California State Assembly

HEALTH

MIA BONTA
CHAIR

1020 N Street, Room 390
(916) 319-2097
FAX: (916) 319-2197

AGENDA

Tuesday, March 19, 2024
1:30 p.m. -- 1021 O Street, Room 1100

Bills heard in file order

Testimony may be limited:

2 witnesses per side, 3 minutes each

1.	AB 1830	Arambula	Corn masa flour: folic acid fortification.
2.	AB 1842	Reyes	Health care coverage: Medication-assisted treatment.
3.	AB 2132	Low	Health care services.

Date of Hearing: March 19, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1830 (Arambula) – As Introduced January 12, 2024

SUBJECT: Corn masa flour: folic acid fortification.

SUMMARY: Requires the California Department of Public Health (DPH), by regulation, to require a manufacturer of corn masa flour (CMF) to add folic acid at a level not to exceed 0.7 milligrams of folic acid per pound of CMF and to include a declaration of folic acid on the nutrition label in accordance with applicable federal law.

EXISTING LAW:

1) Authorizes, through the Federal Food, Drug, and Cosmetic Act (Act) and the regulations adopted pursuant to the Act, folic acid to be used in food as a nutrient in accordance with specified prescribed conditions, folic acid is allowed to be added to corn masa flour at a level not to exceed 0.7 milligrams of folic acid per pound of corn masa flour. [Title 21 of United States Code (USC) § 341; Title 21 of the Code of Federal Regulations (CFR) § 172.345]**.**

2) Requires any state requirement for nutrition labeling of food to conform with federal law, and requires the declaration of folic acid to be included when added as a nutrient supplement, as specified. [21 USC § 343-1(a)(4); 21 CFR § 101.9(c)(8)(ii)]

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

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

5) Defines the following under the Sherman Law:

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

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

6) Requires all labels of foods, drugs, devices, or cosmetics to conform to federal requirements, as specified. [HSC §110340]

7) Requires that when a definition and standard of identity for an enriched food has been established pursuant to HSC § 110505, only the enriched form of the food is to be sold at retail in California. [HSC §110530]

8) Authorizes the nonenriched form of a food identified and standardized pursuant to HSC § 110505 to be used as an ingredient of another food only if it comprises less than 25% of the total ingredients, or it comprises 25% or more of the total ingredients and vitamins and minerals have been added to make it nutritionally equivalent to the enriched form of the ingredient. [HSC §110535]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, daily consumption of folic acid decreases the risk of neural tube defects (NTDs), such as spina bifida and anencephaly, by more than half. Babies with spina bifida can experience symptoms ranging from mild nerve damage to severe paraplegia. Anencephaly is fatal for infants. Since NTDs occur in the earliest stages of fetal development, it can be too late to take folic acid supplements by the time a person knows they are pregnant. The author states that to address high rates of NTDs, the United States Food and Drug Administration (FDA) required that all enriched cereal grain products be fortified with folic acid in 1998. While masa is a staple in many Latino cuisines, masa was omitted from the 1998 mandate. As a result, Latinos were left without a culturally appropriate avenue for obtaining folic acid in their diets through fortification. Unfortunately, Latino communities remain at a disproportionately high risk for NTDs. The higher rate of NTDs in Latino communities is a symptom in the broader disease of health inequity. The author concludes that mandatory fortification of masa prevents parents from losing children to NTDs.

2) **BACKGROUND.** NTDs are severe defects in a fetus's or newborn baby's neural tube, the structure that forms the early brain and spine. The most common types of NTDs are spina bifida (1,400 U.S. births per year), which can cause mild to severe disabilities, and anencephaly (800 U.S. births per year), which results in stillbirth or infant death. Numerous scientific studies demonstrate the effectiveness of folic acid, a B vitamin, in reducing NTDs. In 1992, the U.S. Public Health Service (PHS) recommended that all women of childbearing age consume 400 μg of folic acid daily to prevent NTDs. Specifically, PHS stated, "All women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 mg of folic acid per day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or other NTDs. Because the effects of higher intakes are not well known but include complicating the diagnosis of vitamin B12 deficiency, care should be taken to keep total folate consumption at <1 mg per day, except under the supervision of a physician." Despite the publicized guidelines, there was still concern that women of childbearing age were not consuming enough [folic acid] and were at risk of NTD-affected pregnancies. To promote compliance, the FDA issued a regulation in 1996 requiring that all enriched cereal-grain products be fortified with folic acid by January of 1998. Enriched cereal-grain products were required to be fortified with folic acid at levels ranging from 0.43 mg to 1.4 mg per pound. Thus, the U.S. became the first country to mandate a national folic acid food fortification program to prevent NTDs. Today, more than 80 other countries fortify cereal grains with folic acid. Per the Centers for Disease Control and

