services are affordable for and accessible to all patients and to provide financial support for safety net providers of these services. AB 2134 is pending hearing in the Assembly Health Committee.

d) AB 2205 (Carrillo), Chapter 563, Statutes of 2022, requires a health care service plan or health insurer offering qualified health plans, as defined, to annually report the total amount of funds in the segregated account maintained pursuant to the federal Patient Protection and Affordable Care Act. Requires the annual report to include the ending balance of the account and the total dollar amount of claims paid during a reporting year.

e) AB 2320 (C. Garcia) would have required DHCS, to establish and administer a pilot program to direct funds to community health clinics that provide reproductive health care services in five counties that agree to participate. AB 2320 was vetoed by the Governor.

f) SCA 10 (Atkins), Chapter 97, Statutes of 2022, amends the California Constitution to prohibit the state from denying or interfering with an individual's reproductive freedom in their most intimate decisions, which includes their fundamental right to choose to have an abortion and their fundamental right to choose or refuse contraceptives.

g) SB 245 (Lena Gonzalez), Chapter 11, Statutes of 2022, eliminates cost sharing in abortion services.

h) SB 1301 (Kuehl), Chapter 385, Statutes of 2002, enacts the Reproductive Privacy Act, which provides that every individual possesses a fundamental right of privacy with respect to reproductive decisions, including the fundamental right to choose or refuse birth control, and the fundamental right to choose to bear a child or obtain an abortion.

REGISTERED SUPPORT / OPPOSITION:

Support

Access Reproductive Justice
Mental Health America of California
Reproductive Freedom for All CA
Steinberg Institute

Opposition

California Catholic Conference

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2726 (Flora) – As Amended March 18, 2024

SUBJECT: Specialty care network: telehealth and other virtual services.

SUMMARY: Requires the California Health and Human Services Agency (CHHSA), in collaboration with the Department of Health Care Access and Information (HCAI) and Department of Health Care Services (DHCS), to establish a demonstration project for a telehealth and other virtual services specialty care network that is designed to serve patients of safety-net providers consisting of qualifying providers, defined as a rural health clinic (RHC), federally qualified health center (FQHC), critical access hospital (CAH), or other community health center, including, but not limited to, an Indian health clinic. Specifically, **this bill**:

1) Requires CHHSA to establish a demonstration project for a telehealth and other virtual services specialty care network that is designed to serve patients of safety-net providers consisting of clinics and hospitals.

2) Authorizes the demonstration to focus on increasing access to behavioral and maternal health services and additional specialties prioritized by CHHSA.

3) Requires the demonstration project to include a grant program, administered by CHHSA, to award funding to grantees based on an application process.

4) Requires an applicant for a grant to meet both of the following conditions:
   a) Establishing, through contracting, direct hire, or partnering, a network of clinical specialists; and,
   b) Providing health information technology and technical assistance to support both the specialists and any primary care provider care coordination, referral, or electronic consultations.

5) Defines a grantee as an entity that meets the all of the following conditions:
   a) Consisting of, or partnering with, a network of health care providers, including at least 50 clinics or hospitals that serve individuals who are uninsured, individuals who are covered under the Medi-Cal program or other state public programs serving expansion populations, and individuals who are covered under the federal Medicare Program or other federal health care programs;
   b) Ensuring interoperable electronic health record bidirectional communication with primary care providers;
   c) Coordinating services, furnished through health information technology tools to individuals, with the primary care providers of those individuals;
   d) Offering evaluation and analysis on specialty service access among underserved communities; and,
   e) Having a demonstrated record of supporting the delivery of health care services and addressing social determinants of health in underserved communities in multiple regions throughout the state.

6) Establishes the purpose of the grant program as follows:
   a) Increasing capacity and efficiencies to address endemic and growing workforce shortages of specialists through enhanced triage capabilities and reduction in missed appointments;
   b) Reducing structural barriers to access experienced by patients, particularly those who have health-related social needs or disabilities, and those experiencing significant health disparities, including by reducing waiting times;
   c) Increasing financial sustainability of health care providers in rural and underserved areas;
   d) Strengthening public health resiliency, including surveillance capabilities and mitigation;
   e) Improving cost-effectiveness and optimizing utilization; and,
   f) Improving interoperability, inter-clinician care coordination, and enhanced care management.

7) Requires a grantee to evaluate its performance on the objectives described in 6) above, and submit a report of its findings to CHHSA.

8) States the intent of the Legislature that implementation of the demonstration project will facilitate compliance with any network adequacy standards set forth under existing law as applicable for health care service plans, health insurers, Medi-Cal managed care plans, or other entities providing health care coverage.

9) Conditions implementation on an appropriation made by the Legislature for this purpose in the annual Budget Act or another statute.

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, including physician, hospital or clinic outpatient, surgical center, respiratory care, optometric, chiropractic, psychology, podiatric, and therapy services, subject to utilization controls. [WIC § 14132]

3) Defines "telehealth" to:

   a) Mean the mode of delivering health care services and public health via information and communication technologies to facilitate the diagnosis, consultation, treatment, education, care management, and self-management of a patient's health care; and,

   b) Include synchronous interactions and asynchronous store and forward transfers. [Business and Professions Code § 2290.5 (a)(6)]

4) Establishes Medi-Cal coverage for health care services provided through telehealth, including specifying that in-person, face-to-face contact between a health care provider and a patient is not required under the Medi-Cal program for covered health care services and provider types designated by DHCS, when those services and settings meet the applicable standard of care and meet the requirements of the service code being billed. [WIC §14132.725 and §14132.100]

5) Establishes time and distance standards by which Medi-Cal managed care plans must demonstrate network adequacy. Allows DHCS to authorize a Medi-Cal managed care plan to use clinically appropriate synchronous video telehealth as a means of demonstrating compliance with time or distance standards. [WIC § 14197 and 14197(e)]

6) Establishes HCAI to collect and analyze health data, administer health workforce programs, oversee hospital and health facility building programs, and administer the Office of Healthcare Affordability. [Health and Safety Code 127000]

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

COMMENTS:

1) PURPOSE OF THIS BILL. According to the author, everyone should have access to timely specialty care, but patients in rural communities face unique challenges. The author asserts the state needs to build clinical capacity, improve patient access, and curtail rising health care costs for rural communities. By allowing patients to use telehealth when finding specialty care, the author notes, rural and underserved communities can quickly access quality, low-cost health care. The author concludes that the bill is a commonsense step that will reduce costly emergency room visits by allowing patients to address the root cause of health concerns before they grow worse. This bill is sponsored by OCHIN, a nonprofit provider of electronic health records systems (EHR) and health information exchange and technology support to safety net providers who collectively serve 2.2 million patients (including 674,300 who are covered under Medi-Cal). OCHIN's client network includes FQHCs, RHCs, critical access hospitals, local public health agencies, and school-based health programs.

2) BACKGROUND.

a) Specialty Care Access. Delays and difficulty accessing specialty care in Medicaid programs are well-documented. In a 2019 survey of community health center medical directors in nine states that expanded Medicaid pursuant to the federal Patient Protection and Affordable Care Act (including California) and Washington, D.C., nearly 60% reported difficulty obtaining new specialist visits and multiple access barriers. Although specialty care access can be difficult in rural areas regardless of coverage and can be challenging even with commercial coverage due to general provider shortages, the problem is more acute in Medicaid programs, including Medi-Cal, posing equity concerns. A 2023 study published in *JAMA (Journal of the American Medical Association) Network Open* found caregivers of children insured by Medicaid were more than twice as likely as caregivers of children with private insurance to report feeling frustrated trying to find specialty medical care for their children.

b) Managed Care Network Adequacy Requirements. Federal law requires Medicaid managed care plans to assure that they have capacity to serve expected enrollment in their service area and maintain a sufficient number, mix, and geographic distribution of providers. A Medicaid managed care plan must make covered services accessible to its enrollees to the same extent that such services are accessible to other state residents with Medicaid who are not enrolled with that plan. State law establishes specific time and distance standards by which a plan must demonstrate that their enrollees can access an adequate network of providers.

SB 184 (Committee on Budget and Fiscal Review), Chapter 47, Statutes of 2022, authorized DHCS to allow telehealth providers to count towards compliance with time or distance standards. Previously, DHCS allowed telehealth as an alternative access standard only if a managed care plan was not able to demonstrate compliance with time or distance standards. Pursuant to All-Plan Letter 23-001, if a plan is able to cover at least 85% of the members in a ZIP code and they can show that they have additional capacity through the use of telehealth providers to serve the remaining members, the plan would be deemed compliant with time or distance standards and no alternative access standard submission is required.

DHCS allows plans to use telehealth providers for purposes of demonstrating adequacy of their networks for primary care and the following specialty provider types: cardiology/interventional cardiology, neurology, dermatology, non-specialty mental health, endocrinology, obstetrics and gynecology; ear, nose, and throat/otolaryngology; oncology; gastroenterology; ophthalmology; hematology; HIV/AIDS specialists; infectious diseases; psychiatry; nephrology; and pulmonology.

Plans must provide access to in-person services rather than telehealth if a Medi-Cal beneficiary requests it, including access to transportation and out of network services when necessary.

c) Need for This Bill. The sponsor of this bill, OCHIN, notes safety net providers with the most clinically and socially complex patients have the greatest need for timely specialty care services to manage patients with co-morbid chronic conditions. OCHIN notes these providers, such as FQHCs and RHCs, expend significant resources trying to identify specialty referral pathways. A recent analysis of safety net providers in the OCHIN network in California found the average wait time to see a specialist is 62 days. The average wait time varies significantly by specialty and is 51 days for behavioral health, 62 days for cardiology, 75 days for neurology, 80 days for dermatology. OCHIN reports within their network, only about 27% of all patient specialty referrals closed between October 2022 and September 2023 because the patient was seen by a specialist.

OCHIN argues efforts to improve maternal health, mental and behavioral health, complex chronic disease management, and transitions to new value-driven payment and delivery models will be hamstrung by this endemic lack of access. OCHIN notes access to virtual modalities such as telehealth, store and forward, and eConsults (provider-to-provider transactions) should have improved access to specialists as it did for primary care during the COVID-19 public health emergency, but that it has not, and will not, without a network of specialist dedicated to serving patients in the safety net.

d) What This Bill Proposes. According to OCHIN, the demonstration authorized by the bill would support the launch of a dedicated safety net virtual specialty care network through an integrated electronic health record platform focused on primary care providers serving rural and underserved communities. The network would provide services to patients who have coverage through federal and state programs such as Medi-Cal and Medicare as well as those who are underinsured. The demonstration would seek to improve access to specialty care by establishing and testing a virtual network to provide specialty care through a range of digital modalities, such as eConsults, telehealth, and EHR-based clinical decision support. While there is a significant evidence base to support the use of

virtual modalities to improve access to care, OCHIN notes, this demonstration focuses on testing a virtual delivery model tailored to the payment and specific needs of rural and underserved communities. The demonstration would test the impact of timely specialty care access that is coordinated with primary care on access, health outcomes, and costs. OCHIN offers that a similar pilot on a smaller scale at an OCHIN member rural clinic in Oregon found that dermatology eConsults were effective in reducing follow-up time for patients by an average of 45 business days with significant savings through avoided specialty referrals.

e) More Details. In response to inquiries from the Committee, OCHIN stated it believes this model could be financially sustainable long-term with limited margins as long as the model is mission-driven and the up-front costs are covered by the grant funding. This demonstration is meant to scale to the next level a broader specialty network similar to the initial successful proof of concept for the dermatology pilot described above.

OCHIN points out California's large number of retired clinicians offers an opportunity for contracting arrangements with individuals who are experienced and are more likely to be motivated by building a legacy while managing demands on their time. OCHIN notes this creates a unique opportunity to create capacity that does not currently exist. In addition, OCHIN notes opportunities to partner with CAHs and other rural hospitals that lack volume for a specialist currently, but where partnerships such as this demonstration could create sufficient volume to increase specialty access in rural communities (both virtual and in-person).

OCHIN notes the demonstration grantee would be responsible for creating the network of specialists including negotiating partnerships, contracting, and hiring; negotiating agreements with payors; managing the training and change management to support clinics; and conducting the evaluation. In addition, there will be technical assistance and addressing technology needs. The goal would be to contract with the payers for patients of clinics to seek reimbursement, as well as employ sliding scale pricing for patients who are underinsured. Staffing levels would be dependent on the number of specialties and clinics involved in the demonstration.

3) SUPPORT. OCHIN supports this bill, noting the importance of access to timely specialty care, the dire state of current access, and the opportunities to improve timely access to many types of specialty care for patients of safety net providers through this demonstration.

4) RELATED LEGISLATION.

a) AB 1943 (Weber) requires DHCS to produce a public report on telehealth in the Medi-Cal program that includes analyses of telehealth access and utilization; the effect of telehealth on timeliness of, access to, and quality of care, including specialty care, for Medi-Cal enrollees; among other things; and requires data to be stratified by geographic, demographic, and social determinants of health categories to identify disparities. Allows DHCS, in consultation with CHHSA, to issue policy recommendations based on the report's findings. AB 1943 passed the Assembly Health Committee on a 15-0 vote on April 2, 2024, and is pending in the Assembly Appropriations Committee.

b) AB 2239 (Aguiar-Curry) expands the situations in which health care providers can be reimbursed by Medi-Cal for services rendered to new patients through asynchronous store and forward telehealth. This is potentially important for specialty care access through telehealth, as many patients would be new patients to a specialist, given it is not their regular source of care, and asynchronous store and forward is commonly used for dermatology and ophthalmology. AB 2339 passed the Assembly Health Committee on a 15-0 vote on April 2, 2024, and is pending in the Assembly Appropriations Committee.

5) PREVIOUS LEGISLATION. SB 184 authorized DHCS to allow Medi-Cal managed care plans to count telehealth providers for purposes of establishing compliance with time or distance standards, established permanent telehealth policy following the COVID-19 pandemic, and also required DHCS to develop a research and evaluation plan addressing, among other things, the relationship between telehealth and access to care.

6) AMENDMENTS. In response to a number of concerns and questions raised by the Committee, the author and committee have agreed to amend this bill to broaden the pool of potential applicants; require that providers served through the demonstration serve underserved populations; require an independent evaluation; require lessons learned, recommendations, and best practices from the demonstration to be publicly disseminated to inform the development of telehealth and specialty care networks to serve the safety net; and clarify a number of aspects, including the purpose of the grant, the distinction between conditions required for an applicant to apply versus the program activities funded by the grant, and that the grantee must report data and information as requested by CHHSA.

REGISTERED SUPPORT / OPPOSITION:

Support

OCHIN, Inc.

Opposition

None on file.

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2756 (Boerner) – As Amended April 3, 2024

SUBJECT: Pelvic Floor and Core Conditioning Pilot Program.

SUMMARY: Authorizes the County of San Diego, commencing January 1, 2026, to establish a pilot program for pelvic floor and core conditioning group classes that would be provided to people twice a week between their six-to-12-week postpartum window. Specifically, **this bill**:

1) Authorizes the County of San Diego, commencing January 1, 2026, until January 1, 2029, to establish a pilot program for pelvic floor and core conditioning group classes.

2) Requires the classes to be a combination of yoga and Pilates exercises that strengthen the pelvic floor muscles provided to people twice a week between their six-to-12-week postpartum window to help people rebuild their pelvic floor after pregnancy.

3) Requires the program to require all postpartum providers who teach the classes to be certified.

4) Requires the program to record the following information to directly assess pelvic floor changes, including, but not limited to, both of the following:
   a) The number of incontinent episodes per week before and after the exercises; and,
   b) Any changes with varied increases or decreases in intra-abdominal pressure, including leaking with a jump, cough, or sneeze.

5) Requires the program to annually report all the information and outcomes recorded pursuant to 4) above to the State Department of Health Care Services (DHCS).

6) Requires DHCS to provide a final report on the program established pursuant to this bill to the Legislature by June 1, 2029.

7) Makes finding and declarations as to the necessity of a special statute for the County of San Diego.

EXISTING LAW:

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

2) Establishes as California's essential health benefits (EHBs) benchmark under the 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) Defines “basic health care services” as all of the following:

a) Physician services, including consultation and referral;
b) Hospital inpatient services and ambulatory care services;
c) Diagnostic laboratory and therapeutic radiologic services;
d) Home health services;
e) Preventive health services;
f) Emergency health care services; and,
g) Hospice care. [HSC §1345]

4) Requires the criteria or guidelines used by health plans and insurers, or any entities with which plans or insurers contract for utilization review or utilization management functions, to determine whether to authorize, modify, or deny health care services to:
   a) Be developed with involvement from actively practicing health care providers;
   b) Be consistent with sound clinical principles and processes;
   c) Be evaluated, and updated if necessary, at least annually;
   d) If used as the basis of a decision to modify, delay, or deny services in a specified case under review, be disclosed to the provider and the enrollee or insured in that specified case; and,
   e) Be available to the public upon request. [HSC §1363.5 and INS §10123.135]

5) Requires reviews, for purposes of Independent Medical Review (IMR), to determine whether the disputed health care service was medically necessary based on the specific medical needs of the enrollee or insured and any of the following:
   a) Peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed service;
   b) Nationally recognized professional standards;
   c) Expert opinion;
   d) Generally accepted standards of medical practice; or,
   e) Treatments that are likely to provide a benefit to a patient for conditions for which other treatments are not clinically efficacious. [HSC §1374.33 and INS §10169.3]

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

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

COMMENTS:

1) PURPOSE OF THIS BILL. According to the author, one in three people who have given birth will experience a pelvic floor disorder in their lifetime. In the media, we have heard of Brittany Mahomes, wife of Kansas City Chiefs Quarterback Patrick Mahomes, who most recently fractured her back because of her weak pelvic floor. This is just one story being highlighted in the media when there are women every day dealing with functional problems that could have been avoided with preventative postpartum pelvic floor care. If we support new parents before they give birth, we should support them through their healing journey. The author concludes that this bill creates a pilot program in the County of San Diego for preventative postpartum pelvic floor and core conditioning group classes to avoid long-term issues with pelvic floor disorders.

2) **BACKGROUND.** According to the California Health Benefits Review Program (CHBRP) pelvic floor physical therapy, also referred to as pelvic floor muscle training (PFMT), refers to a set of modalities that are used to prevent and treat pelvic floor dysfunction (PFD). Symptoms of PFD include urinary incontinence, fecal incontinence, pelvic organ prolapse, and pelvic pain. Primary risk factors for PFD include childbirth, which increases with number of births, and aging (menopause).

   a) **CHBRP analysis.** AB 1996 (Thomson), Chapter 795, Statutes of 2002, requests the University of California to assess legislation proposing a mandated benefit or service and prepare a written analysis with relevant data on the medical, economic, and public health impacts of proposed health plan and health insurance benefit mandate legislation. CHBRP was created in response to AB 1996. SB 125 (Hernandez), Chapter 9, Statutes of 2015, added an impact assessment on EHBs, and legislation that impacts health insurance benefit designs, cost sharing, premiums, and other health insurance topics. CHBRP reviewed AB 1904 (Boerner) of 2020, which would have required all state-regulated health insurance, including Medi-Cal managed care, to cover pelvic floor physical therapy after pregnancy, and stated the following in its analysis:

      i) **Benefit coverage.** CHBRP estimated that 99.9% of enrollees with insurance that would have been subject to AB 1904 already had coverage for pelvic floor physical therapy. The 0.1% of the population subject to AB 1904 who did not have benefit coverage for pelvic floor physical therapy were a segment of those enrolled in CDI-regulated grandfathered individual market policies.

      ii) **Medical effectiveness.** CHBRP found:

         (1) There is inconclusive evidence that PFMT is effective at treating urinary incontinence in postpartum women (0–12 months after delivery);
         (2) There is a preponderance of evidence that PFMT is effective at treating urinary
         (3) incontinence in non-postpartum women;
         (4) There is limited evidence that PFMT is not effective at treating fecal incontinence in women;
         (5) There is limited evidence that PFMT is effective at treating pelvic organ prolapse in postpartum or nonpostpartum women; and,
         (6) There is insufficient evidence as to whether PFMT is effective at treating pelvic pain in postpartum women (0–12 months after delivery).

