Date of Hearing: June 27, 2023

ASSEMBLY COMMITTEE ON HEALTH
Jim Wood, Chair
SB 257 (Portantino) – As Introduced January 30, 2023

SENATE VOTE: 35-0

SUBJECT: Health care coverage: diagnostic imaging.

SUMMARY: Requires a health plan contract, a disability insurance policy that provides hospital, medical, or surgical coverage, or a self-insured employee welfare benefit plan to provide coverage without cost-sharing for screening mammography and medically necessary diagnostic breast imaging, including diagnostic breast imaging following an abnormal mammography result and for an enrollee or insured indicated to have a risk factor associated with breast cancer, except as specified. Specifically, **this bill**:

1) Requires a health plan contract, a disability insurance policy that provides hospital, medical, or surgical coverage, or a self-insured employee welfare benefit plan issued, amended, or renewed on or after January 1, 2025, as specified, to cover without cost-sharing screening mammography, medically necessary diagnostic or supplemental breast examinations, diagnostic mammography, tests for screening or diagnostic purposes, and medically necessary diagnostic breast imaging, including diagnostic breast imaging following an abnormal mammography result and for an enrollee or insured indicated to have a risk factor associated with breast cancer, including family history or known genetic mutation.

2) Specifies that diagnostic breast imaging includes breast magnetic resonance imaging (MRI), breast ultrasound, and other clinically indicated diagnostic testing, and that diagnostic breast imaging, diagnostic mammography, and diagnostic and supplemental breast examinations, or other clinically indicated diagnostic testing are covered under this bill to the extent it is consistent with nationally recognized evidence-based clinical guidelines.

3) Applies 1) above to a health plan contract or insurance policy that meets the federal definition of a high deductible health plan only after an enrollee or insured's deductible has been satisfied for the year.

4) Prohibits an enrollee or insured from receiving the services by a nonparticipating provider, except if those services are unavailable within the network to ensure timely access to covered health care services, as specified. Permits a health plan or insurer that provides coverage for out-of-network benefits from imposing cost-sharing requirements for the items or services that are delivered by an out-of-network provider, except as specified.

5) Defines the following:

   a) Breast MRI as a diagnostic tool that uses a powerful magnetic field, radio waves, and a computer to produce detailed pictures of the structures within the breast;

   b) Breast ultrasound as a noninvasive diagnostic tool that uses high-frequency sound;

c) Cost-sharing as a deductible, coinsurance, or copayment, and any maximum limitation on the application of that deductible, coinsurance, or copayment, or a similar out-of-pocket expense;

d) Diagnostic breast examination as a medically necessary and appropriate examination of the breast, including an examination using diagnostic mammography, breast MRI, breast ultrasound, or other clinically indicated diagnostic testing that is either of the following:

   i) Used to evaluate an abnormality seen or suspected from a screening examination for breast cancer; or,

   ii) Necessary based on personal or family medical history or additional factors, including known genetic mutations, that may increase the individual's risk of breast cancer.

e) Diagnostic mammography as a diagnostic tool that uses X-ray and is designed to evaluate an abnormality in the breast.

f) Supplemental breast examination as a medically necessary and appropriate examination of the breast, including an examination using breast MRI, breast ultrasound, or other clinically indicated diagnostic testing, that is either of the following:

   i) Used to screen for breast cancer when an abnormality is not seen or suspected; or,

   ii) Necessary based on personal or family medical history or additional factors, including known genetic mutations, that may increase the individual's risk of breast cancer.

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*. 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) Requires a group or individual nongrandfathered 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 United States Preventive Services Task Force (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 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); 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]

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

5) Deems mammography for screening or diagnostic purposes covered if there is a referral by a participating nurse practitioner, participating certified nurse-midwife, participating physician assistant, or participating physician providing care to the patient and operating within the scope of practice provided under existing law. Applies this provision to health plans, individual and group policies of disability insurance, and self-insured employee welfare benefit plans. [HSC §1367.65 and INS §10123.81]

6) Permits an enrollee or insured to receive the services in 5) above when furnished by a nonparticipating provider, if the enrollee or insured is referred to that provider by a participating physician, nurse practitioner, or certified nurse-midwife providing care. [HSC §1367.65 and INS §10123.81]

FISCAL EFFECT: According to the Senate Appropriations Committee:

1) DMHC estimates minor, absorbable costs;
2) CDI estimates costs of $37,000 for staffing (Insurance Fund); and,
3) Unknown, ongoing General Fund cost increases related to increased state expenditures for CalPERS health plan benefits.