Prevention (CDC) reported NTDs in the U.S. decreased from 10.8/10,000 births in 1995–1996 to 6.9/10,000 births in 2006. A systematic review (179 studies) and meta-analysis (123 studies) published in 2016 by the *American Journal of Public Health* which covered the prevalence of spina bifida in response to folic acid fortification status, geographic region, and study population indicated a lower prevalence of spina bifida in geographic regions with mandatory folic acid fortification (33.86 per 100,000 live births) versus voluntary fortification (48.35 per 100,000 live births). According to a study published in 2018, based on 59 countries meeting the criteria of mandatory folic acid fortification of at least 1.0 part per million, it is estimated that 50,270 spina bifida and anencephaly births were prevented out of a possible 280,500. Overall, these reports suggest that national folic acid fortification protects against NTDs.

a) **The omission of CMF and its potential impacts on the Latinx community.** CMF is used to make many corn products such as tortillas, tamales, pupusas, and empanadas that are staples in the foodways of Mexico and several other Latin American countries. Corn masa flour was not included in the 1998 FDA fortification regulation. Before the fortification policies of 1998 rates of NTDs were significantly higher in the Latinx population. As of 2011, rates of NTDs among Latinx people in the United States were still higher, at seven NTDs per 10,000 births, compared to five NTDs per 10,000 births in white and Black populations. Researchers and advocates have proposed that adding CMF to the list of fortified foods could help increase folic acid intake and help address the elevated rate of NTDs in the U.S. Latinx population. In response to a regulatory petition submitted by a diverse coalition of nonprofit and industry stakeholders, the FDA issued a rule in 2016 allowing folic acid to be voluntarily added to CMF. In a preamble to the rule, the FDA predicted that corn masa fortification would lead to an increase in folic acid intake among Mexican American women of reproductive age from 164 mcg/d to 206 mcg/d. The Center for Science of Public Interest (CSPI) states that recent data show the predicted impact has not been realized.

b) **Assessment of Manufacturers' Uptake of Voluntary Corn Masa Fortification.** The CSPI conducted a study to assess the food industry's uptake of the 2016 voluntary corn masa fortification rule by examining the prevalence of folic acid fortification of corn masa and comparing the proportion of corn masa products that contain folic acid to the proportion of wheat products that contain folic acid. The study included an examination of a large national sample of corn masa products on the market at least two years after the FDA began permitting folic acid fortification of CMF. The study found that only eight of the 59 (14%) unique CMFs included in the sample contained folic acid. CSPI also noted that compared to wheat flour and wheat tortillas, folic acid fortification of corn masa is substantially lagging.

c) **Challenges associated with folic acid fortification of corn masa products.** According to the CSPI, in an informal poll of manufacturers conducted by a trade association and shared with CSPI via email, one manufacturer reported that they grind whole corn to make their own corn masa and have had difficulty extrapolating the FDA guideline of 0.7 mg folic acid per pound of corn masa flour to determine the right fortification level for their process. Another manufacturer reported a lack of availability of fortified corn masa from their ingredient supplier. Other manufacturers noted concerns regarding the impact of folic acid on product quality, the need for label changes, and consumer demand for simple labels with recognizable ingredients. Despite these challenges, the fortification of

CMF is an important step to bridge the gap in folic acid intake and reduce NTD rates, especially among the Latinx populations with whom this flour is a main ingredient in culturally relevant foods.

d) Other jurisdictions requiring folic acid fortification of CMF. Evidence of feasibility comes from Mexico, where CMF is required by law to be fortified with folic acid. Despite some ongoing issues with enforcement and uptake by smaller producers, much of the CMF and corn tortillas sold in Mexico is fortified, and corn tortillas represent the single greatest food source of folic acid in people's diets.

3) SUPPORT. The American College of Obstetricians and Gynecologists District IX (ACOG), the sponsor of this bill, states that according to the Centers for Disease Control and Prevention (CDC), and supported by ACOG, all women of reproductive age should get 400 micrograms (mcg) of folic acid each day, in addition to consuming food with folate from a varied diet, to help prevent NTDs. NTDs are major birth defects of the baby's brain (anencephaly) and spine (spina bifida). In 1998, the FDA mandated flour to be fortified with folic acid. However, masa was omitted from this mandate and the masa flour manufacturers were allowed to participate "voluntarily" without guidelines. Since the 1998 mandate to fortify enriched cereal grain products with folic acid, the U.S. has experienced a 35% decrease in the rate of NTDs. However, while rates of NTDs may have experienced an overall decline, disparities remain with Hispanic women having the highest risk of giving birth to a baby with a NTD. This may largely be attributed to Hispanic communities relying heavily on CMF as their staple. The incidence of NTDs is seven out of 1000 in Hispanics while average incidence overall in the U.S. is two out of 1000. We also know that many Hispanic communities are in areas where there is limited access to preconception counseling and healthcare in general. By requiring the same folic acid fortification to CMF that currently applies to wheat flour, this bill will help address this prevalent cultural variation and work to lower NTD's in all communities.