      This bill would authorize the County of San Diego to implement a Pelvic Floor and Core Conditioning Pilot Program, similar to an existing program at Scripps Health system in San Diego which currently offers pelvic floor and core conditioning group exercise classes as a voluntary option for patients experiencing issues with their pelvic floor muscles.

   b) **Pelvic Floor Physical Therapy Provider Certifications.** Pelvic floor physical therapy (used to treat symptoms of incontinence, pelvic organ prolapse, and sexual dysfunction) teaches correct contractions, muscle and body awareness, coordination and motor control, muscle strength and endurance, and relaxation. This bill does not define which providers would be authorized to provide pelvic floor physical therapy. Although licensed health providers (physical therapists, medical doctors, doctors of osteopathic medicine, nurse

practitioners, etc.) are not required to have particular training to offer these types of therapies, those without specific training do not regularly offer pelvic floor physical therapy; pelvic floor physical therapy is usually provided by physical therapists with specialized pelvic floor physical therapy training. The Academy of Pelvic Health Physical Therapy (APTA Pelvic Health) offers a Certificate of Achievement in Pelvic Health or Obstetric Physical Therapy. Licensed physical therapists who complete required coursework through APTA Pelvic Health and a case reflection within a year of completing coursework are eligible to apply for these certifications. The American Board of Physical Therapy Services offers a Specialist Certification in Women's Health, which requires licensed physical therapists to complete an exam, along with patient care requirements, to receive certification. The Herman & Wallace Pelvic Rehabilitation Institute also offers specialized training for physical therapists.

c) **Disparities and Social Determinants of Health in Pelvic Floor Disorders.** Disparities exist in prevalence of pelvic floor disorders. For example, one study demonstrated an increasing prevalence of pelvic floor disorders as cohorts aged, with about 50% of women over age 80 years experiencing at least one disorder. Other studies presented evidence of racial/ethnic disparities in stress urinary incontinence and urge urinary incontinence. Asian American women appear to have the lowest risk of urinary incontinence overall as compared with white and Hispanic women. Several studies showed that black women had highest rates of urge urinary incontinence while white women had three times the risk of stress urinary incontinence as black women and two times the risk of Asian American women. Finally, Hispanic women appear to have significantly elevated risk of pelvic organ prolapse as compared with white women.

d) **Knowledge and Treatment Seeking.** According to CHBRP, most women do not seek medical treatment despite high rates of pelvic floor disorders, although this pattern is more frequent among women of color than white women. Reasons for not seeking treatment include: Embarrassment; Urinary incontinence assumed to be a normal part of postpartum status or aging; and, Poor understanding of pelvic floor dysfunction/disorders and treatment options. According to one study, women of color were significantly less likely than white women to know that childbirth was a cause of urinary incontinence and that exercises can help control leakage. Women of color were also less likely than white women to know that pelvic organ prolapse can occur at any age, and to know that treatment options are available, including exercises that can be done to prevent progression. There is conflicting evidence in identifying potential socioeconomic barriers for accessing PFMT.

3) **SUPPORT.** Maternal and Child Health Access (MCHA) writes in support this bill which would, subject to state funding, authorize a three-year pilot program for group class exercises to help people rebuild their pelvic floor after pregnancy. MCHA notes that DHCS would report on the data from the pilot by June 1, 2029. Ideally, data from the pilot would be used to: 1) establish protocols for addressing postpartum pelvic floor issues without the need for surgical intervention; and 2) expand insurance coverage to include pelvic floor and core conditioning exercises as needed postpartum. MCHA notes that according to research published in January 2024 in the *Journal of Obstetrics & Gynecology*, pelvic floor disorders after childbirth have distressing lifelong consequences for women, requiring more than 300,000 women to have surgery annually. This represents approximately 10% of the 3 million women who give birth vaginally each year. Vaginal birth is the largest modifiable

risk factor for prolapse, the pelvic floor disorder most strongly associated with birth, and is an important contributor to stress incontinence. MCHA points to their work with low-income families throughout Los Angeles County, and states that they know there is an urgent need for this bill's services particularly in Medi-Cal, which covers 40% of all California births. Most Medi-Cal-funded deliveries are to Latinas. Postpartum pelvic floor and core conditioning exercises should be included in DHCS's draft Medi-Cal Birthing Pathways initiative, scheduled for release in June 2024. In addition, funding for the pilot for other insurance types might be available from the recent needs assessment grant on perinatal health equity awarded to DHCS and three other partner agencies by the federal Health Resources and Services Agency.

4) PREVIOUS LEGISLATION.

a) AB 47 (Boerner) of 2023 would have required a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2024, to provide coverage for pelvic floor physical therapy after pregnancy. AB 47 was not heard in the Assembly Health Committee.

b) AB 1904 (Boerner) of 2020 would have required all state-regulated health insurance, including Medi-Cal managed care, to cover pelvic floor physical therapy after pregnancy. AB 1904 was not heard in the Assembly Health Committee.

REGISTERED SUPPORT / OPPOSITION:

Support

Maternal and Child Health Access
Reproductive Freedom for All California (formerly NARAL Pro-Choice California),

Opposition

None on file.

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2767 (Santiago) – As Introduced February 15, 2024

SUBJECT: Financial Solvency Standards Board: membership.

SUMMARY: Expands the Department of Managed Health Care (DMHC) Financial Solvency Standards Board (FSSB) members from seven to 10 members. Authorizes the DMHC to appoint health care consumer advocates and representatives of organized labor unions representing health care workers, and individuals with experience in large group health insurance purchasing.

EXISTING LAW:

1) Establishes the DMHC to regulate health plans, and, which, among other duties, ensures the financial stability of health plans under the Knox-Keene Health Care Service Plan Act (Knox-Keen Act) of 1975. [Health and Safety Code (HSC) §1340, *et seq*.]

2) Establishes, within the DMHC, the FSSB, which is comprised of the DMHC Director and seven members, appointed by the DMHC Director. [HSC §1347.15]

3) Authorizes the seven appointed members to be from specified subject areas or fields, including, but not limited to, medical and health care economics, accountancy, with experience in integrated or affiliated health care delivery systems, and management and administration in integrated or affiliated health care delivery systems. Requires the members appointed by the DMHC Director to be appointed for a term of three years, but may be removed or reappointed by the DMHC Director before the expiration of the term. Specifies that the purpose of the FSSB is to do all of the following:

    a) Advise the DMHC Director on matters of financial solvency affecting the delivery of health care services;

    b) Develop and recommend to the DMHC Director financial solvency requirements and standards relating to plan operations, plan-affiliate operations and transactions, plan-provider contractual relationships, and provider affiliate operations and transactions; and,

    c) Periodically monitor and report on the implementation and results of the financial solvency requirements and standards. [HSC §1347.15(a)]

4) 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. [HSC §127501]

5) Requires the OHCA board to be composed of eight members which each person appointed to have demonstrated and acknowledged expertise in at least one of the following areas: health care economics; health care delivery; health care management or health care finance and

administration, including payment methodologies; health plan administration and finance; health care technology; research and treatment innovations; competition in health care markets; primary care; behavioral health, including mental health and substance use disorder services; purchasing or self-funding group health care coverage for employees; enhancing value and affordability of health care coverage; or organized labor that represents health care workers. [HSC §127501.10]

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 establishment of the OHCA, the FSSB was the primary space where the financial health of health plans and medical groups was discussed. With the establishment of OHCA, the FSSB's role still matters greatly, if OHCA is seen as regulating the ceiling, the FSSB can be seen as bringing oversight and transparency to the financial floor. Both are vital to understanding, discussing, and regulating the financial health of the state's health care delivery system. Now it is time that we update and modernize the makeup of FSSB to guarantee that additional, valuable perspectives are at the table. Like the Advisory Committee that assists and advises the OHCA Board, the author concludes that both individual and large group consumers voices as well as a health care worker voice are important when deliberating on financial solvency standards regulations and oversight.

2) **BACKGROUND.**

   a) **DMHC Licensure Requirements.** According to a 2018 State Health and Value Strategies report entitled, "Case Studies: State Examples of Safeguarding Financial Stability of Provider Risk-Bearing Organizations," California's Knox-Keene Act is the legal framework through which health care entities in the state are governed. The long-standing practice of providers accepting financial risk in California, and the bankruptcies of large provider groups in the 1990s, led DMHC to adopt prescriptive regulations governing health plans and provider risk bearing organizations. The state has adopted different requirements for entities based on the scope of services for which they accept financial risk and the entities with which they contract. The Knox-Keene Act requires licensure by DMHC of health plans that accept global risk, defined as risk for both institutional and professional services, for the provision of health care services.

   b) **FSSB**. According to the DMHC, the purpose of the FSSB is to advise the DMHC Director on matters of financial solvency that affect the delivery of health care services, and to develop and recommend financial solvency requirements and standards relating to plan operations, plan-affiliate operations and transactions, plan-provider contractual relationships, and provider-affiliate operations and transactions. Additionally, the FSSB periodically monitors and reports on the implementation and results of the financial solvency requirements and standards and reviews proposed regulation changes.

      The FSSB meets quarterly at DMHC. At the most recent FSSB meeting on February 28, 2024, the DMHC presented on items relating to large group aggregate rates, national trends on individual and small group premiums, the financial summary of Medi-Cal Managed Care plans, and a provider solvency quarterly update.

This bill will increase the membership of the DMHC FSSB from seven to 11 members and increase the number of members appointed by the DMHC Director from seven to ten to add requirements for expertise in large group health insurance purchasing; a representative of organized labor representing health care workers; and, a representative of health care consumers to the list of DMHC Director-appointed board members

3) **SUPPORT.** Service Employees International Union California, sponsor of this bill, writes that this bill ensures that DMHC's oversight and transparency process benefits from considering the perspectives of patients, health care workers, and purchasers when considering the impacts of health plan stability or instability. This bill codifies the consumer voice and adds experience with large health insurance purchasing and a representative of organized labor representing health care workers as additional criteria for FSSB membership. In total, this bill codifies three additional Director appointed seats. This change in board makeup will also better parallel the expertise at OHCA's Advisory Committee, where purchaser, labor, and consumer perspectives are statutorily required.

4) **PREVIOUS LEGISLATION.**

a) SB 184 (Committee on Budget and Fiscal Review), Chapter 47, Statutes of 2202, establishes OHCA within HCAI.

b) AB 731 (Kalra), Chapter 807, Statutes of 2019, expands medical rate review requirements to apply to large group health plan contracts and health insurance policies, and would impose additional rate filing requirements on large group contracts and policies.

c) AB 1404 (Santiago) of 2019 was substantially similar to this bill, as introduced, and subsequently amended to require a nonprofit sponsor to make specified annual disclosures publicly available by posting those disclosures on the nonprofit sponsor's public internet website in the same location where it posts copies of its annual report. AB 1404 died on the Senate inactive file.

d) SB 17 (Hernandez), Chapter 603, Statutes of 2017, requires carriers that file medical rate information to report to DMHC or CDI, on a date no later than the reporting of the rate information, specified cost information regarding covered prescription drugs, including generic drugs, brand name drugs, and specialty drugs, dispensed as provided.

e) SB 908 (Hernandez), Chapter 498, Statutes of 2016, requires health plans and insurers to notify purchasers in the individual and large group market if medical premium rates have been determined unreasonable.

f) SB 546 (Leno), Chapter 801, Statutes of 2015, establishes weighted average rate increase disclosure requirements for a health plan's or insurer's aggregated large group market products and requires DMHC and CDI to conduct a public meeting.

5) **AUTHOR'S AMENDMENT**. The author wishes to amend this bill to delete the reference to organized labor unions representing health care workers.

REGISTERED SUPPORT / OPPOSITION:

Support

California State Council of Service Employees International Union (SEIU California)
Health Access California
Western Center on Law & Poverty, INC.

Opposition

None on file.

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2786 (Bonta) – As Introduced February 15, 2024

SUBJECT: Mobile farmers' markets.

SUMMARY: Revises the California Retail Food Code (CRFC) to include a mobile farmers' market (MFM), as defined, and impose upon the MFM the uniform health and sanitation standards for mobile food facilities and general food safety requirements, and require DPH to establish criteria to authorize MFMs as vendors for the Special Supplemental Nutrition Program for Women, Infants and Children (WIC). Specifically, **this bill**:

1) Defines "MFM" as any vehicle used in conjunction with a commissary or other permanent food facility upon which food is sold or distributed at retail, with a focus on selling fresh fruits, vegetables, and other healthy food options, grown by local farmers and distributed directly to communities.

2) Authorizes MFMs to sell or provide a variety of foods, including shell eggs, honey, and refrigerated fresh meats.

3) Authorizes a MFM to be operated by a third party, including a nonprofit organization incorporated in California that buys, aggregates, sells, or distributes foods grown by local farmers.

4) Requires that agricultural products sold by the MFM be grown or produced by local farmers, with an emphasis on small- and medium-sized farms, socially disadvantaged farmers or ranchers, as defined, and food grown using regenerative, organic, or other climate-smart practices. Requires packaged agricultural products to be labeled with the name and address of the farm of origin.

5) Requires DPH to establish criteria for the authorization of mobile farmers' markets when establishing criteria for WIC vendor authorization.

EXISTING LAW:

1) Requires the State Department of Public Health (DPH), under the California Special Supplemental Food Program for Women, Infants, and Children (WIC), to authorize retail food vendors, by written agreement, to accept nutrition coupons and reimbursement according to the system developed by DPH. [Health and Safety (HSC) § 123310]

2) Requires DPH to establish requirements for all of the following in order to effectively manage and administer the federal and state requirements for the vendors in the WIC Program, and remain in compliance with the conditions of federal funding:

   a) Peer groups and a corresponding reimbursement system;

   b) Criteria used for vendor authorization; and,

   c) The WIC Program authorized foods. [HSC § 123322]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, too many Californians, particularly Californians of color, are living with largely preventable chronic conditions. The author asserts adequate food and nutrition are a fundamental part of preventing and treating chronic conditions, and can significantly improve a patient's quality of life and health status while also reducing healthcare costs. Further, the author asserts that low-income communities of color have disproportionate access to fresh fruits and vegetables. The author continues that MFM have emerged as a strategy to improve fruit and vegetable access and consumption, particularly among low-income, minority, and other vulnerable populations (eg, older adults and children) in food desert neighborhoods. Across California, the author indicates, there are five active mobile markets in the Counties of Butte, Contra Costa County, Marin, Sacramento, Santa Barbara, as well as the City and County of San Francisco. The author states that these programs are innovative strategies to increase fruit and vegetable consumption. The author concludes that this bill would allow WIC participants to use their WIC benefits at mobile farmer's markets, increasing access to fresh and healthy food.

2) **BACKGROUND.**

   a) **WIC.** WIC is a federally funded nutrition and health program that provides education and food. The program is designed to provide temporary assistance during those brief periods in life which can become more challenging: during pregnancy, the birth of a newborn or having a young child with nutrition and/or health conditions.

      WIC revenues are comprised of the federal grants and retained manufacturer rebates. The maximum number of participants served by WIC depends largely on food package costs.

      To be eligible to receive WIC, applicants' annual household income must fall at or below 185% of the federal poverty level (currently $55,500 for a family of four). Current recipients of Supplemental Nutrition Assistance Program (SNAP/CalFresh), Medi-Cal beneficiaries, or persons receiving Temporary Assistance for Needy Families, are adjunctively eligible. In federal fiscal year 2019 (October 1, 2018 to September 30, 2019), WIC served about 6.4 million participants per month nationwide, including nearly one million participants per month in California. In California, nearly 60% of infants born each year are eligible for WIC.

      WIC responds, up to a child's fifth birthday, with nutritious food, parenting and nutrition education, support for breastfeeding mothers and babies, referrals for services needed by the family, and requirements for medical care to continue participation.

   b) **California WIC.** California WIC, administered by DPH, contracts with 84 local agencies that operate 500 service sites statewide. The WIC local agencies, which include local health departments and non-profit agencies, certify participant eligibility, provide nutrition education and counseling as well as breastfeeding support, and provide referrals to healthcare and other community resources. In addition, the WIC local agencies issue the California WIC Card for families to purchase specific foods that provide key nutrients needed by pregnant and breastfeeding mothers, infants and young children. The WIC

Program recognizes and promotes breastfeeding as the natural source of nutrition and immunity from disease for infants. For women who choose to not fully breastfeed their infants, participants are provided with monthly benefits to purchase iron-fortified infant formula. Participants can use their WIC Card to purchase nutritious food items at nearly 4,000 WIC-authorized grocery stores throughout California. In addition, many WIC families are provided checks to purchase fresh fruits, vegetables, and herbs from local WIC authorized farmers' markets through the WIC Farmers' Market Nutrition Program.

c) **WIC Farmers' Markets.** The WIC Program supports the consumption of fresh, locally grown fruits and vegetables, and encourages shopping at farmers' markets. The WIC Farmers' Market Nutrition Program (FMNP) provides one booklet of three $10 checks ($30 total) to eligible recipients for use at WIC-authorized Farmers' Markets between May and November of each year which WIC participants can use alongside their regular WIC benefits. These coupons can be used to buy eligible foods from farmers, farmers markets or roadside stands that have been approved by the state agency to accept FMNP coupons. According to DPH's website, in August of 2019, the first farmer in California was authorized to accept the electronic Cash Value Benefit using a wireless terminal. Currently, there are over 64 farmers authorized to accept the California WIC Card.

d) **Strategies to Address Diet- Related Chronic Diseases.** Diet-related chronic diseases such as heart disease, cerebrovascular disease, cancer, and diabetes, are the leading causes of death and disability in the United States. Nutrition interventions for preventing and managing chronic disease commonly focus on improving diet quality. Some communities have limited access to, and inadequate consumption of, fruits and vegetables. Many food system and community-based strategies, including farmers markets, community gardens, community-supported agriculture, and food hubs, have emerged to address health disparities related to these realities. One such strategy to address disparities in access to produce are MFMs.

e) **MFMs.** According to the sponsor, MFMs are innovative models designed to bring fresh, locally grown produce directly to underserved communities. A MFM serves as a consolidated farmers' market that can be transported in a vehicle to food deserts, low-income communities, senior housing sites, and areas with limited fresh, healthy food options. Unlike traditional farmers' markets, which are stationary and typically located in more affluent areas, MFMs operate on wheels, traveling to neighborhoods where access to fresh, healthy foods is limited. MFMs bridge the gap between food deserts—areas lacking access to fresh produce—and local farms, filling a gap in logistics that have long created barriers to nourishment in our communities. By bringing fruits, vegetables, and other farm-fresh goods directly to communities, MFMs make nutritious, culturally relevant options more accessible to individuals who might otherwise rely on convenience stores with limited availability of fresh produce. According to a program evaluation provided by the Agricultural Institute of Marin (AIM) on the Rollin' Root mobile farmer's market (which AIM operates) found that Rollin' Root had an impact on increasing the consumption of fresh fruits and vegetables. Specifically, they state: "We found that regardless of whether the customers were consuming light to medium or medium to heavy levels of fresh fruits and vegetables before shopping at the Rollin' Root they increased their consumption of fresh fruits and vegetables by two-thirds and at least one-half respectively after shopping at the Rollin' Root."

MFMs are typically operated by community-based organizations, and not necessarily operated by the farmers/producers selling their own agricultural products. California is home to five active MFMs—operating across Alameda, Contra Costa, Marin, Sacramento, San Francisco, San Mateo, Santa Barbara, and Santa Clara counties, with an additional four MFMs in the planning stages in Napa, Los Angeles, and San Luis Obispo counties.

There is no current definition of MFMs in HSC. MFMs are currently recognized as mobile food facilities under CRFC, and meet strict health and safety guidelines set forth by local environmental health authorities for permitted mobile food facilities. MFMs are also licensed by the State Department of Food and Agriculture (CDFA), Market Enforcement Branch, as produce dealers, enabling their purchase of California Farm Products. MFMs meet strict health and safety guidelines set forth by local environmental health authorities for permitted mobile food facilities.

MFMs can be authorized as "Delivery Routes" by the U.S. Department of Agriculture to accept SNAP benefits—the federal name of the CalFresh program—and offer a Market Match through the California Nutrition Incentive Program,

MFMs are unable to redeem benefits from the WIC Program. The WIC vendor application process managed by DPH does not recognize MFMs as a vendor type. WIC families are unable to use the monthly cash-value benefit on their California WIC Card for fruits and vegetables purchases at MFMs.

3) **SUPPORT.** A coalition called Fresh Approach and AIM, cosponsors of this bill, states, as organizations focused on addressing food insecurity in California, support this bill because it will create a formal definition for MFMs in CRFC which will be a pathway to establish criteria for the authorization of MFMs as WIC vendors. This will allow many customers already using benefits such as CalFresh at MFM sites to utilize other nutrition safety net programs. A pathway for WIC retail approval would have positive ripple effects across the state by getting more fresh produce to underserved communities while simultaneously supporting the economic resiliency of our small farmers.

4) **RELATED LEGISLATION.** AB 1975 (Bonta) of 2024 adds medically supportive food and nutrition interventions as a covered Medi-Cal benefit. AB 1975 passed the Assembly Committee on Health on April 16 with a vote of 14-1 and is currently pending in the Assembly Appropriations Committee.

5) **PREVIOUS LEGISLATION.**

   a) AB 2322 (Gatto), Chapter 787, Statutes of 2012, requires DPH to adopt regulations to specify the criteria to be used and actions to be taken when initiating a moratorium on new WIC Program retail food vendor location applications.

   b) SB 1240 (Burton), Chapter 21, Statutes of 1999, requires the Department of Health Services (now DPH) to adopt and enforce standards to control food reimbursement costs in order to maximize participant access and ensure the integrity of the Special Supplemental Food Program for WIC.