COMMENTS:

1) **PURPOSE OF THIS BILL**. According to the author, breast cancer is the second leading cause of death among women of all races. Although it is rare, men can also get breast cancer. Patients who receive abnormal results on a breast cancer screening or who have a genetic risk factor associated with breast cancer, including family history or known genetic mutation, can be instructed to undergo follow-up testing to ensure that the abnormality is not cancerous. However, the author states that health insurance companies in California provide full coverage only for the initial screening mammogram and impose significant cost-sharing for diagnostic imaging if the patients are directed to additional screenings. Such costs cause many to delay or avoid appointments following an abnormal mammography result. The author concludes that this bill provides coverage without imposing cost-sharing for medically necessary diagnostic breast imaging, including diagnostic breast imaging following abnormal mammography, and for an enrollee indicated to have a genetic risk factor associated with breast cancer, including family history or known genetic mutation.

2) **BACKGROUND**. According to the California Health Benefits Review Program (CHBRP), breast cancer in California occurs predominantly in females. The annual breast cancer incidence rate in California is 122/100,000 or about 32,000 new cases diagnosed annually. The American Cancer Society estimates an average breast cancer death rate of 19/100,000 or about 4,700 breast cancer deaths annually in California. Breast cancer does occur in males, but at a much lower rate with about 170 cases diagnosed and 40 deaths annually in California. Rate Differences in breast cancer incidence and mortality by race and ethnicity persist. Although the most recent data (2012-2016) for age-adjusted incidence of breast cancer remains highest among California's non-Hispanic white (NHW) women (140/100,000), followed by non-Hispanic Black (NHB) women (129/100,000), non-Hispanic Asian and Pacific Islander (NHA/PI) women (102/100,000), and Hispanic women (91/100,000), mortality rates remain highest among NHB women. NHB have a breast cancer mortality rate of 31/100,000, followed by NHW women (21/100,000), and Hispanic women (16/100,000). NHA/PI have the lowest breast cancer mortality rate of 13/100,000.

CHBRP writes that primary screening mammography is a first step in the detection of breast cancers for women at any risk level. Patients who are considered above average or high risk for cancer may undergo additional imaging, known as supplemental screening, with other types of imaging such as breast MRI, breast ultrasound, or digital breast tomosynthesis (DBT). Patients with abnormalities upon screening mammography and/or clinical exam may undergo additional imaging for diagnosis and/or they may directly undergo a biopsy of the suspicious area(s) to confirm whether there is a malignancy in the breast tissue. It should be noted that although clinical terminology refers to imaging exams as "diagnostic," breast cancer is diagnosed based on examination of breast tissue by a pathologist (usually from biopsy). By enabling the detection of certain forms of invasive cancer at an earlier stage of disease, breast imaging exams have the potential to reduce breast cancer morbidity and mortality. Achieving appropriate care is the goal; according to most practice guidelines, supplemental screening, usually with breast MRI, is recommended for those women with a high lifetime risk of breast cancer.

a) **California's Preventive Services**. California codified the ACA's mandate that most plans must cover a set of preventive services at no cost-sharing in SB 406 (Pan), Chapter 302, Statutes of 2020. For women age 40 to 74, the federal Preventive Services mandate, through reference to the recommendations of HRSA, already prohibits cost-sharing for primary screening mammography. This bill amends existing law as follows:

   i) For women aged 40-74 years, this bill prohibits cost-sharing for all medically necessary breast imaging when used for any of the following purposes: (1) diagnostic; (2) primary screening for those not known to be at higher risk; or, (3) supplemental screening for those at high risk for breast cancer. This bill expands an existing prohibition on cost-sharing for primary screening mammography to also prohibit cost-sharing for supplemental screening and diagnostic breast imaging;

   ii) For others, women and men, at high risk for breast cancer, this bill creates a new cost-sharing prohibition for all medically necessary breast imaging when used for either of the following purposes: (1) diagnostic; or, (2) supplemental screening for those at high risk for breast cancer.

iii) For others, women and men, not known to be at higher risk, this bill creates a new cost-sharing prohibition for all medically necessary breast imaging when used for diagnostic purposes.