4) RELATED LEGISLATION.

a) AB 2066 (Reyes) prohibits, commencing January 1, 2027, a person or entity from using methylene chloride in the process of decaffeinating coffee. AB 2066 makes it a violation of these provisions punishable by a civil penalty not to exceed $5,000 for a first violation and not to exceed $10,000 for each subsequent violation, upon an action brought by the Attorney General (AG), a city attorney, a county counsel, or a district attorney. AB 2066 is pending referral in the Assembly Rules Committee.

b) AB 2217 (Weber) prohibits, commencing January 1, 2027, a person or entity from manufacturing, selling, delivering, distributing, holding, or offering for sale, in commerce a food product for human consumption that contains tianeptine. AB 2217 makes it a violation of these provisions punishable by a civil penalty not to exceed $5,000 for a first violation and not to exceed $10,000 for each subsequent violation, upon an action brought by the AG, a city attorney, a county counsel, or a district attorney. AB 2217 is pending referral in the Assembly Rules Committee.

c) AB 2365 (Haney) states it is the intent of the Legislature to regulate kratom. AB 2365 is pending referral in the Assembly Rules Committee.

5) PREVIOUS LEGISLATION.

a) AB 418 (Gabriel), Chapter 328, Statutes of 2023 prohibits, commencing January 1, 2027, a person or entity from manufacturing, selling, delivering, distributing, holding, or offering for sale, in commerce a food product for human consumption that contains any specified substance, including, among others, brominated vegetable oil and red dye 3. AB 418 makes it a violation of these provisions punishable by a civil penalty not to exceed $5,000 for a first violation and not to exceed $10,000 for each subsequent violation, upon an action brought by the AG, a city attorney, a county counsel, or a district attorney.

b) AB 899 (Muratsuchi), Chapter 668, Statutes of 2023, requires in-state or out-of-state manufacturers of infant formula or baby food sold or distributed in this state to: i) test their infant formula or baby food products for toxic heavy metals, including levels of lead, mercury, cadmium, and arsenic; ii) post on their website the name and level of toxic heavy metals in the final infant formula or baby food product; and, iii) include a label on the product that it has been tested.

6) SUGGESTED AMENDMENTS. This bill requires DPH, by regulation, to require manufacturers to add folic acid at a level not to exceed 0.7 milligrams of folic acid per pound of CMF and to include a declaration of folic acid on the nutrition label in accordance with applicable federal law. The Committee may wish to amend this bill to directly require manufacturers, commencing January 1, 2026, to add folic acid to their corn masa products and include a declaration of folic acid on the nutrition label in accordance with applicable federal law.

REGISTERED SUPPORT / OPPOSITION:

Support

American College of Obstetricians and Gynecologists District IX
California Catholic Conference
California Pan-Ethnic Health Network
County Health Executives of California
Latino Coalition for a Healthy California
March of Dimes

Opposition

None on file.

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

Date of Hearing: March 19, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1842 (Reyes) – As Introduced January 16, 2024

SUBJECT: Health care coverage: Medication-assisted treatment.

SUMMARY: Prohibits a health plan or health insurer from subjecting any of the following to prior authorization or step therapy: 1) A naloxone product or another opioid antagonist approved by the United States Food and Drug Administration (FDA); or, 2) a buprenorphine product or long-acting injectable naltrexone for detoxification or maintenance treatment of a substance use disorder (SUD).

EXISTING LAW:

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

2) 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]

3) 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]

4) Requires every health plan contract and insurance policy that provides hospital, medical, or surgical coverage to provide coverage for medically necessary treatment of mental health and SUDs under the same terms and conditions applied to other medical conditions, as specified. [HSC §1374.72 and INS §10144.5]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, there is an urgent need to expand access to rapid initiation of medications to treat addiction. This bill expands on the recent work of the federal government to mainstream addiction treatment by eliminating unnecessary barriers to treatment. As a policy, commercially insured Californians are the only group where prior authorization delays are still allowed. The author concludes that

removing this last barrier will expand low barrier treatment options for at risk patients, prevent overdose, and save lives.

2) **BACKGROUND.** This bill prohibits health plans and insurance policies from requiring prior authorization for a naloxone product or another opioid antagonist approved by the FDA or a buprenorphine product or long-acting injectable naltrexone for detoxification (medically supervised withdrawal) or maintenance treatment of a SUD. According to the California Health Benefits Review Program (CHBRP), the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) defines opioid use disorder (OUD) as "a problematic pattern of opioid use leading to clinically significant impairment or distress" and persons must meet defined criteria within a 12-month period to receive a diagnosis. OUD applies to the class of medications or drugs that includes illegal drugs such as heroin, synthetic opioids such as fentanyl, and prescription pain medications such as oxycodone, hydrocodone, codeine, and morphine that are misused for indications other than prescribed. Prescription opioids are used to treat moderate to severe pain, and persons who take prescription opioids can develop opioid use disorder. The DSM-5 characterizes alcohol use disorder as a pattern of alcohol use (e.g., wine, beer, and spirits) that results in significant impairment or distress. People meeting at least two of 11 specified criteria within a 12-month period are diagnosed with mild, moderate, or severe alcohol use disorder depending on the number of criteria met.