6) **POLICY COMMENTS.** DPH indicates that the federal regulations governing the WIC FMNP currently do not include a definition of a MFMs. The author may wish to consider continuing to work with DPH and CDFA to ascertain how to best ensure that MFMs are authorized to receive WIC in accordance with existing federal regulations.

REGISTERED SUPPORT / OPPOSITION:

Support

Agricultural Institute of Marin (cosponsor)
Fresh Approach (cosponsor)
American Diabetes Association
Blue Zones Project- Upper Napa Valley
Butte County Local Food Network
California Food and Farming Network
Center for Land-Based Learning
Ceres Community Project
Dare 2 Dream Farms
Dragonspunk GRO
Everyone's Harvest
ExtraFood
Farming Hope
Foodwise
GLIDE
Interfaith Sustainable Food Collaborative
Marin Food Policy Council
Marin County Cooperation Team
Mercy Housing
Napa Farmers Market
North Coast Growers Association
Occidental Community Farmers Market
Orange Home Grown Foundation
Patricia Caplan Consulting
Roots of Change
Route One Farmers Market
Sustainable Agriculture Education (SAGE)
The Praxis Project
Urban Village Farmers' Market Association

Opposition

None on file.

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2789 (Wallis) – As Amended March 21, 2024

SUBJECT: Marriage: change of name.

SUMMARY: Requires the State Department of Public Health (DPH) to create and maintain an internet website that contains instructional information regarding how a person can change their name after they get married and a list of all agencies that need to be notified of a name change that occurs after a marriage.

EXISTING LAW requires DPH to prepare and publish a brochure containing specified information for distribution to applicants for marriage licenses and persons who qualify as domestic partners that includes, among other things, information concerning options for changing a name upon solemnization of marriage. [Family Code § 358]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, this bill will remove barriers to the name change process for newlywed couples throughout the state. The author states that as the most technologically innovative state, we must lead with data transparency and this bill creates a one-stop shop for all Californians so there is no confusion about what to report and to whom, when changing a last name.

2) **BACKGROUND. Information about name changes.** DPH provides an informational brochure entitled "Your Future Together" for marriage license applicants in the State of California. It notes that the Name Equality Act of 2007 AB 102 (Ma), Chapter 567, Statutes of 2007, amended by AB 2882 (Committee on Judiciary), Chapter 474, Statutes of 2016, allows one or both applicants for a California marriage license to elect to change the middle and/or last names by which each party wishes to be known after solemnization of the marriage. The brochure also includes information about living a healthy lifestyle, genetic conditions that can passed down to children, information for regarding the California Prenatal Screening Program and the California Newborn Screening Program. The brochure also states that the domestic violence is against the law and provides contact information for the National Domestic Violence Hotline or National Sexual Assault Hotline, as well as information on HIV/AIDS and communicable diseases.

   In addition to DPH's "Your Future Together" brochure, the California Courts have an online Self-Help Guide entitled "Change your name when you get married," which shares steps individuals can take to update their name on their marriage license. It notes that an individual's records are not automatically updated with the name, and individuals must take an authorized copy of the marriage certificate to each government agency where the individual needs to update their ID or record. The online website also links to information where individuals can update their driver's license or ID, birth certificate, and passport. There is also currently a free website which details how to change your name in California. There are also kits available for purchase on websites such as "NewlyNamed" which provide

individuals with step-by-step instructions on how to change their name on their Social Security card, US passport, driver's license, vehicle title and registration, professional licenses, the Internal Revenue Services, banks, Transportation Security Administration pre-check, and other loyalty programs. The author contends that many newlyweds resort to purchasing kits from private companies that assist them through the name change process, as such the internet website that this bill creates will allow equitable access to this information for couples who may not be able to afford such kits.

3) RELATED LEGISLATION.

a) AB 3045 (Ta) of 2024 requires the State Registrar to, upon request and payment of a fee, provide an applicant a decorative Asian Zodiac heirloom certificate.

b) AB 2156 (Pacheco) of 2024 requires, commencing January 1, 2027, the State Registrar of Vital Statistics (State Registrar) to require a diacritical mark on an English letter to be properly recorded on a certificate of live birth, fetal death, or death, and a marriage license

4) PREVIOUS LEGISLATION.

a) AB 2882 allows prospective spouses to combine their last names into a new last name that is more than one word, without the need to hyphenate the names.

b) AB 2176 (Wood), Chapter 34, Statutes of 2022, increases the time to register a live birth with the local registrar from within 10 days following the date of the event, to within 21 days.

5) POLICY COMMENTS. Given the fact that DPH, the state court system, and the internet have free resources on how individuals can change their name after they get married, the author may wish to consider whether or not this bill duplicates existing resources.

REGISTERED SUPPORT / OPPOSITION:

Support

None on file.

Opposition

None on file.

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2843 (Petrie-Norris) – As Introduced February 15, 2024

SUBJECT: Health care coverage: rape and sexual assault.

SUMMARY: Requires a health plan or insurer to provide coverage for emergency room medical care and follow up treatment for an enrollee or insured who is treated following a rape or sexual assault without cost sharing. Specifically, **this bill**:

1) Requires a health plan contract or insurance policy to provide coverage for emergency room medical care and follow-up health care treatment for an enrollee who is treated following a rape or sexual assault, as defined, without imposing cost sharing, including copayments and deductibles.

2) Prohibits a health plan or insurer from requiring any of the following to provide coverage under this bill:
   a) An enrollee or insured to file a police report on the rape or sexual assault;
   b) Charges to be brought against an assailant; and,
   c) An assailant to be convicted of an offense in 1) above.

3) Prohibits this bill from authorizing an enrollee or insured to receive the services required to be covered by this bill if those services are furnished by a nonparticipating provider, except as specified in 4) below.

4) Requires a plan or insurer to arrange for the provision of services required by this bill from providers outside the plan's network if those services are unavailable within the network to ensure timely access to covered health care services.

5) Defines cost sharing to include any copayment, coinsurance, or deductible, or any other form of cost sharing paid by the enrollee or insured other than premium or share of premium.

6) Exempts specialized health plan and insurance, Medicare supplement insurance, supplement insurance, or TRI-CARE supplement insurance, or to hospital indemnity, accident-only, or specified disease insurance.

7) Makes various findings and declarations including:
   a) The Center for Disease Control and Prevention's National Intimate Partner and Sexual Violence Survey published in 2017 reported that one in four American women reported they were subjected to a completed or attempted rape at least once in their life. One in three women are injured during their assault. About one in 26 American men reported being subjected to a completed or attempted rape in their lifetime;
   b) The average costs for medical care following a rape or sexual assault is $3,673. For pregnant survivors, those costs average closer to $4,500;
   c) Insured survivors pay about 14% of emergency department (ED) costs out of pocket; and,

d) High-cost medical care expenses not only discourage sexual assault reporting, but the lack of reporting also prevents a survivor from seeking justice and prevents law enforcement from obtaining the evidence necessary to bring an assailant to justice.

EXISTING LAW:

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

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

3) Defines "basic health care services" as all of the following:
   a) Physician services, including consultation and referral;
   b) Hospital inpatient services and ambulatory care services;
   c) Diagnostic laboratory and therapeutic radiologic services;
   d) Home health services;
   e) Preventive health services;
   f) Emergency health care services, including ambulance and ambulance transport services and out-of-area coverage; and,
   g) Hospice care, as specified. [HSC § 1345]

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

COMMENTS:

1) PURPOSE OF THIS BILL. According to the author, after experiencing the trauma of sexual assault, cost should not be a factor in a person's decision to seek care, evidence gathering, and hopefully reporting. Furthermore, the bureaucracy of paying for medical debt means that invoices related to post-rape medical care may force survivors to disclose their assault to others in their home, including partners, children, and parents, before they are emotionally prepared to do so. The author concludes that incurring debt for post-assault medical care also suggests to survivors they are responsible for their assault.

2) BACKGROUND. According to the California Health Benefits Review Program (CHBRP), California law requires all public and private general acute care hospitals to comply with certain standards for the examination and treatment of victims of sexual assault and attempted sexual assault, including child abuse. Hospitals that cannot comply with these standards must adopt a protocol for the immediate referral of these victims to a local hospital that is able to do so. The minimum standards include: notification of law enforcement authorities; use of statutory protocols if conducting an forensic medical exam (FME); consent for a physical examination, treatment, and collection of evidence; taking a history of sexual assault; and, for those adults and minor victims of sexual assault that consent to an FME, a physical examination and collection, preservation, and disposition of evidence through specified protocols. With regard to costs of medical services and treatments related to sexual

assault, existing law states that an any costs incurred by a qualified health care professional, hospital, clinic, sexual assault FME team, or other emergency medical facility examination related to an FME are prohibited from being charged directly or indirectly to the sexual assault victim. These costs must be treated as a local cost and charged to and reimbursed within 60 days by the local law enforcement agency in whose jurisdiction the alleged sexual assault was committed. California law further clarifies that the costs for FMEs may be reimbursed regardless of whether a victim chooses to report the sexual assault to law enforcement. It should be noted that if a sexual assault victim chooses not to undergo an FME, under existing law, any medical services received by the victim as a result of the sexual assault may be subject to cost sharing. California law also requires county hospitals to provide victims of sexual assault with testing for venereal disease and pregnancy without charge, as well as information regarding assistance available from the California Victim Compensation Board.

Sexual assault victims may choose to receive medical, counseling, and other support services in places of service other than their primary care physician's office, the ED, or other hospital settings. For example, they may prefer to receive services at a rape crisis center or other independent sexual assault service providers. Many of these organizations offer free medical or behavioral health services to victims of sexual assault and may be able to provide patients with privacy that they may not otherwise receive if they used services through health insurance. For instance, the victim may be a minor who does not wish to disclose the sexual assault to a parent due to shame, or they may be a victim of intimate partner violence and fear retaliation. CHBRP assumes many enrollees who receive sexual assault services at rape crisis centers and other locations outside their primary health insurance network may continue to do so, even if this bill was enacted, due to personal reasons unrelated to cost.

a) CHBRP analysis. AB 1996 (Thomson), Chapter 795, Statutes of 2002, requests the University of California to assess legislation proposing a mandated benefit or service and prepare a written analysis with relevant data on the medical, economic, and public health impacts of proposed health plan and health insurance benefit mandate legislation. CHBRP was created in response to AB 1996. SB 125 (Hernandez), Chapter 9, Statutes of 2015, added an impact assessment on EHBs, and legislation that impacts health insurance benefit designs, cost sharing, premiums, and other health insurance topics. CHBRP's analysis of this bill includes the following:

   i) Assumptions. Under California law, all sexual assault victims are entitled to an FME from a trained medical professional, free of charge, regardless of whether they choose to report the assault to the police. Follow-up services are not covered. All FMEs conducted by any qualified health care professional are reimbursable through local law enforcement agencies. Therefore, CHBRP assumes that services associated with an FME would be reimbursed by the local law enforcement agency, so CHBRP does not include those costs or services in this analysis.

   ii) Utilization. At baseline, CHBRP estimates 402 enrollees utilize sexual assault services without an ED visit, and 644 enrollees utilize these services with an ED visit. CHBRP assumes this bill would result in a 3% increase in utilization of services due to new users, and a 5% increased utilization of services by enrollees who used them at baseline. Thus, postmandate, CHBRP estimates 415 enrollees would use sexual assault services without an ED visit, and 663 enrollees would use services with an ED visit.

iii) **Impact on expenditures.** CHBRP estimates this bill would result in an increase $600,000 (0.0004%) of total net annual expenditures for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a $1,051,000 increase in premiums paid by employers and enrollees, and an estimated $451,000 reduction in cost sharing. At baseline, CHBRP estimates enrollees who receive sexual assault services without an ED visit are responsible for, on average, $170 in cost sharing, and those with an ED visit are responsible for, on average, $594 in cost sharing. Postmandate, all enrollees would have $0 in cost sharing, regardless of whether their services were delivered in an ED.

(1) CalPERS. For enrollees associated with the California Public Employees' Retirement System (CalPERS) in DMHC-regulated plans, CHBRP estimates that this bill would increase premiums for employer-sponsored and CalPERS employer insurance premiums by about $34,000 (0.0005%) postmandate.

(2) Covered California. CHBRP estimates that this bill would result in an increase in premiums for enrollees of individually purchased Covered California plans of about $268,000 (0.0013%). The reduction in cost sharing per user in these plans would be $250 and $1,200 for those without an ED visit and with an ED visit, respectively.

(3) Number of Uninsured in California. Since the change in average premiums does not exceed 1% for any market segment, CHBRP estimates this bill would have no measurable impact on the number of uninsured persons.

iv) **Medical effectiveness.** To assess the impact of cost sharing, requirements of criminal justice involvement, and requirements to use in-network providers impact enrollees' use of emergency and follow-up services after sexual assault, CHBRP examined health care utilization (such as, ED visits or visits for mental health services) as the outcome of interest. To assess the effectiveness of behavioral health treatment following sexual assault on enrollees' mental health, CHBRP examined physiological, behavioral, functional, and quality of life measures (such as, post-traumatic stress disorder (PTSD) symptoms, anxiety, depression, social functioning) as outcomes of interest. CHBRP found there is insufficient evidence to assess how cost sharing, requirements of criminal justice involvement, and requirements to use in-network providers impact enrollees' use of emergency room medical care and follow-up treatment for sexual assault. This does not indicate that these requirements do not have an impact; solely that no evidence was located. There is a preponderance of evidence that behavioral health treatment is effective at reducing symptoms of PTSD and depression among adults who have experienced sexual assault, as well as reducing symptoms of PTSD, anxiety, depression, and internalizing behavior among children and adolescents who have experienced sexual assault, when compared to no or minimal treatment. There is a preponderance of evidence that some behavioral health treatments are more effective at reducing mental health symptoms among adults and children/adolescents who have experienced sexual assault.

(1) Trauma-focused interventions yield significant reductions in PTSD and depression symptoms at three-months post-treatment compared to non–trauma-focused interventions among adults who have experienced sexual assault.

(2) Cognitive behavioral therapy is more effective than child-centered therapy at reducing symptoms of PTSD, anxiety, depression, and social functioning as well as internalizing behavior and sexualized behavior, among children and adolescents who have experienced sexual assault. Internalizing behaviors are those directed inwards towards oneself, such as worry, somatic symptoms,

avoidance, and suicide. Child-centered therapy focuses on enabling the child to identify their feelings by providing them with the opportunities to recognize, clarify, and express those feelings (e.g., through play).

(3) Interpersonal therapy is more effective at reducing symptoms of PTSD than prolonged exposure or relaxation therapy for adult victims of sexual assault.

v) Public health. In the first year postmandate, although a small increase in utilization of ED and follow-up services among enrollees is expected, the public health impact of this bill is unknown due to insufficient evidence regarding the impact of cost sharing on enrollees' utilization of these services. However, at the person-level, enrollees who seek care at the ED following a sexual assault may have impactful reductions in out-of-pocket costs due to having no cost sharing postmandate, in addition to health and quality of life improvements.

vi) Long-term impacts. CHBRP estimates that after the initial one year postmandate period, annual cost-sharing savings to enrollees would likely be similar to the first year. It is possible that long-term utilization for follow-up services for sexual assault would increase with the elimination of cost sharing due to this bill. With regard to behavioral health follow-up care, CHBRP notes that there is a significant supply-side barrier with a shortage of behavioral health professionals that may not be able to meet any increased demand for follow-up mental health care for sexual assault. There could be a potential for improved mental health for enrollees for whom cost was a barrier at baseline to receiving services if in the longer term, they choose to continue receiving behavioral health services due to the elimination of cost sharing as a barrier. If the reduced cost barriers resulting from this bill enables better access to behavioral health services following a sexual assault for enrollees, it could potentially reduce the risk of developing PTSD and subsequent long-term mental health consequences for those enrollees.

3) SUPPORT. The American Association of University Women California (AAUW), sponsor of this bill, states that this bill will ensure rape survivors can access emergency medical care and forensic exams. Sexual violence is a traumatic assault perpetrated by partners, individuals known to survivors, and by strangers. Sexual violence has short and long-term health impacts for survivors, including PTSD, suicidal ideation and suicidal attempts. Approximately 70% of rape or sexual assault victims experience moderate to severe distress, a larger percentage than for any other violent crime. Women make up 90% of all rape victims, however, under-reporting is rampant. Eighty percent of rapes are reported by white women, yet women of color are more likely to have been assaulted and are unfortunately reluctant to report. Men and the LGTBQ+ community are likewise subject to underreporting, as more than half of all transgender people have experienced intimate partner violence. Men, on the other hand, are socialized to believe that they cannot be victims of sexual violence. AAUW writes that cost presents a structural barrier for rape survivors who wish to access medical care and those who wish to pursue charges to bring their predator to justice, including those who are from historically marginalized groups. This barrier also creates significant challenges to law enforcement and ultimately, to their ability to bring the perpetrator to justice. While forensic exams and rape kits are free, other costs associated with an ED visit are not. This bill ensures that those individuals who wish to report a rape and those who wish to file charges will have the benefit of a rape kit test and forensic exam to provide evidence to secure more convictions for acts of sexual violence. Moreover, they can receive the medical and health care they need following a traumatic sexual attack. In many cases, health care invoices related to post-rape medical care may endanger survivors who live

with their rapist, such as a spouse, domestic partner, or roommate when an invoice is mailed to their home. AAUW concludes that this bill will also likely increase the potential for identification, arrest, and conviction of sexual predators.

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

REGISTERED SUPPORT / OPPOSITION:

Support

American Association of University Women – California (sponsor)
California Women's Law Center
Equal Rights Advocates
Family Assistance Program
Indivisible Ca: StateStrong
Lumina Alliance
Planned Parenthood Affiliates of California
SF Black and Jewish Unity Coalition
VALORCalifornia / ValorUs
Western Center on Law & Poverty, INC.

Opposition

None on file.

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2893 (Ward) – As Amended April 17, 2024

SUBJECT: The Shared Recovery Housing Residency Program.

SUMMARY: Requires the Department of Health Care Services (DHCS) to establish a certification process for recovery homes and adds a standard for recovery homes that meets the state's Housing First requirements. Specifically, **this bill**:

1) Requires DHCS to oversee certification of recovery houses by establishing a criteria for the certification of recovery housing conditions under which a recovery home may be certified and regain certification.

2) Defines "recovery house" as a residence that serves individuals experiencing, or who are at risk of experiencing, homelessness or who are experiencing serious mental illness or substance use disorders (SUDs) and that does all of the following:

    a) Satisfies the core components of Housing First pursuant to existing law;

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

    c) Emphasizes abstinence.

3) Authorizes DHCS to charge a fee of not more than $1,000 for certifying recovery houses.

4) Establishes the Shared Recovery Housing Residency Program Fund to receive all funds collected for certifying recovery housing.

5) Authorizes recovery houses that are certified by DHCS to receive referrals from DHCS, its agencies, or contractors as housing available for persons experiencing or at risk of experiencing homelessness or who are experiencing serious mental illness or SUDs.

6) Prohibits recovery housing from providing services on-site, including, but not limited to, incidental medical services, as defined.

7) Adds provisions regarding recovery housing to existing law governing Housing First, including the following:

    a) Allows state departments and agencies to fund recovery housing that use substance use-specific services, peer support, and physical design features supporting individuals and families on a path to recovery from addiction that emphasizes abstinence so long as the state program meets all of the following requirements:

        i) The state program uses at least 75% of the funds for housing or housing-based services using a harm reduction model;

ii) Requires the state program to require an application for funding, and in the submission of an application for funding, to demonstrate engagement with people with lived experience of homelessness and substance use that informs the local decision to seek funding for recovery housing options. Requires an applicant to include minutes or notes of at least two meetings between the applicant and a new or existing body of people with lived experience of homelessness and substance use in order to demonstrate engagement with people with lived experience of homelessness and substance use; and,

iii) Requires the state program to require a grantee under the program, prior to awarding subgrants, to confirm that the subgrantee has achieved successful outcomes in promoting housing retention, similar to rates of housing retention as harm reduction programs.

iv) Requires the state to perform periodic monitoring of select recovery housing programs to ensure that the recovery housing complies with the following:

(1) An individual or family is offered options and chooses recovery housing over housing offering a harm-reduction approach;

(2) The recovery housing otherwise complies with all other components of Housing First, in existing law, including low-barrier to entry;

(3) Participation in a program is self-initiated;

(4) Core components emphasize long-term housing stability and minimize returns to homelessness;

(5) Policies and operations ensure individual rights of privacy, dignity and respect, and freedom from coercion and restraint, as well as continuous, uninterrupted access to housing;

(6) Holistic services and peer-based recovery supports are available to all program participants along with services that align with participants' choice and prioritization of personal goals of sustained recovery and abstinence from substance use;

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

(8) Relapse is not a cause for eviction from housing and tenants receive relapse support;

(9) Eviction from recovery housing shall only occur when a tenant's behavior substantially disrupts or impacts the welfare of the recovery community in which the tenant resides. A tenant may apply to reenter the housing program if expressing a renewed commitment to living in a housing-setting targeted to people in recovery with an abstinence focus; and,

(10) If a tenant is no longer interested in living in a recovery housing model or the tenant is at risk of eviction, the housing program provides assistance in accessing housing operated with harm-reduction principles that is also permanent housing.