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 reviewed SB 974 (Portantino) of 2022 and AB 2024 (Friedman) of 2022, which is similar to this bill and stated the following in its analysis:

i) **Enrollees covered.** At baseline, 35% of enrollees with health insurance that would be subject to this bill have benefit coverage for breast imaging that does not include cost-sharing for any breast imaging, including imaging for diagnostic and supplemental screening purposes. These are the MediCal beneficiaries enrolled in DMHC-regulated plans, who generally have no applicable cost-sharing, including no applicable deductibles. Postmandate, 100% of enrollees in DMHC-regulated plans or CDI-regulated policies would have $0 cost share for medically necessary breast imaging. At baseline, 942,908 enrollees have breast imaging annually. Utilization is unevenly distributed by age and gender, with services mostly utilized among women aged 50-74 years. A significant number of breast imaging services, however, are performed for enrollees who are younger or older than the clinical guidelines would indicate for population-based screening. Postmandate, breast imaging utilization is estimated to increase by an average of 4.05% for all types of breast imaging, ranging from 0.81% to 7.01% depending on the type.

ii) **Impact on expenditures.** CHBRP estimates this bill would increase total net annual expenditures by $43,742,000, or 0.0293%, for commercial/CalPERS enrollees in DMHC-regulated plans and CDI-regulated policies. This is due to a $117,550,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by a decrease of $73,808,000 in enrollee expenses for covered and/or noncovered benefits.

(1) At baseline, for three of the types of breast imaging used for supplemental/ diagnostic purposes (mammography, breast MRI, and breast ultrasound), cost-sharing is present for less than half of the services, 42%, 46% and 47%, respectively. For DBT, cost-sharing is present for 7% of services. Postmandate, all supplemental/diagnostic breast imaging would be provided without cost-sharing. This bill would result in an additional 38,226 enrollees to become new users of or to make additional use of supplemental/diagnostic breast imaging. As a group, these enrollees would see the $74 million reduction in cost-sharing. The average per supplemental/diagnostic breast imaging service cost-sharing that this bill would prohibit (for enrollees for whom cost-sharing had been applicable) would be between $104.40 (for an enrollee in a large group market plan or policy) and $212.70 (for an enrollee in an individual market plan or policy). For enrollees in plans and polices with applicable deductibles, especially those enrolled in high deductible plans and polices, the reduction in total out-of-pocket spending could

be greater. Depending on the enrollee's spend towards the deductible in that plan/policy year, the enrollee could have been, at baseline, responsible for the full unit cost of the breast imaging test;

(2) Medi-Cal - No impact would be expected on the premiums paid to enroll Medi-Cal beneficiaries in DMHC-regulated plans, as their coverage generally includes no cost-sharing;

(3) CalPERS - Aggregate premiums for CalPERS would increase by $5,386,000 (0.09%);

(4) Covered California – Premiums for all persons purchasing individual market plans and policies through Covered California would increase by $25,687,000 (0.14%); and,

(5) Number of Uninsured in California – Since the change in average premiums does not exceed 1% for any market segment, CHBRP expects no measurable change in the number of uninsured persons due to this bill.

iii) **EHBs.** This bill does not appear to exceed the definition of EHBs in California**.**

iv) **Medical effectiveness.** CHBRP notes that the medical effectiveness of mammography for primary screening has been widely recognized in the United States and abroad for more than 25 years. There is a preponderance of evidence that DBT and breast MRI are effective for increased detection of breast cancer when used in a supplemental role. There is limited evidence that ultrasound is effective for the increased detection of breast cancer when used in a supplemental role. There is clear and convincing evidence that DBT and MRI are effective for the diagnosis of breast cancer. The evidence is inconclusive regarding the risks and harms associated with supplementary screening imaging for breast cancer.

vi) **Public health.** This bill would produce an unknown impact on breast cancer morbidity and mortality. An additional 38,226 enrollees would obtain an additional 91,161 breast imaging tests. Results would vary and many would yield negative results (no cancer detected). Some would yield false-positive results that would require unnecessary recall treatment (biopsy) and costs. A smaller number would yield earlier cancer detection. The marginal impact of the earlier cancer detection is unknown, as is the marginal impact of the additional adverse events stemming from false-positives (i.e., physical pain, anxiety, added biopsy expense, and overtreatment). Measurable impacts at the population level are unlikely, though some persons could experience improved outcomes and some could experience more adverse events.

i) **Long-term impacts**. CHBRP estimates that assuming that current technology remains in place, utilization of breast imaging in years following the first year postmandate will be relatively stable. Postmandate, CHBRP does not anticipate long term population-level measurable change in the annual number of cancer treatments since the additional imaging results in earlier, but not additional, diagnoses. On the person level, some persons might receive less intensive cancer treatments because cancers were identified at an earlier stage than otherwise would have occurred. However, others might experience adverse impacts due to unnecessary treatment related to false positive imaging results.