   a) **Opioid Related Overdose Deaths in California**. The Department of Public Health reports on its Opioid Overdose Death Dashboard that in 2022, there were 7,385 opioid related deaths in California. The annual crude mortality rate for 2022 was 18.39 per 100k residents, an increase of 33% from 2020. Of those over 83% involved fentanyl, a potent synthetic opioid drug that is approximately 50 times stronger than heroin and 100 times stronger than morphine. The number of deaths each year involving fentanyl increased dramatically between 2012 and 2021. During this time period fentanyl related overdose deaths increased by more than 7,250% -- from 82 deaths to 5,961 deaths in 2021.

      In 2019, almost one third of white persons with OUD received medications for treatment compared to 20% of Black or other non-Latino multiracial groups and 15% of Latino persons. Prescribing practices changed significantly for medications prescribed for OUD (buprenorphine and long-acting injectable naltrexone) after the beginning of the COVID-19 pandemic, with 30.5% decrease for buprenorphine and 10.5% decrease of long-acting injectable naltrexone across all races/ethnicities. However, Black, Latino, and Asian persons experienced greater decreases in buprenorphine prescription fills compared to white persons. Racial disparities in overdoses have emerged with greater increases among Black and Latino persons. In California, the opioid-related overdose death rate was highest among American Indian/Alaskan Native and Black persons compared to white persons and healthcare utilization for opioid-related overdoses in the emergency department and hospitalization was highest among Black persons during 2021.

   b) **Medication-assisted treatment (MAT).** Treatments for SUD include prescription medication (medications for OUD or medications for alcohol use disorder), also called, MAT, as well as counseling, residential facilities, and mutual help groups (e.g., Alcoholics Anonymous, Narcotics Anonymous). This bill identifies two FDA-approved MAT options for OUD and alcohol use disorder: buprenorphine products or long-acting injectable naltrexone.

The Substance Abuse and Mental Health Services Administration (SAMHSA) describes maintenance treatment as "providing medications to achieve and sustain clinical remission of signs and symptoms of OUD and support the individual process of recovery without a specific endpoint." Some persons with OUD may require long-term medication treatment to ensure sustained recovery. There is evidence that relapse of OUD occurs less often for patients on medications (buprenorphine-naloxone and long-acting injectable naltrexone) for treatment (16%) compared to patients with no medication for treatment (40%). Some persons with alcohol use disorder experience a chronic condition with recurring treatment, abstinence, and relapse. Data from a nationally representative sample from 2012 to 2013 found that one third of adults with alcohol use disorder prior to the past year still had persistent alcohol use disorder, over half had remission from alcohol use disorder as classified by the DSM-5, and of the respondents that met criteria for remission, one third were indicative of recovery.

The American Society of Addiction Medicine (ASAM) provides the National Practice Guidelines for the Use of Medications in the Treatment of Addiction Involving Opioid Use and SAMHSA provides the Treatment Improvement Protocol that reviews the clinical standards of care for patients with OUD including buprenorphine, methadone, and long-acting injectable naltrexone. In 2020, the ASAM updated requirements to include that all FDA approved medication prescribed for the treatment of OUD should be available to all persons seeking treatment (this bill does not include methadone).

c) State programs. In 2017, California received more than $476 million in discretionary grants from SAMHSA to aid in the opioid crisis. The California Department of Health Care Services (DHCS) initiated the California MAT Expansion Program in response to the opioid epidemic in the state and to help stop overdose deaths. The goals of the program are to increase access to MAT, reduce unmet treatment need, and reduce opioid-related overdose deaths. The program targets populations who do not have access to medication including youth, people in rural areas, and American Indians and Alaska Native tribal communities. The program supports more than 30 projects in the state with 650 access points for treatment including more than 140,000 new Californians with opioid disorder who received medication through this program.

CalRx Naloxone Access Initiative. In 2023, Governor Newsom announced through the CalRx Naloxone Access Initiative, that California will work with a pharmaceutical partner or partners who can develop, make, and distribute naloxone nasal spray at a much lower cost. Additionally, California is providing $30 million to support this project, which will help with research, manufacturing, and getting FDA approval. The goal is to offer naloxone at a single, affordable price that everyone can afford. A more affordable version of this life-saving medication will enable state programs to purchase more supply and to reduce financial barriers for other purchasers, particularly community-based organizations and individuals and families.

At least 18 states have laws that limit prior authorization on medications used to treat SUDs, as does the District of Columbia. The federal Consolidated Appropriations Act of 2023 removed the federal requirement that providers submit a Notice of Intent (waiver) to prescribe buprenorphine for OUD treatment. This legislation also removed the limits on the number of patients a practitioner may treat. This allows providers with a current Drug Enforcement Administration registration with Schedule III authority to prescribe

buprenorphine for OUD treatment as allowed by scope of practice in each state. With the removal of this waiver requirement, more providers are now able to prescribe buprenorphine.