8) Defines "Housing first model" as housing that satisfies the core components of Housing First as described in 7) of existing law, below.

9) Defines "trauma-informed practices" to means a trauma-informed approach to care guided by the principles of safety, trustworthiness and transparency, peer support, collaboration and mutuality, empowerment and choice, and culture, historical, and gender issues.

EXISTING LAW:

1) Grants DHCS the sole authority in state government to license alcoholism or drug abuse recovery or treatment facilities (RTFs). [Health and Safety Code (HSC) §11834.01]

2) Defines "alcoholism or drug abuse RTF" as any, place or building that provides 24-hour residential nonmedical services to adults who are recovering from problems related to alcohol, drug, or alcohol and drug misuse or abuse, and who need alcohol, drug, or alcohol and drug recovery treatment or detoxification services. [HSC §11834.02]

3) Defines a "recovery residence" (RR) as a residential dwelling that provides primary housing for individuals who seek a cooperative living arrangement that supports personal recovery from a SUD and that does not require licensure by DHCS or does not provide licensable services, as specified, including residential dwellings commonly referred to as "sober living homes," "sober living environments," or "unlicensed alcohol and drug free residences." [HSC §11833.05]

4) Prohibits any person, firm, partnership, association, corporation, or local governmental entity from operating, establishing, managing, conducting, or maintaining an alcoholism or drug abuse RTF to provide recovery, treatment, or detoxification services without first obtaining a current valid license from DHCS. [HSC §11834.30]

5) Establishes the California Interagency Council on Homelessness with the purpose of coordinating the state's response to homelessness by utilizing Housing First practices. [Welfare and Institutions Code Section (WIC) §8255]

6) Requires agencies and departments administering state programs created on or after July 1, 2017 to incorporate the core components of Housing First. [WIC §8255]

7) Defines "Housing First" to mean the evidence-based model that uses housing as a tool, rather than a reward, for recovery and that centers on providing or connecting homeless people to permanent housing as quickly as possible. Housing First providers offer services as needed and requested on a voluntary basis and that do not make housing contingent on participation in services. [WIC §8255]

8) Defines, among other things, the "core components of Housing First" to mean:
   a) Acceptance of referrals directly from shelters, street outreach, drop-in centers, and other parts of crisis response systems frequented by vulnerable people experiencing homelessness;

b) Supportive services that emphasize engagement and problem-solving over therapeutic goals and service plans that are highly tenant-driven without predetermined goals;

c) Participation in services or program compliance is not a condition of permanent housing tenancy;

d) Tenants have a lease and all the rights and responsibilities of tenancy, as outlined in existing law; and,

e) The use of alcohol or drugs in and of itself, without other lease violations, is not a reason for eviction. [WIC §8255]

9) Prohibits, under the Fair Employment and Housing Act, discrimination against any person in any housing accommodation on the basis of race, color, religion, sex, marital status, national origin, ancestry, familial status, or disability. Specifies that discriminatory land use regulations, zoning laws, and restrictive covenants are unlawful acts. [GOV §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, this bill would direct DHCS to create a statewide certification program for recovery houses that would be in compliance with housing first policies under the federal Department of Housing and Urban Development definition. The author continues that this bill would instruct DHCS to create a certification program for these homes at a state level to standardize their care as well as reign in bad actors. The author concludes that this is a working model that the state can use housing funds to solve its acute homelessness and addiction crisis.

2) **BACKGROUND.**

   a) **Prevalence of SUD in California.** A 2022 publication from the California Health Care Foundation, entitled "Substance Use in California: Prevalence and Treatment," reported that substance use in California is widespread with over half of Californians over age 12 reporting using alcohol in the past month and 20% reporting using marijuana in the past year. According to the 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. The California Department of Public Health'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.

   b) **Homelessness in California**. Based on the 2023 point in time count, California has the largest homeless population in the nation with 181,399 people experiencing homelessness on any given night. Many of those people (113,660) are unsheltered, meaning they are living outdoors and not in temporary shelters. Nearly half of all unsheltered people in the

country were in California during the 2023 count. The homelessness crisis is driven in part by the lack of affordable rental housing for lower income people. In the current market, 2.2 million extremely low-income and very low-income renter households are competing for 664,000 affordable rental units. Of the six million renter households in the state, 1.7 million are paying more than 50% of their income toward rent. The National Low Income Housing Coalition estimates that the state needs an additional 1.5 million housing units affordable to very-low income Californians.

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

As part of their licensing function, DHCS conducts reviews of RTF operations every two years, or as necessary. DHCS's Substance Use Disorder Compliance Division checks for compliance with statute and regulations to ensure the health and safety of RTF residents and investigates all complaints related to RTFs, including deaths, complaints against staff, and allegations of operating without a license. DHCS has the authority to suspend or revoke a license for conduct in the operation of an RTF that is inimical to the health, morals, welfare, or safety of either an individual in, or receiving services from, the facility or to the people of the State of California.

AB 118 (Committee on Budget), Chapter 42, Statutes of 2023, requires other non-residential, outpatient alcohol or other drug programs be certified by DHCS. Certification is required when at least one of the following is provided: outpatient treatment services; recovery services; detoxification; or medications for addiction treatment. DHCS does not license alcohol and drug RRs with six or less beds that don't provide licensable services, known as RRs.

d) RRs. An RR is a residence for people in recovery from substance abuse. It may serve as support for individuals undergoing treatment but it does not provide treatment or care, whether medical or nonmedical. The state laws and licensing requirements that govern treatment and care facilities do not currently include RRs. Therefore, the state does not keep any list of registered RRs, conduct inspections of RRs, or perform any of the other activities associated with licensing facilities. An RR may be completely self-governed or have formal on-site management, but in the latter case, the managers' duties relate to the administration of the house rather than the tenants or their recovery (as in "case management"). The tenants of an RR pay rent and abide by house rules, which always include maintenance of sobriety and participation in a self-help program. Multiple studies have shown the effectiveness of this kind of environment as a support for people transitioning out of drug or alcohol treatment. The effectiveness of sober living as one component of a person's successful recovery program is not controversial. The California Research Bureau estimates that there are at least 12,000 sober living beds in the state to serve an eligible population of between 25,000 and 35,000 individuals. If an RR is providing any licensable services then it must obtain a valid RTF license from DHCS.

DHCS's Drug Medi-Cal-Organized Delivery System waiver permits counties to use RRs in their continuum of services if they adhere to the following guidelines: the RR does not provide SUD services that would require licensure by DHCS; all residents of an RR are actively engaged in medically necessary recovery support services to be provided off-site; each county develops guidelines for contracted RR entities; and, the county provides monitoring and oversight of the RR.

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

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

f) Harm Reduction. According to the National Institutes of Health (NIH) website, harm reduction is a strategy that aims to reduce the harms associated with certain behaviors. When applied to SUDs, harm reduction accepts that a continuing level of drug use (both legal and illegal) in society is inevitable and defines objectives as reducing adverse consequences. It emphasizes the measurement of health, social, and economic outcomes, as opposed to the measurement of drug consumption. Harm reduction has evolved over time, from its initial identification in the 1980s, as an alternative to abstinence-only focused interventions for adults with SUDs. At the time, it was recognized that abstinence was not a realistic goal for those with SUDs. In addition, those individuals who were interested in reducing, but not eliminating, their use were excluded from programs that required abstinence. NIH's website states there is persuasive evidence that harm reduction approaches greatly reduce morbidity and mortality associated with risky health behaviors. For example, areas that have introduced needle-exchange programs have shown mean annual decreases in HIV prevalence compared with those areas that have not introduced needle-exchange programs. Access to and use of methadone maintenance programs are strongly related to decreased mortality, both from natural

causes and overdoses, which suggests that these programs have an impact on overall socio-medical health. The most recent addition to the harm reduction continuum is that of safe consumption spaces, which have been successfully implemented in over 100 sites around the world.

g) Shifting Funding. SB 1380 (Mitchell), Chapter 847, Statutes of 2016 required the state to adopt a Housing First approach and required all state-funded programs to comply with Housing First. Traditional recovery housing does not necessarily conform to Housing First because it is an abstinence-based approach to addressing substance abuse. This bill aims to set new guidelines for how recovery homes could continue to provide an option for abstinence but also comply with Housing First. This bill would allow state programs to use 25% of available funding for homelessness for licensed recovery homes, as defined.

3) SUPPORT. According to the sponsors, SHARE! Collaborative Housing, this bill would establish recovery houses at the end of the continuum of care that do not provide any licensed medical services onsite. The sponsors argue that this definitional bill is crucial to ensure that during these difficult budgetary times, only the most effective programs that have a certified and proven track record should gain access to our strapped state funds.

4) RELATED LEGISLATION.

a) AB 2479 (Haney) adds requirements for recovery housing to Housing First. AB 2479 is currently pending in the Assembly Housing and Community Development Committee.

b) AB 2574 (Valencia) exempts sober living homes (SLHs) from being considered a residential use of property when evidence demonstrates that the SLH is an integral part of a licensed drug treatment facility located elsewhere. AB 2574 is currently pending in the Assembly Health Committee.

c) SB 1438 (Niello) changes the core components of Housing First to allow the eviction of a resident for the use of drugs or alcohol if children are housed in the same location, and include "recovery housing" programs, as specified. SB 1438 is currently pending in the Senate Housing Committee.

d) SB 913 (Umberg) permits a city attorney of a city in which housing units are located or a district attorney, if the units are located in the unincorporated area of the county, to enforce parts of DHCS licensing laws, as specified. Requires DHCS to adopt a process that permits a city or county to conduct announced and/or unannounced site visits to facilities licensed by DHCS and to SLHs/RRs that do not require DHCS licensure. SB 913 is currently pending in the Senate Judiciary Committee.

e) SB 1334 (Newman) defines an RR, for purposes of licensing RTFs, as a residential dwelling that provides primary housing for individuals who seek a cooperative living arrangement that supports personal recovery from a SUD, does not require DHCS licensure, and does not provide licensable services, and clarifies that an unlicensed RR may provide services to its residents, including, but not limited to, dining, housekeeping, security, transportation, and recreation. Exempts RRs from being required to be licensed RTFs if the facility does not offer recovery services, as defined, and would allow residents of an RR to actively participate in recovery services outside of the home.

Requires RRs to be operated as a separate business from a licensed RTF and require RRs to maintain separate agreements with each resident for the housing and services it provides SB 1334 is currently pending in the Senate Health Committee.

f) SB 1339 (Allen) requires DHCS to establish and provide for the administration of a voluntary certification program for supportive community residences. Defines "supportive community residence" as a residential home serving adults with SUD, a mental health diagnosis, or a dual diagnosis that does not provide licensable services.

5) PREVIOUS LEGISLATION.

a) AB 1696 (Sanchez) of 2021 would have required any government entity that contracts with a privately owned RR to provide recovery services to require the RR to comply with specified requirements. AB 1696 was vetoed by the Governor.

b) SB 349 (Umberg), Chapter 15, Statutes of 2022, creates the California Ethical Treatment for Persons with Addiction Act to provide protection for SUD treatment clients and their families. Imposes requirements and proscribed unlawful acts relating to marketing and advertising with respect to treatment provide. Requires treatment providers to adopt a client bill of rights for persons seeking treatment for SUD, and to make the bill of rights available to all-clients and prospective clients; a treatment provider to maintain records of referrals to or from a RR, as specified and, provides that acts made unlawful by the bill be subject to a civil fine of up to $20,000 per violation.

c) AB 1158 (Petrie Norris), Chapter 443, Statutes of 2021, requires an RFT licensed by DHCS serving more than six residents to maintain specified insurance coverages, including commercial general liability insurance and employer's liability insurance. Required a licensee serving six or fewer residents to maintain general liability insurance coverage. Requires any government entity that contract with privately owned RR or RTF serving more than six residents to require the contractors to, at all times, maintain specific insurance coverage.

d) AB 1098 (Daly) of 2021 would have created the Excellence in Recovery Residence Housing Act. Would have required the Secretary of the California Health and Human Services Agency to develop and publish on the DHCS internet website consensus-based guidelines and nationally recognized standards for counties to use to promote the availability of high-quality RR housing for individuals with a SUD and to dissuade the use of contracting with, or referral to, RRs that do not meet these guidelines and standards. AB 1098 was held on the Assembly Appropriations Committee suspense file.

6) POLICY COMMENTS. While the effectiveness of sober living as a component of successful recovery is not controversial, RRs have been subject to intense scrutiny by local governments and residents across the state. RRs are an especially important type of housing for persons with disabilities, and are thus afforded protections under the Fair Housing Act (FHA), Americans with Disabilities Act (ADA), and state fair housing laws. In recent years, numerous local governments have amended their zoning ordinances to add discriminatory regulations for RRs. This led the California Department of Housing and Community Development (HCD) to issue an extensive Group Home Technical Advisory (GHTA) providing guidance to local governments on how discriminatory ordinances interact with obligations under state planning and zoning laws to promote more inclusive communities and

affirmatively further fair housing. Even so, RRs and their presence in residential neighborhoods continue to be a focus of fierce debate. This year alone multiple bills targeting RRs have been introduced in direct contradiction of policies and recommendations outlined in HCD's GHTA.

This bill defines a new term in "recovery housing." But beyond meeting the core components of Housing First, it is unclear what the difference is between an RR and a "recovery home." In addition to creating this new term, this bill requires DHCS to certify "recovery homes" and give those preferential referrals and funding.

In the context of a shortage of adequate housing for persons with disabilities, which is a particularly acute problem within California's broader housing crisis and the overlapping SUD epidemic, the Legislature should question if the focus of statewide efforts to support sober living should solely be on this narrow type of "recovery housing." Specifically, the Legislature should consider:

a) **Should we be creating new terminology?** RR is a term already codified in state statute and is recognized by state and national organizations and entities. At a time when these types of housing are under such scrutiny does it make sense to bring in new definitions and terminology that could increase confusion? Or, are there pathways to formally recognize RRs that also meet higher standards, such as Housing First?

b) **Should certification, and the standards, referrals, and funding that come along with it, only be afforded to a narrow subset of housing?** Given the state's extreme shortage of housing and SUD treatment capacity, the goal should be to support and develop as much of this housing as possible. Could we certify as many RRs as possible, ensuring we have ample housing supply that meets statewide standards, and then further recognize those who go beyond the baseline standards?

c) **Is Housing First an appropriate model for sober living?** Housing First approaches homelessness by providing permanent, affordable housing as quickly as possible, then providing supportive services to prevent their return to homelessness. This strategy focuses on the idea that individuals experiencing homelessness should be provided shelter and stability before underlying issues can be successfully addressed. Housing First, as defined in state law, explicitly states that "the use of alcohol or drugs in and of itself, without other lease violations, is not a reason for eviction." The RR model is generally abstinence based, with the focus on an individual's successful recovery from SUD. While advocates for the industry state that residents are not immediately evicted upon usage, there are steps that need to be taken to support an individual to get them back on track for recovery. Even so, these principles are seemingly contradictory and the impacts of substance usage in a residence that is housing multiple people in recovery needs to be thoroughly considered. The Legislature should question if Housing First, as currently defined in state law, is an appropriate principle to apply to housing that is meant to support recovery.

7) **DOUBLE REFERRAL**. This bill is double referred; it passed the Assembly Committee on Housing and Community Development with a vote of 7-0 on April 17, 2024.

REGISTERED SUPPORT / OPPOSITION:

Support

Share! Collaborative Housing (sponsor)

Opposition

None on file.

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2914 (Bonta) – As Amended April 10, 2024

SUBJECT: Health care coverage: essential health benefits.

SUMMARY: Expresses the intent of the Legislature to review California's essential health benefits (EHBs) benchmark plan and establish a new EHB plan for the 2027 plan year.

EXISTING LAW:

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

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

3) Defines "basic health care services" as all of the following:
   a) Physician services, including consultation and referral;
   b) Hospital inpatient services and ambulatory care services;
   c) Diagnostic laboratory and therapeutic radiologic services;
   d) Home health services;
   e) Preventive health services;
   f) Emergency health care services, including ambulance and ambulance transport services and out-of-area coverage. Basic health care services includes ambulance and ambulance transport services provided through the 911 emergency response system; and,
   g) Hospice care. [HSC §1345]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, this bill states the intent of the Legislature to consider a new benchmark plan for California's EHBs. California's benchmark plan does not currently include hearing aids for children or durable medical equipment (DME) that will allow individuals to use such DMEs outside of the home, even if medically necessary. The author concludes that this bill will allow California to consider new benefits that must be covered as an EHB and will avoid having the state to defray the cost of additional benefits that exceed the EHB.

2) BACKGROUND.

a) ACA and federal requirements. Enacted in March 2010, the ACA provides the framework, policies, regulations and guidelines for the implementation of comprehensive health care reform by the states. The ACA expands access to quality, affordable insurance and health care. As of January 1, 2014, insurers are no longer able to deny coverage or charge higher premiums based on preexisting conditions. These aspects of the ACA, along with tax credits for low and middle income people buying insurance on their own in new health benefit exchanges, make it easier for people with preexisting conditions to gain insurance coverage. Additionally, the ACA requires health plans sold in the individual and small group markets to offer a comprehensive package of items and services, known as EHBs. The federal government gave each state the authority to choose its "benchmark" plan.

b) California's Current EHB. The federal Department of Health and Human Services (DHHS) define EHB based on State-specific EHB benchmark plans. The base-benchmark plan California selected for 2014 (Kaiser Foundation Health Plan Small Group HMO 30 plan) was the largest plan by enrollment in one of the three largest small-group insurance products in the state's small-group market. According to the California Health Benefits Review Program (CHBRP), California chose to supplement this plan with the pediatric oral benefit from its Children's Health Insurance Program, and the pediatric vision benefits from a federal plan to create the EHB-benchmark plan. Additionally, California chose to define habilitative services and required that these services be provided "under the same terms and conditions applied to rehabilitative services."

c) New Benchmark Selection. In late 2023, DHHS published a proposed rule that would, among other things, allow states to mandate new benefits without exceeding EHB or triggering the requirement that the state cover the costs of those new benefits (as explained below), if the state adopts a new benchmark plan that includes the new benefits. If enacted, this rule change would allow California to adopt a new benchmark plan that requires health plans to cover new benefits (such as hearing aids for children) without also incurring the cost for those benefits for on-Exchange enrollees. States must submit a proposed modified benchmark plan selection by the first Wednesday in May two years prior to the effective date of the new benchmark plan (i.e., by May 2024 for plan year beginning in 2026). Based on these time frames, the earliest that California could have a new benchmark plan in place is for plan year 2027.

Current DHHS regulations provide states with three options for choosing a new benchmark plan as follows:

i) Adopt another state's benchmark plan as used for the 2017 plan year;
ii) Replace one or more categories of EHBs under the state's 2017 benchmark plan with the same category or categories of EHB from another state's benchmark plan as used in plan year 2017; or,
iii) Select a set of benefits that would become the state's new benchmark plan.

According to the DMHC, federal law dictates the process a state must follow when selecting a new benchmark plan. These requirements include the following:

i) The state must select a benchmark plan that provides a scope of benefits equal to or greater than the scope of benefits provided by a "typical employer plan." This sets the floor for the generosity of the benefits. The benchmark plan also cannot exceed the generosity of the state's most generous "comparison plan." This sets the ceiling for the generosity of the benefits. The state must submit to DHHS an actuarial certification and report affirming the selected benchmark plan meets these floor and ceiling requirements;

ii) The benefits in the proposed benchmark plan cannot be "unduly" weighted toward any particular category of benefits, must provide benefits for diverse segments of the population, and cannot include discriminatory benefit designs;

iii) The state must submit a formulary drug list in a format and manner specified by DHHS;

iv) The state must provide reasonable public notice regarding the proposed new benchmark plan and must give the public a reasonable time to comment on the proposed plan; and,

v) The state must notify DHHS of the selected new benchmark plan and submit supporting documentation, including the required actuarial certification and report, "by the first Wednesday in May of the year that is two years before the effective date" of the new benchmark plan.

d) Health insurance mandates. The ACA establishes that while states are permitted to require coverage of benefits in addition to those considered EHBs, they must defray the cost of providing those state-mandated benefits, either by paying the enrollee directly or by paying the qualified health plan (offered on Covered California). For California, it is unclear which entity or person would be responsible for the determination of whether a benefit mandate requires defrayal. According to CHBRP, federal guidance established the "State" as the entity that would identify when a state benefit mandate exceeds EHBs; however, the state entity would be subject to federal oversight. Additionally, California has not yet officially determined who or which agency would be the responsible party for determining whether a benefit exceeds EHBs. It should be noted that since the passage of the ACA and the selection of the Kaiser benchmark plan, no legislation has been signed into law that exceeded the EHBs and required the state to defray the cost of that service. As recently as last year, SB 635 (Menjivar) of 2023 would have required hearing aids for children and was vetoed by Governor Newsom as exceeding EHBs.