3) **SUPPORT**. The American Cancer Society Cancer Action Network (ACS CAN) write that individuals facing high out-of-pocket costs associated with screening and diagnostic imaging are less likely to have their recommended follow-up imaging. This can mean the person will

delay diagnosis and care until the cancer has spread to other parts of the body, making it much deadlier and more costly to treat. Thanks to the ACA, widespread access to preventive screening mammography is available to millions of people at no cost. However, an estimated 16% of screening mammograms require a follow-up diagnostic exam to completely rule out breast cancer or confirm the need for a biopsy if an abnormality is detected. Diagnostic imaging is also often recommended as the primary breast imaging for breast cancer survivors, women at high risk for breast cancer, and those who have undergone a lumpectomy followed by radiation therapy. Unfortunately, these patients often face exorbitant costs ranging from hundreds to thousands of dollars for follow-up diagnostic imaging. ACS CAN concludes that patients who incur high expenses prior to even starting treatment run a much higher risk of financial hardship and often put off needed care.

4) **OPPOSITION**. The California Chamber of Commerce (Chamber) writes in oppositionthat when health plans and insurers are required to cover new services or to waive/limit cost-sharing requirements for certain services, premiums for all enrollees and purchasers go up. This is true even though only some enrollees will utilize the mandated product or services, or benefit from the reduction in cost-sharing. CHBRP analyzed the cost impact of a substantially similar bill that was vetoed last year, SB 974, and concluded that if the mandate went into effect, it would increase employer and enrollee health care premiums by $117,550,000 adjusted by a decrease of $73,808,000 in enrollee expenses for covered and/or noncovered benefits. Additionally, while this bill is certainly well intentioned, it approaches health care affordability with a piecemeal approach. This bill favors one disease over other diseases. When looking at the coverage mandate cost increases in isolation they seem tolerable, however, this bill must be considered in context. Premiums for employers and enrollees consistently increase year after year due to a number of issues including benefit mandates. The 2022 Kaiser Family Foundation Employer Health Benefits Survey indicated that the average premium for family coverage has increased 20% over the last five years and 43% over the last 10 years. Additionally, annual premiums for employer-sponsored family health coverage reached $22,463 in 2022, with workers on average paying $6,106 toward the cost of their coverage. The Chamber states that California should not increase health care coverage costs for employers and employees with another mandate.

5) **RELATED LEGISLATION**.

   a) SB 421 (Limon) makes permanent existing law provisions that prohibit an individual or group health plan contract or health insurance policy, that provides coverage for prescribed, orally administered anticancer medications used to kill or slow the growth of cancerous cells from requiring an enrollee or insured to pay a total amount of copayments and coinsurance that exceeds $250 for an individual prescription of up to a 30-day supply of a prescribed orally administered anticancer medication, as specified. SB 421 is pending in Assembly Appropriations Committee.

   b) SB 496 (Limon) requires a health plan contract or health insurance policy issued, amended, or renewed on or after July 1, 2024, to provide coverage for medically necessary biomarker testing, as prescribed, including whole genome sequencing, for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's or insured's disease or condition to guide treatment decisions if the test is supported by medical and scientific evidence, as prescribed. SB 496 is pending in Assembly Health Committee.

6) PREVIOUS LEGISLATION.

a) SB 974 (Portantino) of 2022 which is similar to this bill was vetoed by Governor Newsom with the following message:

This bill would require a health care service plan contract issued, amended, or renewed on or after January 1, 2024, to provide coverage without imposing cost-sharing for screening mammography, medically necessary diagnostic or supplemental breast examinations, diagnostic mammography, testing for screening or diagnostic purposes, and medically necessary diagnostic breast imaging.

Breast cancer screenings save lives, which is why health plans must provide coverage for mammograms. However, this bill proposes to implement a standard that is not included by the United States Preventive Services Task Force (USPSTF) and the federal United States Health Resources and Services Administration. The USPSTF is currently in the process of updating their recommendations on breast cancer screening; until those recommendations are released, this bill is premature.

Furthermore, the bill prohibits health plans and insurance policies from imposing cost-sharing for these services, which exceed the requirements of the federal Affordable Care Act, and will result in increased health care costs. According to the California Health Benefits Review Program, this bill would increase premiums by $117,550,000, a significant impact that would be felt by many Californians. The State must weigh the potential benefits of all mandates with the comprehensive costs to the entire delivery system.

For these reasons, I cannot sign this bill.

b) AB 2024 (Friedman) of 2022 was similar to SB 974 and held in Senate Appropriations Committee.

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

REGISTERED SUPPORT / OPPOSITION:

Support
Susan G. Komen (sponsor)
American Association of University Women (AAUW) San Jose
American Cancer Society Cancer Action Network INC.
American College of Obstetricians and Gynecologists District IX
California Academy of Preventive Medicine
California Chronic Care Coalition
California Life Sciences
California Medical Association
California Professional Firefighters
California State Council of Service Employees International Union (SEIU California)
City of Hope National Medical CenterColor Health, INC.

National Association of Social Workers, California Chapter
National Health Law Program

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

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