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 states the following in its analysis of AB 1288 (Rendon) of 2023 which is substantially similar to this bill:

- **i) Enrollees covered.** The medications addressed by this bill are most commonly covered through a pharmacy benefit. For Medi-Cal beneficiaries in DMHC-regulated managed care plans, the pharmacy benefit is separate and is administered by DHCS. Therefore, these beneficiaries have a pharmacy benefit that is not subject to DMHC regulation. Approximately 95.6% of commercial/CalPERS enrollees in plans and policies regulated by DMHC or CDI have a pharmacy benefit regulated by DMHC or CDI that would be subject to this bill. CHBRP estimates that 1% to 5% of these enrollees (the figure varies by medication) have a prior authorization requirement that would be prohibited by this bill. Postmandate, none of these enrollees would have a prior authorization requirement applicable to these medications when they are on formulary.
- **ii) Impact on utilization and expenditures.** According to CHBRP, no measurable change in utilization or expenditures at the state level is expected because benefit coverage would change for very few commercial/CalPERS enrollees (1% to 5% of depending on the medication) and few in that group would both have one of the disorders and be a likely user of one of the medications. However, it is possible that a few enrollees might increase utilization of the medications addressed by this bill, postmandate.
- **iii) EHBs.** This bill would not require coverage for a new state benefit mandate and would not appear to exceed the definition of EHBs in California.
- **iv) Medical effectiveness.** There is limited evidence that removal of prior authorization requirements for buprenorphine products is associated with increased use and higher treatment retention for OUD. There is insufficient evidence on the impact of prior authorization on methadone use for OUD. It should be noted that this bill does not include methadone. There is insufficient evidence on the impact of prior authorization on long-acting injectable naltrexone use for either OUD or alcohol use disorder. For treatment of OUD, there is clear and convincing evidence that buprenorphine products and methadone are more effective with regard to treatment retention, reduction in use of illicit opioids, relapse, and improved health outcomes, compared to a placebo or no treatment. There is a preponderance of evidence that long-acting injectable naltrexone is effective with regard to treatment retention and abstinence, but not for overdose prevention, compared to a placebo or oral naltrexone. For treatment of alcohol use disorder, there is a preponderance of evidence that long-acting injectable naltrexone is more effective with regard to reducing return to drinking compared to a placebo or oral naltrexone.

v) **Public Health.** CHBRP projects no measurable public health impact at the population level because this bill is not expected to create measurable changes in benefit coverage for or utilization at the state level. However, it is possible that this bill could yield some person-level health improvements if some enrollees increase utilization of the medications this bill addresses.

vi) **Long-Term Impacts.** Since the change in benefit coverage is so limited, no state-level long-term impacts of this bill on health outcomes, including premature death associated with OUD and alcohol use disorder, can be projected. However, if some enrollees increase utilization of the medications addressed by this bill, it is possible that there could be some reduction in premature deaths at the person level.

3) **SUPPORT.** The Ella Baker Center for Human Rights writes that this bill is urgently needed to address the overdose crisis in our state. Drug overdose has been the number-one cause of accidental death in California for over a decade and cannot continue to allow this catastrophe to continue unabated. Almost 11,000 Californians died in 2021 as a result of a preventable drug overdose. In addition, another 19,000 Californians died that same year due to excessive alcohol use. Medications such as buprenorphine or long-acting naltrexone can dramatically improve health outcomes for substance use disorders by treating withdrawal and preventing use of dangerous controlled substances, including fentanyl. There is currently no prior authorization needed for accessing MAT for Medi-Cal beneficiaries, and seventeen states have already adopted policies to remove prior authorization requirements for commercial health insurers. But many commercial insurers in California are not allowing these medically-appropriate treatments to be given to patients that pay for coverage. The Ella Baker Center for Human Rights concludes that prior authorization requirements create unnecessary barriers that delay or interrupt access to effective treatment.

4) **SUPPORT IF AMENDED.** The California Association of Alcohol and Drug Program Executives request amendments to expand this bill to include all MAT options and formulas approved by the FDA. The Union of American Physicians and Dentists (UAPD/AFSCME Local 206) requests the following amendment to ensure professional ethical standards of treatment:

   No physician shall prescribe any naloxone product or another opioid antagonist approved by FDA or a buprenorphine product or long-acting injectable naltrexone for detoxification or maintenance treatment of a SUD without doing due diligence in keeping with professional ethical standards of treatment.