New health benefit mandates do not require defrayal when they do not exceed the state's definition of EHBs. According to CHBRP, state rules around service delivery method (such as telemedicine), provider types, cost sharing, or reimbursement methods are not considered state benefit mandates that would trigger the requirement for the state to defray the costs even though plans and policies in a state must comply with these requirements. Premiums, however, may increase as a result of a new benefit mandate. It should also be noted that states adopting a new benchmark plan or revising the existing one, will not result in triggering defrayal. Premiums, however, may increase as a result of setting a new benchmark plan.

3) SUPPORT. Children Now and Let California Kids Hear write in support that this bill provides a policy solution that will permanently close coverage gaps and ensure that all children in California have access to affordable and comprehensive health insurance that meets all of their health needs.

4) **SUPPORT IF AMENDED.** The California Dental Association (CDA) urges the state to clearly define a minimum dental benefit design to ensure consumers receive a meaningful benefit. CDA urges the state to consider at minimum the following items when considering a dental benefit design: A separate dental deductible for embedded dental benefits; no annual or lifetime limits on covered dental services; and, a reasonable annual out-of-pocket maximum.

5) **SUPPORT IN CONCEPT.** The California Association of Health Plans (CAHP), a support in concept position on this bill. The process envisioned by this bill is preferrable to the current approach of haphazardly considering one-off benefit mandate bills that inflate health care premiums for all Californians. As lawmakers, health plans, and many others are working to make health care more affordable, other interest groups continue to propose a slew of individual coverage mandate bills that collectively significantly increase the cost of health plan premiums. While relatively few consumers benefit from most health care mandates, ALL Californians would pay higher premiums. According to CAHP, this is the wrong approach.

6) **RELATED LEGISLATION.**

   a) SB 1290 (Roth) is substantially similar to this bill. SB 1290 is pending in Senate Health Committee.

   b) AB 2753 (Ortega) includes DME, as specified, under EHBs coverage of rehabilitative and habilitative services and devices.

7) **PREVIOUS LEGISLATION.**

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

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

   c) SB 729 (Menjivar) would have required large and small group health plan contracts and disability insurance policies issued, amended, or renewed on or after January 1, 2024, to provide coverage for the diagnosis and treatment of infertility and fertility services. SB 729 was held on the Assembly Appropriations Suspense file.

REGISTERED SUPPORT / OPPOSITION:

Support

Children Now
Children's Specialty Care Coalition
City of Santa Clarita
Crohns and Colitis Foundation

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2942 (Villapudua) – As Amended March 21, 2024

SUBJECT: Novel Allogeneic Adipose Cell-Based Viral Therapies Clinical Trials Grant Program.

SUMMARY: Establishes the Novel Allogeneic Adipose Cell-Based Viral Therapies Clinical Trials Grant Program to be administered by the State Treasurer for the purpose of providing funding for clinical trials of novel allogeneic adipose cell-based viral therapies for cancer treatment. Specifically, **this bill**:

1) Establishes the Novel Allogeneic Adipose Cell-Based Viral Therapies Clinical Trials Grant Program to be administered by the Treasurer.

2) Requires the Treasurer to award grants on a competitive basis. Requires the Treasurer establish minimum standards, funding schedules, and procedures for awarding grants.

3) Requires the Treasurer to prioritize awarding grants to health facilities with a demonstrated commitment to patient safety and ethical research practices.

4) Requires a health facility that applies for a grant to meet both of the following requirements:
   a) Provide to the Treasurer patient safety data on adipose stem cells combined with vaccinia virus; and,
   b) Possess a proof of concept using allogeneic adipose cell-based viral therapies via a phase 1 safety or clinical trial.

5) Requires grants to be used pursuant to the following requirements:
   a) Requires the first $20 million of awarded grants to be allocated for phase 1 of a clinical trial;
   b) Requires a significant portion of grant money to be used in clinical trials conducted in low-income communities, traditionally excluded from leading-edge clinical trials;
   c) Requires clinical trials funded by the grant program to include wraparound services for participants from low-income communities;
   d) Allows wraparound services to include transportation, childcare, and paid medical leave; and,
   e) Requires on or before July 1, 2026, or 18 months following future appropriations by the Legislature, the Treasurer to submit a report to the Legislature, in compliance with existing law, on the progress of clinical trials funded pursuant to this article, including the impact on underserved communities and the success of wraparound services.
6) Specifies that this bill is operative upon an appropriation by the Legislature.

7) Specifies the provisions of this bill are in effect only until January 1, 2031, and as of that date are repealed.

8) Makes related findings and declarations.

EXISTING LAW:

1) Requests the University of California (UC) to establish and administer the Breast Cancer Research Program, as a comprehensive grant and contract program to support research efforts into the cause, cure, treatment, earlier detection, and prevention of breast cancer. [Health and Safety Code (HSC) § 104145.

2) Requires State Department of Health Care Services (DHCS) to develop and maintain the Breast and Cervical Cancer Treatment Program to expand and ensure quality breast and cervical cancer treatment for low-income uninsured and underinsured individuals who are diagnosed with breast or cervical cancer. [HSC § 104145]

3) Establishes the Human Leukocyte Antigen Testing Fund within the State Treasury, to be administered by the State Department of Health Services (now administered by DHCS). [HSC § 104170]

4) Establishes the Cancer Research Fund within the State Treasury. Requires moneys in the fund to be made available for expenditure by DHCS, upon appropriation by the Legislature. Requires the fund to consist of money accepted by DHCS from grants and donations from private entities and of public moneys transferred to the fund. [HSC § 104180}

5) Establishes the California Firefighter Cancer Prevention and Research Program, administered by the Department of Public Health to award grants to eligible institutions to conduct research on biomarkers of exposure that quantify chemical carcinogens absorbed and metabolized by firefighters that ultimately lead to a cancer diagnosis. [HSC § 104210.1]

6) Defines the duties of the Treasurer, which include, but are not limited to, keeping an account of all money received and disbursed to and from the Treasury. [Government Code § 12320 – 12334]

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 American Cancer Society reports that 2 million new cancer cases are expected in 2024 alone and from this approximately 611,720 deaths are anticipated. The author notes that typical cancer trials are costly and require patients to repeatedly travel to a central site for assessments, administration of therapies, tests to monitor results, and medications to take at home. The author states that these requirements create a selection bias by eliminating many people with little disposable income, few transportation options, inflexible work hours, and family-care obligations. The author concludes that this bill establishes a grant program that will provide the non-invasive novel allogenic adipose cell-based cancer therapies to low-income individuals, people of color and women, who would otherwise go without.

2) BACKGROUND.

a) Novel allogenic adipose cell-based viral therapies. Novel allogenic adipose cell-based viral therapies are used in the treatment of several types of cancer including but not limited to, breast cancer, ovarian cancer, prostate cancer, thyroid cancer, and squamous

cell head and neck carcinoma. This treatment is non-invasive and costs significantly less per-dose than radiation and chemotherapy. Calidi Biotherapeutics (Calidi), who supports this bill, manufactures this kind of treatment. Other vendors include Akamis Bio; GCG oncology; Genelux; IconOVir Bio; KaliVir Immunotherapeutic; and, TILT Biotherapeutics. This bill establishes a statutory framework for a grant program to fund clinical trials for this treatment.

b) Barriers to access clinical trials. According to the National Cancer Institute, when it comes to paying for clinical trials, the sponsor of the study and health insurance plans cover many of the costs. Patient costs in clinical trials are costs such as doctor visits, hospital stays, standard cancer treatments, treatments to improve symptoms of cancer or side effects from treatment, lab tests, X-rays and other imaging tests. These costs are often covered by health insurance. Research costs are those related to taking part in the trial. Examples of research costs include the study drug; lab tests performed purely for research purposes; added X-rays and imaging tests performed solely for the trial; and, extra doctor visits that patients would not have with usual care. These costs are often not covered by health insurance, but may be covered by the trial's sponsors. Before participating in a clinical trial, patients are encouraged to learn about which costs are covered by the study, which costs they or their health plan need to pay. Participants may be asked to pay for treatments and procedures not covered by insurance. The typical trial also requires patients to repeatedly travel to a central site — such as a university hospital — for assessments, administration of therapies, tests to monitor results, and medications to take at home. This often involves several hours per trip as well as paying for transportation, food, child and elder care. These requirements create a selection bias by eliminating many people with little disposable income, few transportation options, inflexible work hours, and family-care obligations.

c) Racial disparities in clinical trial participation. Given barriers to access clinical trials, these trials are often limited to those who have the resources to afford participating in the trial, leading to disparities in participation for low-income communities of color. A 2020 report from the U.S. Food and Drug Administration showed, 75% of research participants are white, while white people are 60% of the population in the U.S.; 8% of research participants are African-American/Black, while African-American/Black people are 13% of the population in the U.S.; 11% of research participants are Latino/Hispanic, while Latino/Hispanic people are 18% of the population in the U.S.; 6% of research participants are Asian, while Asian Americans are 6% of the population in the U.S.

d) Importance of diversity in clinical trials. According to Hopkins Medicine, it is critical to advance diversity in clinical trials for the following reasons: i) race, disability and socioeconomic status, and other demographic factors can affect people's risk of developing certain conditions. It also can impact their responses to medical interventions and their overall health outcomes. The more that participants who take part in clinical research make up a diverse group, the more likely that the research results — and any decisions to start or stop clinical treatments — will apply to a diverse group of patients; and, ii) It is important that research participants represent the people who are most impacted by the disease or condition being studied. For example, certain cancers and sickle cell disease are much more common among people of color, making it crucial that people of color take part in clinical studies of these serious illnesses.

The author contends that the intent of this bill is to increase access to clinical trials for underrepresented populations by providing funding for clinical trials as well as wrap-around services for participants. The bill includes a report back to the legislature on the success of the program.

3) **SUPPORT.** Calidi writes in support, stating that currently clinical trials in California are almost exclusively funded by consumers, directly out-of-pocket. This does not account for the limited availability of trials in facilities across California and this means that access to clinical trials is severely limited. Calidi continues that this bill establishes a pilot program that when funded would provide two clinical trials and all wrap-around services for 80 total patients for novel allogenic adipose cell-based viral therapies. Calidi notes that without this pilot program this extraordinary treatment remains available only for those who have the economic and geographic resource to locate a trial and pay out-of-pocket. According to Calidi, by including wrap-around services in this bill is the first of its kind, making this treatment obtainable for single mothers, veterans, non-native speakers, and those lacking access to consistent transportation. Calidi concludes that this bill is essential to advancing California's long-term goal of increasing access to care and innovating through diverse clinical trials.

4) **PREVIOUS LEGISLATION.**

   a) SB 184 (Committee on Budget and Fiscal Review), Chapter 47, Statutes of 2022, i) expands, effective July 1, 2022, the routine patient care coverage requirements for qualifying clinical cancer trials for purposes of the Medi-Cal program, to conform to the federal Medicaid definition of a qualifying clinical trial; ii) requires treatment to be provided in a qualifying clinical trial, which means a clinical trial, in any clinical phase of development, that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition and is described in Section 1396d(gg)(2)(A) of Title 42 of the United States Code; and, iii) implements this section only if federal approvals are obtained, and federal financial participation is available and not otherwise jeopardized.

   b) AB 1810 (Committee on Budget), Chapter 34, Statutes of 2018, eliminates length-of-treatment caps for breast and cervical cancer treatments within the Breast and Cervical Cancer Treatment Program.

5) **AMENDMENTS.** The author wishes to amend the bill to strike the reference to the report's July 1, 2026 due date to instead make the report due 18 months following funding for the program upon appropriation by the legislature.

REGISTERED SUPPORT / OPPOSITION:

Support
Calidi Biotherapeutics, Inc.
One individual

Opposition
None on file.

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 3045 (Ta) – As Amended March 21, 2024

SUBJECT: Birth certificate: decorative Asian Zodiac heirloom birth certificate.

SUMMARY: Requires the State Registrar to, upon request and payment of a fee, provide an applicant a decorative Asian Zodiac heirloom certificate. Specifically, **this bill**:

1) Requires the decorative Asian Zodiac heirloom certificate to be of a distinctive design as determined by the State Department of Public Health (DPH) to include Asian Zodiac artwork by local artists, the seal of the State of California, and a facsimile of the State Registrar's signature.

2) Provides that when the original form of the certificate of a live birth furnished by the State Registrar contains a printed section at the bottom containing medical and social data or labeled "Confidential Information for Public Health Use Only," the confidential information is prohibited from being reproduced in the copy of the record.

3) Prohibits information included on sealed certificate of live birth from being included on the decorative Asian Zodiac heirloom certificate.

4) Requires DPH to set the fee for the decorative Asian Zodiac heirloom certificate to capture the reasonable costs of developing, preparing, and providing the decorative Asian Zodiac heirloom certificate.

5) Require the moneys collected by the State Registrar to be deposited with the Treasurer for credit to the Health Statistics Special Fund (the Fund).

6) Specifies that, upon appropriation, the moneys in the Fund be used by DPH for the administrative costs of developing, preparing, and providing the decorative Asian Zodiac heirloom certificate, including payment of local artists.

EXISTING LAW:

1) Establishes the Office of Vital Records within DPH. [Health and Safety Code (HSC) § 131051]

2) Prescribes the duties of the State Registrar of Vital Statistics (State Registrar) and local registrars of births and deaths with respect to the registration of certificates of live birth, fetal death, or death, and marriage licenses. [HSC § 102100-102155}

3) Prescribes the information to be listed on a certificate of live birth. [HSC § 102425}

4) Requires the State Registrar, upon request and payment of a fee, as specified, to provide an applicant a decorative heirloom certificate of any birth registered to that official, containing only identification information and the seal of the State of California and a facsimile of the State Registrar's signature. [HSC § 103590]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, there are over six million Asian-Americans in California, comprising of 15% of our state's population. The author states this bill would allow individuals to ask the State Registrar to include the Asian zodiac sign corresponding with their date of birth when applying for a decorative heirloom birth certificate. The author notes through collaboration with California's Asian American and Pacific Islander (AAPI) community, the State of California would obtain pieces of artwork to add to these decorative birth certificates upon request and additional payment. The author states this bill would only apply to decorative heirloom birth certificates upon the specific request from the applicant to add their Asian zodiac sign, and would authorize the State Registrar to set a fee to capture the reasonable costs of developing, preparing, and providing the decorative Asian Zodiac heirloom certificate. The author concludes this bill will help enhance community pride in the AAPI community and their allies and celebrate the rich traditions and heritage of Asian cultures.

2) **BACKGROUND.** According to the 2020 United States Census, California has a population of over six million Asian-Americans, accounting for about 15% of our state's population. Despite comprising a significant portion of the state's population, AAPI individuals often face marginalization and lack of visibility in various aspects of society, including cultural recognition and representation. For many AAPI individuals, the Asian zodiac holds deep personal significance, reflecting beliefs, traditions, and values passed down from generation to generation.

   According to Asian mythology, there are animals each assigned to a year in a twelve year cycle. Each assigned animal has personality traits that transcend to people born in that year. In Asian philosophy and culture, the zodiac sign is an indicator of personal and professional success.

   California authorizes a commemorative birth certificate with the state seal on it. Florida and Maryland have commemorative birth certificates, but they are not specifically geared for AAPI audiences and are of a generic commemorative nature. Victoria, Australia offers a commemorative birth certificate which the author indicates serves as the model for this bill.

   This bill requires DPH to obtain pieces of artwork to add to these decorative birth certificates upon request and additional payment. Further, this bill authorizes the State Registrar to set a fee to capture the reasonable costs of developing, preparing, and providing the decorative Asian Zodiac heirloom certificate.

   The author notes the intent of this bill to celebrate diversity and foster a sense of pride among AAPI communities.

3) **RELATED LEGISLATION.** AB 2156 (Pacheco) of 2024 requires the State Registrar of Vital Statistics (State Registrar) to require a diacritical mark on an English letter to be properly recorded on a certificate of live birth, fetal death, or death, and a marriage license.

REGISTERED SUPPORT / OPPOSITION:

Support

None on file.

Opposition

None on file.

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 3059 (Weber) – As Amended March 11, 2024

SUBJECT: Human milk.

SUMMARY: Requires a health plan contract or insurance policy, as specified, to cover the same health benefits for human milk and human milk derivatives covered under the Medi-Cal program as of 1988. Exempts from tissue bank licensure, the storage or distribution of pasteurized human milk that was obtained from a mothers' milk bank, as defined, by a general acute care hospital (GACH).

EXISTING LAW:

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

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

3) Defines "basic health care services" as all of the following:
   a) Physician services, including consultation and referral;
   b) Hospital inpatient services and ambulatory care services;
   c) Diagnostic laboratory and therapeutic radiologic services;
   d) Home health services;
   e) Preventive health services;
   f) Emergency health care services; and,
   g) Hospice care, as specified. [HSC § 1345]

4) Establishes the Medi-Cal program, administered by 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*.] Establishes a schedule of benefits under the Medi-Cal program, which includes benefits required under federal law and benefits provided at state option but for which federal financial participation is available. [WIC §14132]

5) Requires human milk and human milk derivatives supplied by a mothers' milk bank for human consumption as a covered service under the Medi-Cal benefits program. Defines mothers' milk bank as any person, firm, or corporation which engages in the not-for-profit procurement, processing, storage, distribution, or use of human milk, contributed by volunteer donors, in compliance with standards prescribed by the Human Milk Banking Association of North America (HMBANA). [WIC § 14132.34]

6) Licenses and regulates health facilities by the Department of Public Health (DPH), including GACHs. [HSC §1250, *et seq*.]

7) Requires a hospital that collects, processes, stores, or distributes human milk collected from a mother exclusively for her own child to comply with the most current standards established for the collection, processing, storage, or distribution of human milk by the HMBANA until or unless DPH approves alternative standards. Requires DPH to assess hospital processes for collecting, processing, storing, or distributing human milk pursuant to its current practice, as required. Does not apply to any hospital that collects, processes, stores, or distributes milk from human milk banks or other outside sources. [HSC § 1648]

8) Requires every tissue bank operating in California on or after July 1, 1992, to have a current and valid tissue bank license issued or renewed by DPH. Exempts some of the following:
   a) The collection, processing, storage, or distribution of human whole blood or its derivatives by blood banks licensed, or any person exempt from licensure, as specified;
   b) The collection, processing, storage, or distribution of tissue for autopsy, biopsy, training, education, or for other medical or scientific research or investigation, when transplantation of the tissue is not intended or reasonably foreseeable;
   c) The collection of tissue by an individual physician and surgeon from their patient or the implantation of tissue by an individual physician and surgeon into their patient. Prohibits this exemption from being interpreted to apply to any processing or storage of the tissue, except for the processing and storage of semen by an individual physician and surgeon when the semen was collected by that physician and surgeon from a semen donor or obtained by that physician and surgeon from a tissue bank licensed under this chapter
   d) The collection, processing, storage, or distribution of fetal tissue or tissue derived from a human embryo or fetus; and,
   e) The storage of a human cell, tissue, or cellular- or tissue-based product, as defined by the federal Food and Drug Administration (FDA), that is either a medical device approved of the Federal Food, Drug, and Cosmetic Act or that is a biologic product approved under federal law by a licensed physician or podiatrist acting within the scope and authority of their license and practicing in a lawful practice setting.

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

COMMENTS:

1) PURPOSE OF THIS BILL. According to the author, addressing disparities in health care means looking at access to life-saving nutrition. The mortality rate for Black infants is three times higher than for white infants, so we need to identify what can be done to address staggering disparities within newborn care. Breast milk is the optimal nutrition source for vulnerable babies, but approximately 12% of neonatal intensive care units in California do not use donor milk. Donor milk is a covered benefit under Medi-Cal, but not under commercial plans. This bill will ensure parity and make it clear that donor milk is a covered health benefit for all babies that have a medical necessity. The author concludes that this bill will pave the way for better health outcomes for all vulnerable babies in California.

