Date of Hearing: April 26, 2022

ASSEMBLY COMMITTEE ON HEALTH
Jim Wood, Chair
AB 2024 (Friedman) – As Amended March 31, 2022

SUBJECT: Health care coverage: diagnostic imaging.

SUMMARY: Requires a health care service plan (health plan) contract or health insurance policy issued, amended, or renewed on or after January 1, 2023, to provide coverage for screening mammography, medically necessary diagnostic or supplemental breast examinations, or testing for screening or diagnostic purposes upon referral by specified professionals. Prohibits a health plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2023, from imposing cost sharing for screening mammography, medically necessary or supplemental breast examinations, or testing. Specifically, **this bill**:

1) Requires a health plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2023, to provide coverage for screening mammography, medically necessary diagnostic or supplemental breast examinations, or tests for screening or diagnostic purposes upon the referral of a participating nurse practitioner, participating certified nurse-midwife, participating physician assistant, or participating physician, providing care to the patient and operating within their scope of practice.

2) Prohibits the health plan or health insurer from imposing a deductible, coinsurance, copayment, or any other cost-sharing requirement for screening mammography, medically necessary diagnostic or supplemental breast examinations, or testing.

3) Defines the following:

    a) Breast magnetic resonance imaging (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 (OOP) expense;

    d) Diagnostic breast examination as a medically necessary and appropriate examination of the breast, including an examination using diagnostic mammography, breast MRI, or breast ultrasound 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; and,

f) Supplemental breast examination as a medically necessary and appropriate examination of the breast, including an examination using breast MRI or breast ultrasound 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 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 insurers.

2) Establishes the federal Patient Protection and Affordable Care Act (ACA), which enacts various health care coverage market reforms including the availability of health insurance exchanges (exchanges) and new individual and small group products offered on and off the exchanges beginning 2014.

3) Requires health plans and health insurers providing health coverage in the individual and small group markets to cover, at a minimum, essential health benefits (EHBs), including the ten EHB benefit categories in the ACA, and consistent with California's EHB benchmark plan, the Kaiser Foundation Health Plan Small Group HMO 30 plan, as specified in state law.

4) Specifies the EHBs in the following 10 categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; 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.

5) Requires all non-grandfathered group health plans and health insurance coverage offered in the individual or group market to cover without cost sharing all evidenced-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force (USPSTF).

6) Requires health plans to provide basic health care services, including: physician services; hospital inpatient and ambulatory care services; diagnostic laboratory and diagnostic and therapeutic radiologic services; home health services; preventive health services; emergency health care services; and, hospice care.

7) Requires health plans to make all services readily available at reasonable times to each enrollee consistent with good professional practice and in a manner providing continuity of care and ready referral of patients to other providers at times as may be appropriate consistent with good professional practice.

8) Requires health plans, except specialized health plans, to provide coverage for screening for, diagnosis of, and treatment for, breast cancer.

9) Requires a health plan contract issued, amended, delivered, or renewed on or after January 1, 2000, or an individual or group policy of disability insurance or self-insured employee welfare benefit plan to provide coverage for mammography for screening or diagnostic purposes upon referral by specified professionals.

10) Establishes the Medi-Cal program, administered by the Department of Health Care Services (DHCS), under which qualified low-income individuals receive health care services.

11) Establishes the Breast and Cervical Cancer Early Detection Program, administered by DHCS through the Every Woman Counts (EWC) program, to provide breast and cervical cancer screening services under the Centers for Disease Control and Prevention grant at the level of funding budgeted from state and other resources during the fiscal year in which the Legislature has appropriated funds for this purpose.

12) Requires a provider or entity that participates in the federal National Breast and Cervical Cancer Early Detection Program to provide screening services to an individual only if the individual's family income has been determined not to exceed 200% of the federal poverty level.

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, early access to breast cancer diagnosis and treatment can save lives. In California alone, 31,720 women will be diagnosed with breast cancer this year and 4,690 women will die from the disease in 2022. Thanks to the ACA, millions of women have access to preventative screening mammography. An estimated 16% of women screened with modern digital mammography require follow-up imaging. Unfortunately, if the results of a screening mammogram require a follow-up exam to determine if the patient has breast cancer, the patient will likely be facing significant OOP costs, even with health insurance, all before they even begin treatment. A recent Susan G. Komen-commissioned study found the OOP costs for diagnostic breast imaging to be high in California, ranging from $265 for a diagnostic mammogram to more than $3,000 for a breast MRI. When patients are unable to afford their share of the cost for diagnostic imaging, many delay care or forego follow-up tests until the cancer has spread to other parts of her body, making it much deadlier and much more costly to treat. No one should have to choose between a necessary medical exam and paying for groceries. The author concludes that reducing OOP costs for diagnostic imaging improves access to care and will lead to more patients receiving early detection services and critical follow-up care.