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 ACLHIC 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.** AB 2271 (Ortega) requires Medi-Cal coverage of prescription or nonprescription naloxone hydrochloride or another drug approved by the FDA for the complete or partial reversal of an opioid overdose. Requires a health plan contract or health insurance policy, as specified, to include coverage for the same medications under the same conditions. Prohibits a health plan contract or health insurance policy from imposing any cost-sharing requirements for that coverage exceeding $10 per package of medication, and prohibits a high deductible health plan from imposing cost sharing, as specified. Makes implementation contingent on funding from the Naloxone Distribution Project and inoperative when the state records 500 or fewer opioid deaths in a calendar year, and repeals these provisions on the following January 1. AB 2271 is pending in Assembly Health Committee.

7) **PREVIOUS LEGISLATION.**

a) AB 1288 (Rendon) of 2023 was similar to this bill and would have prohibited health plans and insurers from requiring prior authorization for methadone. AB 1288 was vetoed by Governor Newsom:

"This bill would prohibit health plans from requiring prior authorization or step therapy for a naloxone product or other opioid antagonist approved by the FDA, buprenorphine product, methadone, or long-acting injectable naltrexone for detoxification or treatment of a SUD.

I appreciate the author's intent to increase access to medication for opioid use disorder (OUD). My Administration takes the opioid crisis seriously, as evidenced by the over $1 billion invested to combat overdoses, support those with opioid use disorder, raise awareness, and crack down on trafficking. However, utilization review is an important tool to contain health care costs, protect patients from unanticipated billing, and ensure medically necessary care. While immediacy of treatment is important, prior authorization also helps avoid fraudulent requests or abuse of the drugs addressed in this bill, such as methadone."

b) SB 854 (Jim Beall) of 2020 would have required health plan contracts and health insurance policies issued, amended, or renewed on or after January 1, 2021, that provide outpatient prescription drug benefits to cover all medically necessary prescription drugs approved by the FDA for treating SUDs that are appropriate for the specific needs of an enrollee or insured. Would have required those drugs to be placed on the lowest cost-sharing tier of the plan or insurer's prescription drug formulary, unless specified criteria are met. Would have prohibited prior authorization or step therapy requirements on a prescription drug approved by the FDA for treating SUDs, unless specified criteria are met. SB 854 was never heard in Senate Health Committee.

c) AB 2384 (Arambula) of 2018 would have required a health insurer or a health plan, not including a Medi-Cal managed care plan, to cover, at a minimum, at least one version of each specified MAT, relapse prevention, and overdose reversal prescription drug approved by the FDA for OUD. Would have provided that at least one version of each MAT, relapse prevention, and overdose reversal prescription drug is not subject to specified requirements of a health plan or policy of health insurance, including prior authorization and an annual or lifetime dollar limit, as specified. Would have specified

that its provisions would apply to an FDA-approved drug for use in MAT for OUD, relapse prevention, or overdose reversal that an enrollee or insured is being prescribed as of January 1, 2019, or, for a new enrollee or insured, that he or she is being prescribed at the time of enrollment. Governor Brown vetoed this bill:

"This bill requires health plans to cover at least one version of each drug used in medication-assisted treatment for opioid disorders and restricts health plans' ability to manage the utilization of these drugs.

While the drugs specified in this bill are useful to treat opioid addiction, I'm not willing to eliminate requirements that may be in the best interest of patients."

8) **COMMENT.** As this bill moves forward, the Committee may wish to recommend to the author to engage the Administration as soon as possible to address the veto of AB 1288 from last year.

REGISTERED SUPPORT / OPPOSITION:

Support

California Academy of Child and Adolescent Psychiatry
California Black Health Network
California Hospital Association
California State Association of Psychiatrists (CSAP)
County Behavioral Health Directors Association of California
Ella Baker Center for Human Rights
Health Access California
Steinberg Institute

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: March 19, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2132 (Low) – As Amended February 27, 2024

SUBJECT: Health care services.

SUMMARY: Requires an adult patient receiving primary care services in specified health care settings, to be offered a tuberculosis (TB) risk assessment and TB screening test, if certain conditions apply. Specifically, **this bill**:

1) Requires an adult patient receiving primary care services in a facility, clinic, unlicensed clinic, center, office, or other setting where primary care services are provided, to be offered a TB risk assessment and screening test, if TB risk factors are identified, and to the extent these services are covered under the patient's health insurance.

2) Requires the screening to be based on the latest screening indications recommended by the United States Preventive Services Task Force (USPSTF), unless the health care provider reasonably believes that one of the following conditions applies:

    a) The patient is being treated for a life-threatening emergency; or,

    b) The patient has previously been offered or has been the subject of a TB risk assessment, TB screening test, or both, and has no new TB risk factors since the last TB risk assessment or screening test.

3) Specifies that the provisions of 2) above do not apply if the health care provider determines that:

    a) A TB risk assessment, TB screening test, or both should be offered again;

    b) The patient has a documented, previously positive Interferon-Gamma Release Assays test or has previously tested positive for a latent tuberculosis infection (LTBI);

    c) The patient lacks capacity to consent to a TB risk assessment, TB screening test, or both; or,

    d) The patient is being treated in the emergency department (ED) of a general acute care hospital (GACH).