2) BACKGROUND. The American Academy of Pediatrics (AAP) recommends exclusive feeding with human milk for the first six months of life, with the continuation of feeding for 1 year or longer as mutually desired by mother and infant. In addition, the AAP recommends

that when mother's own milk is not available that donor human milk (DHM) be provided to all preterm and low-birthweight. DHM is provided through human milk banks that collect DHM, screen it for disease, pasteurize it, and freeze it for distribution to hospitals for use in the neonatal intensive care unit (NICU) setting. Necrotizing Enterocolitis (NEC) is a severe disease of the intestinal tract and is one of the main causes of morbidity and mortality among very low–birthweight (VLBW) infants.

a) Tissue bank requirements. All California hospitals that collect, process, store, or distribute human milk collected from a mother exclusively for her own child must follow HMBANA standards. DPH requires all hospitals that store DHM to hold a tissue bank license. California law defines a tissue bank as a place, establishment, or institution that collects, processes, stores, or distributes tissue for transplantation into human beings. Transplantation is defined as the act or process of transferring tissue, including by ingestion, from a donor to the body of the donor or another human being. Tissue is defined as a human, human cell, group of cells, including the cornea, sclera, or vitreous humor and other segments of, or the whole eye, bones, skin, arteries, sperm, oocytes, embryos, blood, other fluids, and any other portion of a human body. California requires tissue banks operating in California on or after July 1, 1992, to have a current and valid tissue bank license from DPH. The law includes exemptions for certain procedures; however, the storage or distribution of pasteurized human milk is not among them. California milk banks that meet the state's statutory definition of a mothers' milk bank that applied for a tissue bank license before January 1, 1995, are exempt from the application and annual renewal fee for a tissue bank license. There are two milk banks that meet the state's definition of a mothers' milk bank: Mothers' Milk Bank in San Jose was founded in 1974, and the University of California (UC) Health Milk Bank was founded in 2020. The UC Health Milk Bank is required to hold a valid tissue bank license to operate, whereas the Mothers' Milk Bank in San Jose is exempt.

According to the author, milk banks that collect and process unpasteurized milk should have a tissue bank license, while hospitals that are only storing and distributing the pasteurized donor milk product should not. California currently exempts hospitals from obtaining a tissue bank license for the purpose of collecting, processing, storing or distributing human milk collected from a mother exclusively for her own child. Hospitals follow the same safety protocols for storing and distributing pasteurized DHM as a mother's own milk. This bill exempts the storage or distribution of DHM in a GACH from tissue bank licensure. The author states that only two other states besides California require a tissue bank license- New York and Illinois.

b) Medi-Cal coverage of donor milk. Since 1998, California law has required the state's Medi-Cal program to provide coverage for DHM and human milk derivatives supplied by a mothers' milk bank for human consumption. Although the law does not define "human milk," "human milk derivatives," or details on coverage requirements, DHCS published a policy letter highlighting the importance of breastfeeding for mothers and infants. The policy letter further specified that the timely provision of human milk must be covered if "a mother is unable to breastfeed due to medical reasons, and the infant cannot tolerate or has medical contraindications to the use of any formula, including elemental formulas." In a May 2023 billing code update, DHCS described Medi-Cal eligibility and noted that mother and infant must have one or more of the following conditions:

i) A mother is unable to breast feed due to medical conditions;
ii) The infant cannot tolerate or has medical contraindications to using formulas including elemental formulas;
iii) The infant is born at a VLBW (less than1500 g) and very premature (less than 32 weeks gestation);
iv) Gastrointestinal anomaly, metabolic/digestive disorder, or recovery from intestinal surgery when digestive needs require additional support;
v) Diagnosed with failure to thrive (not appropriately gaining weight/growing);
vi) Formula intolerance, with documented feeding difficulty or weight loss;
vii) Infant hypoglycemia (low blood sugar); congenital heart disease, pre or post organ transplant;
viii) Other serious health conditions when the use of banked DHM is medically necessary and supports the treatment and recovery of the infant; and,
ix) The mother's milk must be contraindicated, unavailable (due to medical or psychological condition), or available but lacking in quantity or quality to meet the infant's needs.

DHCS further clarified that authorized providers who can prescribe pasteurized DHM are physicians and advance practice nurses (Nurse Practitioners, Clinical Nurse Specialists, Certified Nurse Midwives or Physician Assistants) and may include state licensed nutritionists or registered dieticians under a physician's supervision. Prescriptions must show the amount and frequency of the feedings, three ounces per unit, 35 ounces per day only good for 30 days. Coverage may be up to 12 months of age as is medically necessary and appropriate. Human milk banks must be accredited by the HMBANA, a nonprofit professional association of milk banks. HMBANA issues safety guidelines on processed DHM for member banks.

c) California Health Benefits Review Program (CHBRP) analysis. AB 1996 (Thomson), Chapter 795, Statutes of 2002, requests the University of California to assess legislation proposing a mandated benefit or service and prepare a written analysis with relevant data on the medical, economic, and public health impacts of proposed health plan and health insurance benefit mandate legislation. CHBRP was created in response to AB 1996. SB 125 (Hernandez), Chapter 9, Statutes of 2015, added an impact assessment on EHBs, and legislation that impacts health insurance benefit designs, cost sharing, premiums, and other health insurance topics. CHBRP's analysis of this bill includes the following:

i) Assumptions. This bill would affect coverage of two health services: DHM and human milk-derived fortifiers (HMF). At baseline, CHBRP estimates that 39.13% of enrollees with health insurance subject to this bill have coverage for DHM and HMF. Postmandate, CHBRP estimates that 100% of enrollees with health insurance subject to this bill would have coverage for these benefits.

(1) Impact on expenditures. In 2025, this bill would result in, approximately, an additional $9,668,000 (0.00006%) in total net annual expenditures. This is inclusive of an approximate $8.6 million shift in expenses for DHM and HMF from providers (hospitals) to health insurance subject to this bill, and cost offsets due to an estimated increase in prevented cases of NEC and Bronchopulmanary Dysplasia (BPD). CHBRP estimates this bill would result in an additional 35 enrollees (1%) utilizing DHM and an additional 11 enrollees utilizing HMF. In the first year postmandate, CHBRP estimates this bill would

lead to universal access to DHM in California through the removal of requirements for hospitals to be licensed as a tissue bank in order to provide DHM to patients, and that there would be a reduction in the average number of NEC and BPD cases of 0.62 and 1.75 cases per year, respectively, as well as a corresponding reduction in length of hospital stay (18 days for medically treated NEC; 50 days for surgically-treated NEC; 26 days for BPD).

(2) Premiums for enrollees in individual plans purchased through Covered California would increase by a total of $1,307,000 in annual expenditures, a 0.0083% increase.

(a) Medi-Cal. At baseline, Medi-Cal beneficiaries in DMHC-regulated plans have 100% coverage for human milk and human milk derivatives. In DMHC-regulated Medi-Cal plans, total premiums would decrease by $36,000 (0.0001%).

(b) CalPERS. For enrollees associated with the California Public Enrollees' Retirement System (CalPERS) in DMHC-regulated plans, premiums would increase by 0.0079% ($0.0621 per member per month, or $553,000 total increase in expenditures).

(c) Number of Uninsured in California. CHBRP estimates this bill would have no measurable impact on the number of uninsured persons.

ii) EHBs. In California, nongrandfathered individual and small-group health insurance is generally required to cover EHBs. According to CHBRP, this bill would not appear to exceed the definition of EHBs in California. Washington is currently pursuing a new EHB benchmark plan that would include DHM for inpatient use for infants and parents that meet certain criteria. Washington requires any update to the state EHB benchmark plan to include coverage for DHM.

iii) Medical effectiveness. CHBRP found clear and convincing evidence that DHM is more effective than preterm formula in the prevention of NEC and BPD in preterm infants. CHBRP found limited evidence that DHM is not as effective as preterm formula for weight gain, and a preponderance of evidence that DHM is no more effective than preterm formula for the prevention of late-onset sepsis in preterm infants. Additionally, findings were inconclusive regarding the effectiveness of DHM versus bovine milk on outcomes for preterm infants.

iv) Utilization. Inpatient utilization of DHM and HMF At baseline, CHBRP estimated that 3,471 enrollees, or 99% of VLBW and very preterm infants in California NICUs, utilize DHM in the inpatient setting. Postmandate, CHBRP estimated that 3,507, or 100%, of medically eligible enrollees would utilize DHM in the inpatient setting, an increase of 1% or 35 infants. At baseline, CHBRP estimated that 1,041, or 30%, of medically eligible enrollees utilize HMF in the inpatient setting. Postmandate, CHBRP estimated that 1,052, or 30%, of medically eligible enrollees would utilize HMF in the inpatient setting, an increase of 1% or 11 infants. At baseline, CHBRP estimates limited use of DHM and HMF in the outpatient setting due to medical necessity guidelines and utilization management approaches such as prior authorization. While coverage for DHM and HMF would increase to 100% postmandate, it is important to note that benefit coverage does not equal utilization. CHBRP assumed continued limited use of DHM in the outpatient setting postmandate due to the continued use of medical necessity guidelines and utilization management approaches and to access barriers such as availability of the local supply, access to a local milk bank, and the requirement of a prescription from a physician.

v) **Public health.** In the first year postmandate, CHBRP estimates that there would be a reduction in the average number of NEC and BPD cases per year, respectively, as well as a corresponding reduction in length of hospital stay (18 days for medically-treated NEC; 50 days for surgically-treated NEC; 26 days for BPD). This estimate is supported by clear and convincing evidence that DHM is medically effective in preventing NEC and BPD in preterm infants and an estimated increase in utilization (1%) of DHM. CHBRP estimates this bill would lead to universal access to DHM in California through the removal of requirements for hospitals to be licensed as a tissue bank in order to provide DHM to their patients and through reimbursement of these treatments. This could reduce disparities in receipt of DHM between infants with an inpatient stay at a smaller hospital.

vi) **Long-term impacts**. In this bill, CHBRP assumes a 1% change in utilization of DHM, which would lead to a reduction in the average number of cases of NEC and BPD over time. As both NEC and BPD are conditions that leave survivors with long-term significant morbidities including cerebral palsy, growth and development challenges, and academic difficulties, the prevention of these conditions could have significant long-term consequences both for the infants and their family and caregivers.

3) **SUPPORT.** The UC, sponsor of this bill, writes that DHM has been used for decades to feed premature infants when their own parents' milk is not sufficient or cannot be used. DHM is used in the NICU to support the health and increase the survival of very low birth weight infants; it has been shown to reduce the incidence of a devastating bowel disease, known as NEC, compared to infant milk formula. Studies have shown that five to ten percent of VLBW babies develop NEC, which disproportionally impacts infants of color. The incidence of NEC is around 60% higher for Hispanic and Black infants when compared to white infants and can be reduced with adequate access to DHM. Expanding access to DHM will help close racial disparities in infant care. This bill would also address a challenge to establishing a DHM program in the requirement that hospitals obtain a tissue bank license to distribute the pasteurized donor milk. Under current law, the milk bank holds a tissue bank license and pasteurizes the milk, thus killing any live cells that can transmit disease. The DHM that arrives at hospitals no longer contains living cells, is ingested and should not be treated the same as tissues and organs. About 12% of NICUs in California do not use DHM, this bill will address this regulatory barrier by exempting hospitals from having to obtain a tissue bank license in order to distribute donor milk to infants in the NICU, setting California on a path of achieving 100% DHM usage in our NICUs.

4) **SUPPORT IF AMENDED.** Prolacta Bioscience writes that it manufactures a first-of-its kind, 100% human milk-derived nutritional product used in NICUs around the country, including across California. Prolacta's products are used to fortify the diets of vulnerable extremely premature infants and have been clinically shown to decrease instances of complications such as NEC. As a human milk bank, Prolacta complies with all tissue banking regulations in California, holds licenses related to human milk banking in several other states, including Maryland, New York, and Pennsylvania, and is registered as an exempt infant formula manufacturer with the FDA. This bill would not cover Prolacta's DHM products due to relying on outdated language from the 1988 Medi-Cal coverage. Unfortunately, such language was drafted prior to the development of California's tissue banking regulations and the ensuing development of other human milk banks in California, such as Prolacta. As such, the reimbursement would only apply to so-called "mothers milk

banks" who are dues-paying members of the HMBANA, a trade group of milk banks. By inadvertently creating this monopoly, this bill would be closing out other participants, including local companies like Prolacta, who create life-saving products and have long complied with California's tissue banking regulations. In addition, this bill would clarify that the state's tissue banking regulations do not apply to "(t)he storage or distribution of pasteurized human milk that was obtained from a mothers' milk bank, as defined in Section 14132.34 of the Welfare and Institutions Code, by a general acute care hospital." At present, any hospital that provides DHM or other DHM products must obtain a tissue banking license, even if they are simply providing donor milk to patients. As written, this bill would remove that requirement, but only for hospitals that obtain milk from a mother's milk bank. If the Legislature believes the tissue bank license is too onerous for hospitals, it should apply the exemption uniformly to milk procured from all licensed tissue banks, not an arbitrary subset.

5) **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) oppose mandates for health plans and insurers to cover specific services, as well as bills that eliminate cost sharing and limit utilization management, which have similar cost impacts as coverage mandates. Moreover, they will increase costs, reduce choice and competition, and further incent some employers and individuals to avoid state regulation by seeking alternative coverage options. These bills will lead to higher premiums, harming affordability and access for small businesses and individual market consumers. CAHP, ACLHIC, and AHIP write that state mandates increase costs of coverage, especially for families who buy coverage without subsidies, small business owners who cannot or do not wish to self-insure, and California taxpayers who foot the bill for the state's share of those mandates.

6) **RELATED LEGISLATION.**

   a) AB 1926 (Connolly) requires health plan contracts or disability insurance policies to provide coverage for formulas, as defined, for the treatment of chronic digestive diseases and inherited metabolic disorders, as specified. AB 1926 is pending in Assembly Appropriations Committee.

   b) AB 2914 (Bonta) and SB 1290 (Roth) expresses the intent of the Legislature to review California's EHB benchmark plan and establish a new benchmark plan for the 2027 plan year. Limits the applicability of the current benchmark plan benefits to plan years on or before the 2027 plan year. AB 2914 is pending in Assembly Health Committee. SB 1290 is pending in Senate Appropriations Committee.

7) **PREVIOUS LEGISLATION.** SB 1316 (Wolk) of 2016 would have required DPH to adopt rules and regulation based substantially on HMBANA guidelines, governing a licensed tissue bank that collects, processes, stores, or distributes human milk. SB 1316 was held in the Senate Appropriations Committee.

REGISTERED SUPPORT / OPPOSITION:

Support

University of California (sponsor)

American Academy of Pediatrics, California
American College of Obstetricians and Gynecologists District IX
BreastfeedLA
California Association of Public Hospitals & Health Systems
California Association of Women's Health, Obstetric and Neonatal Nurses
California Hospital Association
California Life Sciences
California Medical Association
California WIC Association
Children's Specialty Care Coalition
County of Santa Clara
Human Milk Banking Association of North America
Human Milk Connection
Mothers' Milk Bank
UC San Diego's Human Milk Institute

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 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 3156 (Joe Patterson) – As Amended March 21, 2024

SUBJECT: Medi-Cal managed care plans: exemption from mandatory enrollment.

SUMMARY: This bill exempts Medi-Cal eligible individuals who receive services from a regional center and use a Medi-Cal fee-for-service (FFS) delivery system as a secondary form of health coverage from mandatory enrollment in Medi-Cal managed care, and requires a Medi-Cal beneficiary seeking an exemption from enrollment in managed care on this basis to complete and submit an exemption form every five years.

EXISTING LAW:

1) Establishes an entitlement to services for individuals with developmental disabilities under the Lanterman Developmental Disabilities Services Act (Lanterman Act). [Welfare and Institutions Code Section (WIC) § 4500, *et seq*.]

2) Establishes a system of nonprofit regional centers throughout the state to identify needs and coordinate services for eligible individuals with developmental disabilities and requires the Department of Developmental Services (DDS) to contract with regional centers to provide case management services and arrange for or purchase services that meet the needs of individuals with developmental disabilities, as defined. [WIC § 4620 *et seq*.]

3) Requires the development of an Individual Program Plan (IPP) for each regional center consumer, which specifies services to be provided to the consumer, based on his or her individualized needs determination and preferences, and defines that planning process as the vehicle to ensure that services and supports are customized to meet the needs of consumers who are served by regional centers. [WIC § 4646]

4) Requires a regional center to identify and pursue all possible sources of funding for consumers receiving regional center services, including Medi-Cal and private entities, to the maximum extent they are liable for the cost of services, aid, insurance, or medical assistance to the consumer. [WIC § 4646]

5) 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. [WIC § 14000, *et seq*.]

6) Establishes the California Advancing and Innovating Medi-Cal (CalAIM) Act as a set of Medi-Cal transformation initiatives, and requires the implementation of the time-limited CalAIM initiative to support a number of goals, including transitioning and transforming the Medi-Cal program to a more consistent and seamless system by reducing complexity and increasing flexibility. [WIC §14184.100]

7) Authorizes DHCS to standardize those populations that are subject to mandatory enrollment in a Medi-Cal managed care plan across all aid code groups and Medi-Cal managed care models statewide, with certain exceptions. [WIC § 14184.200]

8) Prohibits a person having private health care coverage to receive the same health care items or services furnished or paid for by a publicly funded health care program. [WIC § 10020 (a)]

9) Requires a carrier of private health care coverage to reimburse a publicly funded health care program for the cost incurred in rendering health care paid for by the public program, to the extent of the benefits provided under the terms of the policy for the items provided or the services rendered. [(WIC) § 10020 (c)]

10) Requires health plans and other entities to provide to DHCS beneficiary information and access to real-time, electronic eligibility verification, in a format provided by the department, for purposes of cost avoidance. [WIC § 14124.90]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, children and adults with developmental disabilities who have private health coverage have been faced with a dilemma whereby accepting enrollment in Medi-Cal managed care to access supplemental services has jeopardized their ability to maintain their existing providers that are part of their private health coverage network.

   As DHCS moved these individuals into Medi-Cal managed care plans, the author asserts, it has caused inexplicable confusion with the delivery of their health care, requiring families to request exemptions from DHCS to keep their existing medical teams. The author indicates his office has been working closely with DHCS and that, although DHCS acknowledges that these issues should not be occurring, the problems persist. The author indicates the administrative work families have had to do to retain their trusted providers has caused anxiety and uncertainty for a particularly vulnerable population.

   This bill would exempt individuals with other health coverage who also receive services though a regional center from mandatory enrollment in the Medi-Cal managed care delivery system. Essentially, this would allow these individuals to choose to be enrolled in Medi-Cal FFS instead of in a managed care plan. The author indicates if the issues were to be addressed administratively, the bill would not be necessary.

2) **BACKGROUND.** Individuals with developmental disabilities who receive services from a regional center, and need a higher level of care, such as home and community-based services, are generally required to enroll in Medi-Cal as a "generic resource" if they are eligible. This is true even if they have other health coverage, because the regional center is a "payer of last resort." This means the regional center must ensure Medi-Cal or other entities pays for services to which an individual may be entitled, prior to funding those services from the regional center budget. Thus, individuals who are the subject of this bill rely on regional center services and, as a condition of accepting regional center services, must enroll in Medi-Cal so they can access Medi-Cal covered services that are not available under their private health plans, such as In-Home Supportive Services.

Medi-Cal provides benefits through both a FFS and managed care delivery system. Medi-Cal is also the payer of last resort if services can be covered by another payer, such as an individual's other health coverage (OHC), which may be through a private commercial health plan. If an individual has OHC, DHCS must ensure the OHC pays for any services covered by that health plan or insurer prior to Medi-Cal paying for services, and seek to recover costs from third parties like OHC that may be liable for payment of such costs.

This bill was prompted by complaints from individuals who indicated they were losing access to providers contracted with their private OHC, because of the transition of their Medi-Cal from FFS to managed care, which has been pursued as part of a larger statewide initiative under CalAIM. More detailed background on several of these components is provided below.

a) Medi-Cal is the Payer of Last Resort. Federal law requires state Medicaid programs to take reasonable measures to ascertain the legal liability of third parties, including other health plans and insurers, to pay for services covered under Medicaid. A beneficiary is required to utilize their private coverage prior to their Medi-Cal benefits when the same service or benefit is available under the beneficiary's private health coverage. When this occurs, Medi-Cal will be secondary to the other health coverage, covering allowable costs not paid by the primary insurance (for instance, copayments) up to the Medi-Cal rate.

b) Mandatory Transition to Managed Care. Over the last several years, most of the Medi-Cal population has transitioned into Medi-Cal managed care. Under CalAIM initiative, several additional eligibility groups have been transitioned into managed care in 2022 and 2023 on a mandatory basis. Prior to CalAIM, enrollment into the FFS delivery system or the managed care delivery system was based upon specific geographic areas, the health plan model, and/or the aid code that a beneficiary is determined to qualify for. DHCS introduced mandatory enrollment in managed care as part of CalAIM to guarantee a similar beneficiary experience across counties, and to simplify, standardize, and streamline Medi-Cal program administration.