4) Requires a health care provider, if a patient accepts the offer of the TB screening test and the test is positive, to offer the patient follow-up health care or refer the patient to a health care provider who can provide follow-up health care.

5) Prohibits the provisions of this bill from affecting the scope of practice of any health care provider or diminishing any authority or legal or professional obligation of any health care provider to offer a TB risk assessment, TB screening test, or both, or to provide services or care for the patient of a TB risk assessment, TB screening test, or both.

6) Prohibits a health care provider that fails to comply with the provisions of this bill from being subject to any disciplinary actions related to their licensure or certification, or to any civil or criminal liability, because of the health care provider's failure to comply. Exempts health care providers who fail to comply with the provisions of this bill from health facility licensing violations related to the operation or maintenance of a long-term health care facility.

7) Defines the following, for purposes of this bill:

   a) "Follow-up health care," to include providing medical management and treatment for TB according to the latest national clinical practice guidelines recommended by the federal Centers for Disease Control and Prevention (CDC) and the American Thoracic Society;

   b) "Tuberculosis risk assessment" or "TB risk assessment" to mean a risk assessment questionnaire developed by the Department of Public Health (DPH), in consultation with the California Tuberculosis Controllers Association, to be used to conduct TB risk assessments pursuant to the provisions of this bill; and,

   c) "Tuberculosis screening test" or "TB screening test" to mean either an approved intradermal tuberculin test or any other test for TB infection that is recommended by the CDC and licensed by the United States Food and Drug Administration.

8) Finds and declares that according to the World Health Organization, an estimated 10,600,000 people fell ill with TB during 2022. Despite being a preventable and curable disease, 1,300,000 people died from TB in 2022, making it the world's second leading infectious killer after COVID-19.

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 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 TB. [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 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 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]

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

8) Establishes as California's essential health benefits 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]

9) Requires a group or individual non-grandfathered health plan contract, at a minimum, to provide coverage for and not impose any cost-sharing requirements for any of the following:

   a) Evidence-based items or services that have in effect a rating of "A" or "B" in the recommendations of the USPSTF, as periodically updated. Indicates the current recommendations of the USPSTF regarding breast cancer screening, mammography, and prevention is considered the most current other than those issued in or around November 2009;

   b) Immunizations that have in effect a recommendation, as periodically updated, from the Advisory Committee on Immunization Practices of the CDC 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); and,

   d) With respect to women, those additional preventive care and screenings as provided for in comprehensive guidelines supported by HRSA. [HSC §1367.002 and INS §10112.2]

FISCAL EFFECT: None.

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, the recent rise in TB cases in Santa Clara County, a 19% increase from 2022 to 2023, presents a significant public health challenge that demands swift action. The author states that by increasing access to TB screening, this bill ensures early detection and treatment to save lives.

2) **BACKGROUND**. Tuberculosis is a life-threatening disease that spreads through the air when a person sick with TB coughs. However, not everyone infected with the bacteria becomes sick, people that are infected but are not sick have LTBI, which may not progress to active TB disease for many years. People living with LTBI may not know they are carrying the disease until it is too late. For those diagnosed with active TB disease, half are hospitalized and one in six die within five years of diagnosis. Those who survive can suffer from lifelong disability.

   a) **TB in California.** According to the DPH report, "*TB in California: 2022 Snapshot*," 86% of all TB cases in California were attributed to the progression of LTBI into active TB disease. Of the estimated 2 million Californians infected with TB, only 20% are aware of their infection and just 12% have been treated. If current trends continue, there will be an estimated 4,200 deaths from TB in 2040 that could have been prevented. Despite the high prevalence of TB in California, many people do not ever undergo a TB risk assessment and screening.

      The report also notes that TB disproportionately affects racial and ethnic minority groups, as well as those with low socioeconomic status: certain Asian, Latinx, and Black populations are 34 to 73 times more likely to have TB compared to US-born whites. People who are born in or who frequently travel to places where TB is prevalent, such as Asia, Africa, and Latin America, are also at risk of contracting the disease. According to a 2021 DPH report, "*Cost and Consequences of Tuberculosis in California*," those living and working in congregate living settings, such as persons experiencing homelessness, incarcerated persons, and persons in long-term care facilities, are more likely to contract the disease. Persons with TB who experience homelessness are 30% more likely to die with TB than those not experiencing homelessness.

   b) **USPSTF screening recommendations.** The USPSTF makes recommendations about the effectiveness of specific preventive care services for patients without obvious related signs or symptoms to improve the health of people nationwide. It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment. The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. The USPSTF is committed to mitigating the health inequities that prevent many people from fully benefiting from preventive services. Systemic or structural racism results in policies and practices, including health care delivery, that can lead to inequities in health. The USPSTF recognizes that race, ethnicity, and gender are all social rather than biological constructs. However, they are also often important predictors of health risk.