Mandatory managed care enrollment means that Medi-Cal beneficiaries who were enrolled in FFS, and were either excluded from managed care or able to choose managed care on a voluntary basis, are now required to enroll in a managed care plan. Beneficiaries with OHC who do not have Medicare transitioned on January 1, 2022, while beneficiaries who are dually eligible for Medi-Cal and Medicare transitioned effective January 1, 2023.

Certain exceptions remain in statute. These include, for instance, individuals eligible for only restricted-scope Medi-Cal benefits, those made eligible on the basis of a "share of cost," meaning they their income is not low enough to qualify for full-scope Medi-Cal without a share of cost, and those made eligible on the basis of a federally approved Medi-Cal Presumptive Eligibility program, during the relevant period of presumptive eligibility. Individuals who are Native American and youth in the foster system are also exempt from managed care enrollment.

c) Maintaining Providers During an Individual's Transition to Managed Care. State law provides additional, temporary exceptions whereby individuals who transition to a managed care plan can retain relationships with their providers who are not contracted

providers with the plan.

i) **Medical Exemption Request (MER).** Beneficiaries can file a MER to request a temporary exemption from enrollment into a managed care plan only until the member's medical condition has stabilized to a level that would enable the member to transfer to a network provider of the same specialty without deleterious medical effects. Members may get a medical exemption if a member has a complex medical condition, as defined in regulation.

ii) **Continuity of Care**. Members transitioning from Medi-Cal FFS to a Medi-Cal managed care plan may request continuity of care from their plan to remain with their current FFS provider for up to 12 months after the enrollment date with the managed care plan. The plan must honor the continuity of care request if the following conditions are met: the individual can establish a pre-existing relationship exists with that provider; the plan has no quality concerns with the provider; and the plan and provider can agree to a rate.

Anecdotally, some of the individuals whose experience has prompted this bill have applied for and been deemed eligible for MERs, but it a MER is a temporary, not permanent, exemption from managed care enrollment.

Once an individual is stabilized and/or continuity of care has run its course, for individuals *without* OHC who rely on Medi-Cal to pay their health care costs, an individual may be required to change providers to a provider in the Medi-Cal managed care plan's network. The situation for an individual *with* OHC is further described below.

d) **How Medi-Cal Managed Care Interacts with OHC**. Most private plans have cost-sharing like copayments or coinsurance, which Medi-Cal will pay on behalf of the Medi-Cal enrollee when an individual has OHC. Medi-Cal prohibits billing patients for cost-sharing. Providers must bill Medi-Cal to recover the cost-sharing amount owed by the Medi-Cal enrollee.

Prior to the transition to managed care, a provider would bill Medi-Cal FFS directly for services not covered by their patient's OHC, or to request reimbursement for cost-sharing required by the patient's OHC.

However, once an individual is enrolled in Medi-Cal managed care, an individual's provider must bill the individual's Medi-Cal managed plan for copayments or other costs not covered by the OHC, instead of billing DHCS. These providers must interact with Medi-Cal managed care plans, even if the provider is not in the network of a Medi-Cal managed care plan and the service is primarily being billed to the private plan. Billing multiple plans may be more complicated for the provider, who must validate and bill the appropriate plan instead of simply billing DHCS for all Medi-Cal claims. Furthermore, DHCS's managed care plan contracts prohibit managed care plans from paying claims for services provided to a member with OHC, without proof that the provider has first exhausted all sources of other payment. Administrative processes and documentation requirements are not standardized across plans, meaning plans may require slightly different forms of proof or have different portals or means to accept this information.

Anecdotally, according to the bill's author and affected constituents, these billing requirements have posed an area of friction between certain patients, providers, and managed care plans with the recent expansion of mandatory enrollment into Medi-Cal managed care.

e) **Can Individuals With OHC Keep Their Providers when Their Medi-Cal Services Transition to Managed Care?** Individuals who rely on OHC as a primary payer for their health care should theoretically should be able to maintain their providers who are paid primarily by the OHC. The providers should be able to simply bill the Medi-Cal managed care plan instead of FFS Medi-Cal for any allowable costs not covered by the OHC.

According to DHCS, if an individual is seeing providers contracted with their OHC who are billing the OHC for services, and Medi-Cal is only paying for other allowable costs such as the patient copayment, the provider is able to bill the Medi-Cal managed care plan for the copayment even if the provider is not contracted with that plan. This guidance is reflected in a fact sheet published by DHCS, titled "Overview of Mandatory Managed Care Enrollment." The fact sheet also reiterates an individual can keep their OHC when they become mandatorily enrolled into managed care.

However, anecdotally, the fact sheet has not resolved issues for individuals seeking to maintain their network of providers. Some providers may refuse to render services to individuals enrolled in Medi-Cal managed care for a variety of reasons, including the providers' choice to adopt a policy of not engaging with Medi-Cal managed care whatsoever, or a lack of understanding that they are allowed to bill the Medi-Cal managed care plan for allowable costs if they are not contracted with the plan.

f) **Regional Centers**. Pursuant to the Lanterman Act, some individuals with developmental disabilities or related risk factors qualify for services offered through 21 regional centers contracted with the state DDS. Regional centers provide each consumer with a service coordinator, who coordinates the activities necessary to develop and implement the consumer's IPP. Regional centers serve as fixed points of contact in the community for consumers and their families to access services and supports. Regional center staff participate in the individual program planning process, assist consumers to obtain necessary services and supports from "generic agencies," like state agencies that offer health benefits, and purchase other services as necessary. They are responsible for the provision of outreach; intake, assessment, evaluation and diagnostic services; and case management/service coordination for persons with developmental disabilities and persons who are at risk of becoming developmentally disabled. Regional center staff conducts a variety of activities to achieve the stated objectives of a consumer's IPP.

g) **Value of Managed Care May Be More Limited for the Specific Population Addressed by This Bill**. Although the transition of certain populations into managed care has not been without challenge and controversy, the state has in recent years moved towards mandatory enrollment of most of the Medi-Cal population into managed care. Policymakers have generally recognized and accepted that enrollment in managed care comes with tradeoffs in access, complexity and administrative burden for the state, beneficiaries, plans and providers. The state has embraced Medi-Cal managed care plans as a single point of accountability for delivery of a number of services and as a vehicle for improving care coordination, improving quality and streamlining program

administration. As it applies to this population, however, a number of important functions of a Medi-Cal managed care plan— including providing person-centered coordination of care and services; ensuring access to primary and specialty care; and managing provider networks from a cost, access, and quality perspective— appear to be of limited value. This population is able to access these those from their OHC or from the regional center. However, it should also be noted that plans may provide more accountability for ensuring access to services covered by Medi-Cal, and that provider availability and participation in FFS Medi-Cal— and the commensurate perceived benefit or desirability of staying in FFS Medi-Cal— varies across the state.

3) **PREVIOUS LEGISLATION.**

   a) AB 1608 (Joe Patterson) of 2023 was similar to this bill. AB 1608 was not heard in the Assembly Health Committee.

   b) AB 133 (Committee on Budget), Chapter 143, Statutes of 2021, establishes statutory authority for various aspects of the CalAIM initiative, including authority to standardize enrollment of most populations in managed care.

   c) AB 203 (Committee on Budget), Chapter 188, Statutes of 2007, establishes in state law a set of federal requirements regarding recovery of costs incurred by Medi-Cal for health care services covered by third-party payers.

4) **AMENDMENTS**. The overall value of managed care may be limited for the specific population impacted by this bill. This limited value is exacerbated by administrative difficulties faced by individuals trying to maintain longstanding and critical provider arrangements for severely developmentally disabled children. These administrative difficulties appear to go beyond general managed care transition issues in that they appear to be inexplicably impacting the families' ability to utilize their other health coverage. There are likely many possible ways to address the difficulties individuals are having; this bill proposes one solution.

   However, the approach also raises significant equity issues by carving out and allowing additional choices to one narrow population group, while requiring the vast majority of others to enroll in managed care. This type of one-off exemption is difficult to justify in a broader context, and strays from the principle of equitable treatment of all Medi-Cal eligible populations. For instance, it is possible the administrative disruptions faced by the small population who inspired this bill may be indicative of challenges faced by more individuals in their transition to managed care, and this narrow exemption would not address any broader concern. It also would take the state back towards maintaining the type of population-based, heterogeneous exemption from managed care enrollment the state has consistently sought to eliminate in recent years, in favor of the CalAIM framework of a more standardized, simplified, and streamlined Medi-Cal program.

   To address these concerns, the author and Committee have agreed to amend this bill to approach the issue differently. The new approach works from the premise of making mandatory managed care enrollment work better for individuals with OHC. Accordingly, the author and Committee have agreed to amend the bill as follows:

a) Require DHCS to ensure that a provider billing the Medi-Cal managed care plan as a secondary payer does not face administrative requirements significantly in excess of requirements for billing those same costs to the Medi-Cal FFS delivery system.

b) Specify, consistent with DHCS guidance, a provider participating in the Medi-Cal FFS delivery system or in the federal Medicare Program is not required to contract with the Medi-Cal managed care plan, in order to bill the plan as a secondary payer.

c) Require, upon request, a Medi-Cal managed care plan to provide assistance to Medi-Cal beneficiaries and their existing OHC providers, on options for maintaining health care relationships between beneficiaries and their providers, if a beneficiary transitions to Medi-Cal managed care.

d) At least annually, from 2025 through 2028, require DHCS to report to the Assembly Committee on Health and the Senate Committee on Health on the effectiveness of implementing this bill.

e) Include other language standard for Medi-Cal changes, including the ability to implement the bill through non-regulatory guidance and conditioning implementation on the receipt of any necessary federal approvals and the availability of federal financial participation.

REGISTERED SUPPORT / OPPOSITION:

Support

None on file.

Opposition

None on file.

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 3245 (Joe Patterson) – As Introduced February 16, 2024

SUBJECT: Coverage for colorectal cancer screening.

SUMMARY: Expands existing law to require a health plan contract and insurance policy to provide coverage without cost sharing for a colorectal cancer (CRC) screening test assigned either a grade of "A" or a grade of "B" by other accredited or certified guideline agencies, including the American Cancer Society and its guidelines. Requires the required colonoscopy for a positive result on a test or procedure that is a CRC screening examination or laboratory test identified assigned either a grade of A or a grade of B by other accredited or certified guideline agencies to also be provided without any cost sharing.

EXISTING LAW:

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

2) Establishes as California's essential health benefits (EHBs) 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) Defines "basic health care services" as all of the following:
   a) Physician services, including consultation and referral;
   b) Hospital inpatient services and ambulatory care services;
   c) Diagnostic laboratory and therapeutic radiologic services;
   d) Home health services;
   e) Preventive health services;
   f) Emergency health care services; and,
   g) Hospice care, as specified. [HSC § 1345]

4) Codifies the federal ACA provisions, in state law, to require a group or individual non-grandfathered health insurance policy to, at a minimum, provide coverage for and not impose any cost-sharing requirements for all of the following:
   a) Evidence-based items or services that have in effect a rating of "A" or "B" in the recommendations of the U.S. Preventive Services Task Force (USPSTF), as periodically updated;
   b) Immunizations that have in effect a recommendation, as periodically updated, from the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention with respect to the individual involved;
   c) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided in the comprehensive guidelines, as periodically updated, supported by the United States Health Resources and Services Administration (HRSA);

d) With respect to women, those additional preventive care and screenings as provided for in comprehensive guidelines supported by HRSA; and,
e) Requires the current recommendations of the USPSTF regarding breast cancer screening, mammography, and prevention to be considered the most current other than those issued in or around November 2009. [HSC §1367.002 and INS §10112.2]

5) 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 CRC screening test assigned either a grade of A or a grade of B by the USPSTF, and requires the colonoscopy for a positive result on a test or procedure identified assigned either a grade of A or a grade of B by the USPSTF to be provided without cost sharing, unless the underlying test or procedure was a colonoscopy. [HSC §1367.668 and INS §10123.207]

FISCAL EFFECT: None.

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, CRC awareness is not just a campaign; it is a call to action for early detection, proactive screenings, and empowering education. In 2023, there were more than 52,000 deaths from CRC. This bill will ensure that coverage for CRC screenings continue irrespective of litigation occurring in other states that jeopardizes this critical preventative care option. At 40 years young, a friend of the author was diagnosed with stage 3 CRC after many months fighting for his own health. Fortunately, he survived, but would not have without a screening. The author concludes this is why continuing to cover CRC screening is so important.

2) **BACKGROUND.** According to the California Health Benefits Review Program (CHBRP), CRC is cancer that occurs in either the colon or rectum. Most CRCs arise from abnormal growth in the linings of the large bowel that take 10 to 15 years on average progress to cancerous tissues. In California, CRC is the third leading cause of cancer death for women and men. For women, the first and second leading causes are lung and breast cancers, respectively; for men, the top two are lung and prostate cancer. CRC is known as a "silent killer" since individuals with the disease tend to remain asymptomatic during early stages, resulting in a larger proportion of late-stage diagnoses; survival declines to 71% and 14% for patients diagnosed with regional and distant metastases, respectively. Although CRC is sometimes observed in younger adults, an individual's risk for large bowel cancers increases rapidly after age 50 years. The USPSTF found little evidence for increased benefit of screenings above the age of 75 years. Accordingly, USPSTF recommends routine screening for all asymptomatic adults between the ages of 50 and 75 years who have an average risk of colorectal cancer based on their genetic and medical history. There are only two CRC screening strategies (Fecal Occult Blood Test (FOBT) and flexible sigmoidoscopy) that have been shown in randomized controlled trials to reduce CRC mortality. The USPSTF does not explicitly recommend any specific screening strategy for CRC, and instead provides information regarding efficacy, suggested screening intervals, and other considerations.

   a) **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. If *Braidwood* is upheld by the Supreme Court, elimination of the coverage requirements for USPSTF recommendations would invalidate the requirement to cover all of these services without cost sharing. California law, however, will still require coverage of recommended preventive care benefits (pursuant to AB 406 (Pan), Chapter 302, Statutes of 2020). One of the reasons preventive care was included in the ACA was because research showed that cost-sharing, even in small amounts, reduces the likelihood that people use preventive services. Millions of people each year report delaying or forgoing needed health care due to costs. The USPSTF is a group of independent experts that use a rigorous evidence-based process to review research, weighing both the benefits and risks of services. In the ACA, the preventive care coverage mandate was tied to recommendations by the USPSTF and other groups as a way of having a standard definition of what preventive care means, including changes over time as new evidence becomes available.

b) USPSTF Draft Recommendations. In 2020, the USPSTF proposed draft recommendations that replace the 2016 USPSTF recommendation on screening for CRC. In 2016, the USPSTF recommended screening for colorectal cancer starting at age 50 years and continuing until age 75 years (A grade recommendation). In addition, the USPSTF concluded that the decision to screen for CRC in adults ages 76 to 85 years should be an individual one, taking into account the patient's overall health and prior screening history (C grade recommendation), and that screening should be discontinued after age 85 years. The current recommendation, while continuing to recommend CRC screening in adults ages 50 to 75 years, now recommends offering screening at age 45 years (B grade recommendation). As it did in 2016, the USPSTF continues to conclude that screening in adults ages 76 to 85 years should be an individual one (C grade recommendation) and screening should be discontinued after age 85 years. As of 2021, the USPSTF issued its final recommendation statement.

c) CHBRP analysis. AB 1996 (Thomson), Chapter 795, Statutes of 2002, requests the University of California to assess legislation proposing a mandated benefit or service and prepare a written analysis with relevant data on the medical, economic, and public health impacts of proposed health plan and health insurance benefit mandate legislation. CHBRP was created in response to AB 1996. SB 125 (Hernandez), Chapter 9, Statutes of 2015, added an impact assessment on EHBs, and legislation that impacts health insurance benefit designs, cost sharing, premiums, and other health insurance topics. CHBRP's analysis of this bill includes the following:

i) No change in benefit. CHBRP determined that this bill would not result in a change of benefit coverage based on currently established recommendations for CRC screening tests, and there would be no impact in the first year postmandate of this bill as introduced. However, should there be new evidence-based guidelines or newly recommended screening test(s) that are different from those currently recommended by the USPSTF, health plans in California would be required to cover these newly specified tests without cost sharing. In such circumstances, these would potentially result in changes to the utilization of these screening tests and potential changes in health care expenditures. CHBRP assumes relevant evidence-based guidelines would not need to use an A/B rating as the USPSTF does, although it is possible to interpret the language of this bill as requiring such. This bill adds the requirement to cover

without cost sharing CRC screening tests identified by accredited or certified guideline agencies, including the American Cancer Society and its guidelines.

ii) **Ambiguities and Assumptions Regarding Bill Language**. CHBRP makes the following assumptions regarding the bill language of this bill as introduced:

(1) "Accredited or certified guidelines" would equate to evidence-based guidelines, which are statements that are informed by a systematic review of the evidence and an assessment of the benefits and harms of alternative options; and,

(2) Screening tests or frequency of testing required to be covered would not include those that have very low-quality evidence. It is possible to interpret this bill language as requiring other guidelines to also use an A/B rating scale when evaluating evidence, but an A/B rating is not a universal measure for determining the strength of evidence-based recommendations.

CHBRP examined guidelines from US-based entities including the American College of Physicians, American College of Radiology, American Cancer Society, American College of Gastroenterology (and summarized by the American Academy of Family Physicians), American Gastroenterological Association, American Society of Clinical Oncology, National Comprehensive Cancer Network, and the US Multi-Society Task Force. Recommendations from these guidelines are in line with the grade A/B USPSTF recommendations. There are no recommendations supported by high-quality evidence that are beyond what USPSTF currently recommends with an A or B grade.

d) Recent innovations. A recent *NY Times* article (article), noted early detection of colon cancer can prevent a majority of deaths from this disease, possibly as much as 73%. Just 50 to 75% of middle-aged and older adults who should be screened regularly are being tested. There are two options for people of average risk: a colonoscopy every 10 years or a fecal test every one to three years, depending on the type of test. A blood test is on the horizon. Gastroenterologists say such tests could become part of the routine blood work that doctors order when, for example, a person comes in for an annual physical exam. About 53,000 Americans are expected to die from CRC this year. It is the second-most common cause of cancer-related deaths in the United States, and while the death rate in older adults has fallen, it has increased in people under age 55. The article notes that the problem is convincing more people to be screened. The blood test takes advantage of the discovery that colon cancers and large polyps — clumps of cells on the lining of the colon that occasionally turn into cancers — shed fragments of DNA into the blood. A study this year in the *New England Journal of Medicine* found that a blood test searching for such DNA called Shield and made by the company Guardant Health detected 87% of cancers that were at an early and curable stage. The false positive rate was 10%. While the blood test detects cancers, it misses most large polyps, finding just 13% of them. In contrast, the fecal test detects 43% and a colonoscopy finds 94%. While polyps are usually harmless, a few can turn into cancers, so doctors want to find all of them and remove them to prevent cancers from forming. In particular, doctors need to understand that while this test helps detect cancer early, it does not prevent it because it is not good at finding precancerous polyps. Doctors will also need to explain to patients that if the blood test result is abnormal, they will have to schedule a colonoscopy to look for polyps or early-stage cancers and remove them if they are present. The article states that it is also

not clear how often people should do the blood test. Guardant suggested every three years but that recommendation is not well established. The big unknown is cost. Guardant has applied to the U.S. Food and Drug Administration (FDA) for approval to market the test. The company sells it now as a "lab-based test," which does not require FDA approval but is also not covered by health insurance. For those who want to pay out of pocket, the price is $895. The Cologuard fecal test costs $581 to $681. Colonoscopies, usually needed half as often, typically cost $1,250 to $4,800, although some hospitals charge more. The average cost of a colonoscopy in the United States is $2,750. These tests are typically covered by insurance.

3) **SUPPORT.** The California Life Sciences (CLS) writes CRC is the third most common cancer diagnosed in both men and women each year in the United States, excluding skin cancer. In 2023, over 153 thousand adults in the United States were diagnosed with CRC. These numbers included over 106 thousand new cases of colon cancer and over 46 thousand new cases of rectal cancer. Over 50,000 deaths from this disease occurred in the United States last year. However, when CRC is found early, it can often be cured. The death rate from this type of cancer in 2020 in the United States was 57% less than what it was in 1970. CLS states this is due to improvements in treatment and increased screening, which detects colorectal changes before they turn cancerous.

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) oppose mandates for health plans and insurers to cover specific services, as well as bills that eliminate cost sharing and limit utilization management, which have similar cost impacts as coverage mandates. Moreover, they will increase costs, reduce choice and competition, and further incent some employers and individuals to avoid state regulation by seeking alternative coverage options. These bills will lead to higher premiums, harming affordability and access for small businesses and individual market consumers. CAHP, ACLHIC, and AHIP write that state mandates increase costs of coverage, especially for families who buy coverage without subsidies, small business owners who cannot or do not wish to self-insure, and California taxpayers who foot the bill for the state's share of those mandates.