      The USPSTF concludes with moderate certainty that there is a moderate net benefit in preventing active tuberculosis disease by screening for LTBI in persons at increased risk for tuberculosis infection. Populations at increased risk for LTBI, based on increased prevalence of active disease and increased risk of exposure, include persons who were born in, or are former residents of, countries with high TB prevalence and persons who live in, or have lived in, high-risk congregate settings (e.g., homeless shelters or correctional facilities). USPSTF notes that clinicians can consult their local or state health departments for more information about populations at increased risk in their community, since local demographic patterns may vary across the US. The USPSTF found no

evidence on the optimal frequency of screening for LTBI, and states that in the absence of evidence, a reasonable approach is to repeat screening based on specific risk factors; screening frequency could range from one-time-only screening among persons at low risk for future TB exposure to annual screening among those who are at continued risk of exposure.

c) **Clinics and outpatient settings.** Community clinics and health centers are nonprofit, tax-exempt clinics that are licensed as community or free clinics, and provide services to patients on a sliding fee scale basis or, in the case of free clinics, at no charge to the patients. These include federally designated community health centers, migrant health centers, rural health centers, and frontier health centers. California is home to nearly 1,000 community clinics serving more than 5.6 million patients (or one in seven Californians) annually through over 17 million patient encounters. More than 50% of these patients are Hispanic and 43% speak a primary language other than English. Outpatient settings also include physicians' offices which are regulated by the Medical Board of California.

d) **Coverage of TB screening and tests.**

   i) **ACA preventive care benefits for adults.** All Marketplace health plans and many other plans must cover certain preventive services without charging a copayment when delivered by a doctor or other provider in the plan's network, including TB screening for certain adults without symptoms at high risk.

   ii) **Medi-Cal.** Medi-Cal, California's Medicaid program, provides essential health services to eligible beneficiaries. Screening is recommended for individuals at increased risk of exposure to TB and, consequently, at an increased risk of LTBI.

3) **SUPPORT.** The Coalition for a TB-Free California, North East Medical Services, and SF Hep B Free – Bay Area are the cosponsors of this bill and state that in 2022, 86% of all TB cases in California were attributed to the progression of LTBI to active TB disease. Those with LTBI may harbor the bacteria in their bodies for many years before it progresses to active TB and may not know they are infected until it is too late. For those diagnosed with active TB disease, half are hospitalized and one in six die within five years of diagnosis. Those who survive can suffer from lifelong disability. The cosponsors note that of the estimated 2 million Californians infected with TB, only 20% are aware of their infection and only 12% have been treated for it. If current trends continue, there will be an estimated 4,200 deaths from TB in 2040 that could have been prevented. The state that this bill would prevent these unnecessary deaths by bringing awareness to the infection and disease, especially for those infected but not aware by requiring primary care physicians to offer a TB risk assessment and TB screening, if TB risk factors are identified, to an adult patient whose insurance covers these services.

   The California Pan-Ethnic Health Network (CPEHN) supports this bill and states that TB disproportionately impacts racial and ethnic minority groups, persons living in low socioeconomic census tracts, and those born in or who travel frequently to countries where TB is endemic, such as Asia, Africa, and Latin America. Non-US-born Asian, Latinx, and Black populations are 34 to 73 times more likely to have TB compared to US-born whites. In addition, those living and working in congregate living settings, such as persons experiencing

homelessness, incarcerated persons, and persons in long-term care facilities, are more likely to contract the disease. People with TB who experience homelessness are 30% more likely to die from TB disease than those not experiencing homelessness. TB is preventable, especially for the millions of Californians whose latent infections have not yet progressed to active TB disease. The infection is detectable with a one-time test, and treatment can clear the TB bacteria from the body. The cost to prevent TB for one person is low ($790) compared with the costs of diagnosing and treating one person with active TB disease ($43,900). In 2022, the California medical and societal costs of TB reached $217 million. CPEHN concludes that prevention, awareness, timely diagnoses and treatment are key to eliminating the TB epidemic as well as reducing health disparities for people of color and immigrants**.**

4) **PREVIOUS LEGISLATION.** 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.

REGISTERED SUPPORT / OPPOSITION:

Support

The Coalition for a TB-Free California (cosponsor)
North East Medical Services (cosponsor)
SF Hep B Free – Bay Area (cosponsor)
API Health Parity Coalition of San Francisco
Asian Americans for Community Involvement
Asian and Pacific Islander Council of San Francisco (API Council)
Association of Asian Pacific Community Health Organizations (AAPCHO)
Breathe California of The Bay Area, Golden Gate and Central Coast
California Consortium for Urban Indian Health
California Pan - Ethnic Health Network
Community Youth Center of San Francisco
Indian Health Center of Santa Clara Valley
Nicos Chinese Health Coalition
On Lok Senior Health Services
Somos TB
Sunset Chinese Cultural District
Together Against TB
We are TB

Opposition

None on file.

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