5) **RELATED LEGISLATION.** AB 2258 (Zbur) 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. AB 2258 passed this Committee on a vote of 13-0 on April 9, 2024 and is now pending hearing in the Assembly Appropriations Committee.

6) **PREVIOUS LEGISLATION.**

   a) 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 would require the required 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.

   b) SB 406 (Pan), Chapter 302, Statutes of 2020, 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.

7) **PROPOSED AMENDMENTS.** To address assumptions raised by CHBRP regarding current bill drafting, the Committee recommends the following amendment:

> …out any cost sharing for a colorectal cancer screening test assigned either a grade of A or a grade of B by the United States Preventive Services Task ~~Force.~~ *Force or in accordance with recommendations established by other accredited or certified guideline agency, including the American Cancer Society and its guidelines*

REGISTERED SUPPORT / OPPOSITION:

Support

California Life Sciences
National Health Law Program
Oncology Nursing Society

Opposition

America's Health Insurance Plans (AHIP)

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

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
HR 58 (Jackson) – As Introduced September 6, 2023

SUBJECT: Access to care.

SUMMARY: Urges the California Health and Human Services Agency (CHHSA) to: 1) hold pharmaceutical companies, distributors, and pharmacies accountable for the current attention deficit hyperactivity disorder (ADHD) medication shortage and develop initiatives for the prevention and management of further shortages of ADHD medications; and, 2) meet with United States Department of Health and Human Services, and the federal Drug Enforcement Agency (DEA) regarding modification of any insufficiently justified quotas on the supply of ingredients to manufacturers of critical ADHD medications. Makes declarations including that reliable and safe access to medical care includes reliable access to psychiatric medications. Makes findings including that increased recognition, diagnosis, and need for treatment of ADHD has led to a shortage of ADHD medications and that irreparable harm from a lack of access to ADHD medications accrues to children who regress behaviorally and academically, adults who are now unable to perform in their jobs and function in other areas of life, and communities that are experiencing increased illicit substance distribution, car accidents, and prevalence of depression, anxiety, and other comorbidities of untreated ADHD.

EXISTING LAW creates the California Affordable Drug Manufacturing Act of 2020 which requires CHHSA to enter into partnerships, in consultation with other state departments as necessary, to increase competition, lower prices, and address shortages in the market for generic prescription drugs, to reduce the cost of prescription drugs for public and private purchasers, taxpayers, and consumers, and, to increase patient access to affordable drugs. [Health and Safety Code §127690, *et seq*]

FISCAL EFFECT: None.

COMMENTS:

1) **PURPOSE OF THIS RESOLUTION.** According to the author, there is a need for this resolution because as it currently stands patients are either having to forego medication all together or switch to other forms of medication that do not adequately treat the symptoms they are experiencing. This leads to avoidable negative health outcomes. This resolution will help ensure future accessibility to the many safe and effective controlled substance medications for mental health disorders. The author concludes that during the current mental health crisis, priority must be given to improving access to effective treatments like these medications.

2) **BACKGROUND.**

   a) **U.S. Food and Drug Administration (FDA) Announcement on Shortage of Adderall.** On October 12, 2022, FDA posted a shortage of the immediate release formulation of amphetamine mixed salts, commonly referred to by the brand name Adderall or Adderall IR, on their drug shortage website. FDA is in frequent communication with all manufacturers of amphetamine mixed salts, and one of those companies, Teva, is

experiencing ongoing intermittent manufacturing delays. Other manufacturers continue to produce amphetamine mixed salts, but there is not sufficient supply to continue to meet U.S. market demand through those producers.

Amphetamine mixed salts, including Adderall, are FDA-approved for the treatment of ADHD and narcolepsy. Until supply is restored, there are alternative therapies including the extended-release version of amphetamine mixed salts available to health care professionals and their patients for amphetamine mixed salts' approved indications.

b) August 1, 2023: FDA Actions to Address Shortages in Prescription Stimulants. On August 1, 2023, the FDA issued a notice on the shortage in ADHD medications stating that the shortage of stimulant medications was the result of many factors that began last fall due to a manufacturing delay experienced by one drug maker. While this delay has since resolved, the country is continuing to experience its effects in combination with record-high prescription rates of stimulant medications. Data show that, from 2012 to 2021, overall dispensing of stimulants (including amphetamine products and other stimulants) increased by 45.5% in the United States. According to a U.S. Centers for Disease Control and Prevention report, particularly during 2020-21, when virtual prescribing was permitted on a widespread basis during the COVID-19 Public Health Emergency, the percentages in certain age groups grew by more than 10%. The FDA called on key stakeholders, including manufacturers, distributors, pharmacies, and payors, to do all they can to ensure access for patients when a medication is appropriately prescribed.

According to the FDA, stimulants are controlled substances with a high potential for abuse, which can lead to addiction and overdose. Therefore, there are limits (also known as quotas) set by DEA for how much of these drugs can be produced. However, for amphetamine medications, in 2022, manufacturers did not produce the full amount that these limits permitted them to make. Based on DEA's internal analysis of inventory, manufacturing, and sales data submitted by manufacturers of amphetamine products, manufacturers only sold approximately 70% of their allotted quota for the year, and there were approximately one billion more doses that they could have produced but did not make or ship. Data for 2023 so far show a similar trend. The DEA and FDA have called on manufacturers to confirm they are working to increase production to meet their allotted quota amount. If any individual manufacturer does not wish to increase production, that manufacturer has been asked to relinquish their remaining 2023 quota allotment. This would allow DEA to redistribute that allotment to manufacturers that will increase production. DEA is also committed to reviewing and improving the quota process.

The FDA are asking professional groups and healthcare providers to accelerate efforts to support appropriate diagnosis and treatment of ADHD, such as further development of additional clinical guidelines for ADHD in adults. In recognition of this need, FDA awarded a grant to the National Academies of Sciences, Engineering, and Medicine to support a scientific meeting on ADHD in adults and considerations for diagnosis and treatment. The FDA also recognized that further research is needed into the diagnosis and treatment of ADHD and that research can help inform the development of alternative treatments and an understanding of the behavioral and societal issues leading to widespread misuse of these medications in certain groups.

3) **RELATED LEGISLATION.** SR 90 (Rubio) proclaims April to be Neurodiversity Awareness Month during which every Californian is encouraged to promote, understand, and accept neurodivergent students and to raise awareness of the challenges neurodivergent students face in their educational journey. States that neurodiversity refers to the diversity of all people and is often used in the context of autism spectrum disorder and other neurological or developmental disorders such as ADHD or dyslexia. SR 90 is currently pending in the Senate Rules Committee.

4) **PREVIOUS LEGISLATION**.

   a) AB 118 (Committee on Budget), Chapter 42, Statutes of 2023, extends the authority of CHHSA to enter into exclusive or nonexclusive contracts on a bid or negotiated basis, for purposes of the California Affordable Drug Manufacturing Act of 2020, indefinitely.

   b) SB 852 (Pan), Chapter 207, Statutes of 2020, requires CHHSA to enter into partnerships, in consultation with other state departments as necessary, to increase competition, lower prices, and address shortages in the market for generic prescription drugs, to reduce the cost of prescription drugs for public and private purchasers, taxpayers, and consumers, and, to increase patient access to affordable drugs.

REGISTERED SUPPORT / OPPOSITION:

Support

None on file.

Opposition

None on file.

Analysis Prepared by: Patty Rodgers / HEALTH / (916) 319-2097

Date of Hearing: April 23, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2960 (Lee) – As Amended April 2, 2024

SUBJECT: Sexually transmitted diseases: testing.

SUMMARY: Requires a licensed primary care clinic or hospital emergency department (ED) to offer a syphilis test at least once per year to all patients who can become pregnant. Prohibits a violation of these provisions from being a crime. Makes findings and declarations regarding the alarming increase of syphilis cases, rising 287% in the last 10 years of Department of Public Health (DPH) data. Specifically, **this bill:**

1) Requires, at least once per year, a primary care clinic or a hospital ED to offer a syphilis test to patients who can become pregnant. Exempts a primary care clinic if the patient's primary care clinic has tested the patient for syphilis or if the patient has been offered a syphilis test and declined the test within the previous 12 months.

2) Authorizes a primary care clinic or ED to charge a patient to cover the cost of syphilis testing. Deems the primary care clinic or ED to have complied with this bill if a syphilis test is offered.

3) States that it is the intent of the Legislature that if there is a shortage of bicillin, the preferred treatment for pregnant persons with syphilis, bicillin should be provided first to persons who are pregnant.

4) Makes findings and declarations regarding the alarming increase of syphilis cases, rising 287% in the last 10 years of DPH data

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 and licensing of health facilities, as specified. Gives the PHO broad authority to detect, monitor, and prevent the spread of communicable disease in the state. [Health and Safety Code (HSC) §131050 and §120130, et seq.]

2) Exempts various types of clinics from licensure and regulation by DPH, including any place or establishment owned or operated as a clinic or office by one or more licensed health care practitioners and used as an office for the practice of their profession, and any clinic operated as an outpatient department of a hospital. [HSC §1206]

3) Defines "outpatient setting," for purposes of establishing standards for accreditation of surgical settings that are not otherwise licensed, as any facility, clinic, unlicensed clinic, center, office, or other setting that is not part of a general acute care hospital (GACH), and where anesthesia, except local anesthesia or peripheral nerve blocks, is used in compliance with the community standard of practice in doses that have the probability of placing a patient at risk for loss of the patient's life-preserving protective reflexes. [HSC §1248]

4) Requires every health care provider, knowing of or in attendance on a case or suspected case of a disease on the list of reportable diseases and conditions, to be reported as required to DPH, including syphilis. [Title 17, California Code of Regulations (CCR) §2500, §2593, §2641.5- 2643.20, and §2800-2812]

5) Requires a person who works in a health facility, service or operation, or who has occupational tuberculosis (TB) exposure in public health services in connection with health care to be periodically screened for TB. [Title 22, CCR Div. 5, Chapters 1-12]

6) Requires an adult patient who receives primary care services to be offered a hepatitis B and C screening test according to the latest recommendations from the U.S. Preventive Services Task Force (USPSTF), and to the extent these services are covered under the patient's health insurance, unless the patient lacks capacity to consent to the test, or is being treated in the ED of a GACH. [HSC §1316.7]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, cases of syphilis have been rising significantly in California, including cases of congenital syphilis (CS) that caused nearly 200 stillbirths or neonatal deaths between 2012 and 2021. This bill seeks to increase testing among people who may be pregnant so that proper treatment can be provided.

2) **BACKGROUND.** Syphilis is an infection caused by bacteria. Most often, it spreads through sexual contact. The disease starts as a sore that's often painless and typically appears on the genitals, rectum, or mouth. Syphilis spreads from person to person through direct contact with these sores. It also can be passed to a baby during pregnancy and childbirth and sometimes through breastfeeding. After the infection happens, syphilis bacteria can stay in the body for many years without causing symptoms, however the infection can become active again. Without treatment, syphilis can damage the heart, brain or other organs. Early syphilis can be cured, sometimes with a single shot of penicillin.

   a) **Centers for Disease Control and Prevention (CDC) guidelines.** According to the CDC, syphilis case reports continue to increase since reaching a historic low in 2000 and 2001. During 2021, there were 176,713 new cases of syphilis (all stages). Gay, bisexual, and other men who have sex with men (MSM) are experiencing extreme effects of syphilis. They account for 36% of all primary and secondary (P&S) syphilis cases in the 2021 sexually transmitted disease (STD) Surveillance Report. They also account for 47% of all male P&S cases. However, case rates are increasing among heterosexual men and women in recent years. CS continues to be a concern in the United States. CS occurs when a pregnant person passes syphilis to their baby. Final 2021 data show more than 2,800 cases of CS. The CDC screening recommendations are as follows:
      i) Screen asymptomatic women at increased risk (history of incarceration or transactional sex work, geography, race/ethnicity) for syphilis infection;
      ii) Pregnant Women:
         (1) All pregnant women at the first prenatal visit; and,

(2) Retest at 28 weeks gestation and at delivery if at increased risk due to geography or personal risk (substance use, sexually transmitted infections (STIs) during pregnancy, multiple partners, a new partner, partner with STIs).

iii) Men Who Have Sex With Women: Screen asymptomatic adults at increased risk (history of incarceration or transactional sex work, geography, race/ethnicity, and being a male younger than 29 years) for syphilis infection;

iv) MSM:

(1) At least annually for sexually active MSM; and,

(2) Every three to six months if at increased risk.

v) Screen asymptomatic adults at increased risk (history of incarceration or transactional sex work, geography, race/ethnicity, and being a male younger than 29 years) for syphilis infection;

vi) Transgender and Gender Diverse People: Consider screening at least annually based on reported sexual behaviors and exposure;

vii) Persons with HIV:

(1) For sexually active individuals, screen at first HIV evaluation, and at least annually thereafter; and,

(2) More frequent screening might be appropriate depending on individual risk behaviors and the local epidemiology.

b) CS. CS is an infection transmitted from pregnant person to child during pregnancy and/or delivery caused by the bacterium Treponema pallidum. CS can cause severe illness in infants including premature birth, low birth weight, birth defects, blindness, and hearing loss. It can also lead to stillbirth and infant death. Tests and treatment for pregnant people are readily available.

Over the last several years, California has experienced a steep increase in syphilis among females and in CS. From 2012 to 2021, female early syphilis cases increased over 1,113% and CS cases increased 1,500%, from 33 cases in 2012 to 528 cases in 2021. This is the highest number of reported CS cases since 1992 when 522 cases were reported. According to the CDC, California had the 11th highest CS rate of all states in 2021. Thirty-seven (60.7%) of California's 61 local health jurisdictions reported at least one case of CS in 2021. Most pregnant females who gave birth to infants with CS received prenatal care late in pregnancy or not at all.

c) DPH guidelines. In response to the alarming rise in CS, DPH recognized an urgent need to expand syphilis detection among people who are or could become pregnant in order to ensure detection, timely treatment, and subsequent CS prevention. California STD screening recommendations to date have aligned with national guidelines, which recommend all pregnant patients receive syphilis screening at the first prenatal visit, with additional screening in the third trimester and at delivery for those with identified risk, including in communities and populations with high syphilis prevalence. Because the majority of California CS cases in 2017 and 2018 were born to pregnant patients with delayed or no prenatal care, DPH supports a more thorough, multipronged approach to case detection and CS prevention, which includes expanded syphilis screening for people who could become pregnant. This is especially important for people identified in settings that serve populations at increased risk for syphilis, as well as patients who might have disruptions in prenatal care and communicable disease treatment due to contributing

social factors (e.g., substance use, incarceration, poverty, homelessness, etc.), such as the ED. DPH recommends:

i) All pregnant patients should be screened for syphilis at least twice during pregnancy: once at either confirmation of pregnancy or at the first prenatal encounter (ideally during the first trimester) – and again during the third trimester (ideally between 28–32 weeks' gestation), regardless of whether such testing was performed or offered during the first two trimesters;

ii) Patients should be screened for syphilis at delivery, except those at low risk who have a documented negative screen in the third trimester;

iii) ED providers in local health jurisdictions with high-CS morbidity should consider confirming the syphilis status of all pregnant patients prior to discharge, either via documented test results in pregnancy, or a syphilis test in the ED if documentation is unavailable;

iv) All people who are or could become pregnant entering an adult correctional facility health jurisdiction with high-CS morbidity should be screened for syphilis at intake, or as close to intake as feasible;

v) All sexually active people who could become pregnant should receive at least one lifetime screen for syphilis, with additional screening for those at increased risk; and,

vi) All sexually active people who could become pregnant should be screened for syphilis at the time of each HIV test.

3) **SUPPORT.** AIDS Healthcare Foundation (AHF) is the sponsor of this bill and states that the epidemic of STIs in California has been growing since 2000. The most alarming increase has been in the number of all syphilis cases, rising 287% in the last 10 years as reported by DPH. The impact of syphilis among females has been even greater, increasing 1,113% over the same period. California is outpacing the rest of the country, with a rate that is 41% higher than the national rate. Particularly tragic is that the persistence of syphilis infections among women in their reproductive years has led to a meteoric rise in CS, when the infection is transmitted from the mother to the child during pregnancy. Cases of CS increased by 1500% during the last 10 years, leading to hundreds of stillbirths, neonatal deaths and other symptoms and complications. According to the CDC, California has the 11th highest rate of CS in the nation, which is 63% higher than the national rate. AHF notes that both DPH and the CDC agree that a priority target for syphilis testing and treatment are people who can become pregnant and who face obstacles in obtaining healthcare. Moreover, the USPSTF found convincing evidence that screening for syphilis infection in asymptomatic, nonpregnant persons at increased risk for infection provides substantial benefit. AHF concludes that a mandate to offer syphilis testing screen persons who are infected and allow medical professionals to treat them before the patient becomes pregnant, will provide an opportunity to educate people about syphilis and expand awareness among the public about the adverse impacts of syphilis infection and how to protect themselves.

4) **OPPOSE UNLESS AMENDED.** The California Emergency Nurses Association (CA ENA) is opposed to this bill unless it is amended. CA ENA states that they believe mandating syphilis screening in EDs, even for a small portion of the qualifying patients cared for in EDs, would add to the burden of emergency providers in caring for very sick or injured patients, with an unintended consequence of increased ED crowding. Crowding occurs when the identified need for emergency services exceeds available resources for patient care in the ED, hospital, or both. Crowding is also related to decreased access/availability of services over the entire health care delivery system (e.g. skilled nursing facility beds, behavioral

health services, hospital inpatient beds, home health care services, wound care services and any other service not available). When routine patient care, testing, and evaluation is required in an emergent environment, ED length of stay is often negatively impacted with prolonged results, and in effect, creates a higher patient volume waiting for those results. As the ED becomes increasingly crowded and patients must wait longer for care, frustration intensifies in patients/families and can lead to violence against healthcare providers.

CA ENA states that multiple studies have reported that the quality of care decreases as EDs become more crowded, and this bill will increase ED length of stay. CA ENA points to a DPH report published in 2019 found that, on average, EDs spend 28 minutes per patient offering the HIV test, securing consent, and providing information and counseling. CA ENA contends that one can presume it would take approximately 28 minutes to meet this mandate for syphilis screening – 28 minutes that could be dedicated to life-threatening or life-changing care for ED patients and their families.

5) **OPPOSITION.** The American College of OB/GYN's District IX (ACOG) writes in opposition that this bill requires syphilis testing to be offered to all women of reproductive age at least once per year regardless of clinical guidelines or recommendations. ACOG recommends all pregnant people are screened for syphilis at their first prenatal visit and potentially retested at delivery if at high risk; however, it does not recommend routine screening for all people who are not pregnant. A broad mandate that requires tests to be offered to all reproductive aged women regardless of risk, even when not needed or recommended through clinical guidance, could strain public health resources, diverting them from other critical areas or from higher risk populations, and take time away from why the women sought healthcare to begin with. Efficient and more cost-effective use of limited public health resources often requires prioritizing interventions based on risk assessments and epidemiological data. Rather than a blanket mandate, we should focus on high-risk groups, improve access to voluntary testing, and invest in education and prevention might yield better outcomes in terms of both health and economics.

   The California Medical Association is opposed to this bill and states that like many other bills legislating medicine, this bill offers a "one-size-fits-all approach" that does not take into consideration the many other clinical factors. Efficient and more cost-effective use of limited public health resources often requires prioritizing interventions based on risk assessments and epidemiological data. Rather than a blanket mandate, public health strategies benefit more from being targeted and nuanced, focusing on higher-risk populations and tailored interventions based on clinical guidance.

6) **RELATED LEGISLATION.** AB 2132 (Low) requires an adult patient receiving primary care services in specified health care settings, to be offered a TB risk assessment and TB screening test, if certain conditions apply. AB 2132 is pending in the Assembly Appropriations Committee.

7) **PREVIOUS LEGISLATION.**

   a) AB 789 (Low), Chapter 470, Statutes of 2021, requires an adult patient who receives primary care services to be offered a hepatitis B and C screening test according to the latest recommendations from the USPSTF, and to the extent these services are covered

under the patient's health insurance, unless the patient lacks capacity to consent to the test, or is being treated in the ED of a GACH.

b) 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.

8) AMENDMENTS. The author is proposing amendments to require syphilis testing in clinics and EDs as follows:

a) As outlined in the most recent guidelines published by the CDC;

b) To apply to a person who is sexually active and at least 15 years of age;

c) To clarify that a clinic or ED may offer a syphilis test to a patient under the age of 15 as permitted under current law; and,

d) To strike intent language regarding the preferred treatment for a pregnant person with syphilis.

REGISTERED SUPPORT / OPPOSITION:

Support

AIDS Healthcare Foundation

Opposition

American College of Obstetricians and Gynecologists District IX
America's Physician Groups
California Medical Association

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