2) **BACKGROUND.** According to the California Health Benefits Review Program (CHBRP) breast cancer 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. 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. After decreasing for 20 years, the National Cancer Institute characterizes the breast cancer death rate in the United States and California as stable. In California, 71% of breast cancer is diagnosed in the early stages of localized disease, which carries a 99% 5-year survival rate. California reports that 68% of women aged 45 years and older are up to date on recommended mammography.

This bill requires coverage, without cost sharing, of medically necessary supplemental screening and diagnostic imaging. 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. However, according to CHBRP, screening imaging can result in some overdiagnoses (false-positive results or benign cancers) leading, in those cases, to unnecessary interventions (further imaging, biopsies, treatment), as well as potential psychosocial consequences. For those with positive screening and diagnostic results, treatment and prognosis of invasive breast cancers are guided by multiple factors, including biological characteristics of the cancer and the stage of disease, which is determined after excision of a tissue sample or surgery to remove the lump or whole breast. CHBRP notes that increases in supplemental screening may identify additional lesions that may or may not be cancerous. Some results will identify cancers that would become invasive, thus resulting in better outcomes due to early diagnosis. Other results may identify cysts or noncancerous lesions leading to interventions that do not result in a cancer diagnosis. According to most practice guidelines, supplemental screening, usually with breast MRI, is recommended for those women with a high lifetime risk of breast cancer as achieving appropriate care is the goal.

a) CHBRP. 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 essential health benefits, and legislation that impacts health insurance benefit designs, cost sharing, premiums, and other health insurance topics. CHBRP states in its analysis of this bill the following:

   i) **Impact on expenditures.** This bill would increase total net annual expenditures by $43,742,000, or 0.0293%, for commercial/California Public Employees' Retirement System (CalPERS) enrollees in DMHC-regulated plans and CDI-regulated policies. This is due to an $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, which includes a $1,018,000 increase in cost sharing for the additional biopsies that will be performed. Changes in premiums as a result of this bill would vary by market segment. Among DMHC-regulated plans, CHBRP estimates that postmandate, premiums will increase by $0.5343 per member per month (PMPM) for large-group plans. Among small-group and individual DMHC plans, premiums will increase by an estimated $0.6719 PMPM and $1.0437 PMPM, respectively. Among CDI-regulated policies, CHBRP estimates that postmandate, premiums will increase by $0.6114 PMPM for large-group policies. Among small-group and individual CDI policies, premiums will increase by an estimated $0.9243 PMPM and $0.9364 PMPM, respectively. Among enrollees in publicly funded DMHC-regulated plans, impacts would vary. For CalPERS enrollees in DMHC-regulated plans, the elimination of cost sharing for breast imaging, postmandate, will increase utilization, and so premiums are expected to increase by $0.2236 PMPM. For Medi-Cal beneficiaries in DMHC-regulated plans, because these enrollees have no cost sharing at baseline, and utilization is not expected to change postmandate, no impact would occur.

(1) 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.

(2) CalPERS. Aggregate premiums for CalPERS would increase by $5,386,000 (0.09%)

(3) Covered California. Aggregate premiums for all persons purchasing individual market plans and policies through Covered California would increase by $25,687,000 (0.14%).

(4) 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 because of this bill.

ii) **EHBs.** In California, nongrandfathered individual and small-group health insurance are generally required to cover EHBs In 2023, approximately 12.1% of all Californians will be enrolled in a plan or policy that must cover EHBs. As this bill does not require coverage for a new benefit, this bill appears not to exceed the definition of EHBs in California.

iv) **Medical effectiveness.** Although primary screening is not the focus of this analysis, 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 (sensitivity and specificity) for the diagnosis of breast cancer. The evidence is inconclusive regarding the risks and harms associated with supplementary screening imaging for breast cancer.

v) **Benefit coverage.** 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 Medi-Cal 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.

vi) **Utilization.** 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, utilization of breast imaging 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.

vii) **Public health.** According to CHBRP, the short- and long-term public health impact of this bill on breast cancer morbidity or mortality is unknown. Ultimately, the differences in outcomes of breast cancers diagnosed earlier than what would have been discovered at regularly scheduled primary mammography screening are unknown. Postmandate, following the removal of cost sharing requirements, CHBRP estimates an additional 38,226 enrollees (4% increase) would obtain an additional 91,161 supplemental and/or diagnostic breast images. These are the enrollees for whom CHBRP assumes cost-sharing is a barrier to care, and would change their behavior to seek supplemental and diagnostic breast imaging once cost sharing was eliminated. Most of the 38,226 new imaging users would have negative readings from supplemental screenings. Those with positive readings indicating suspicious anomalies could progress to diagnostic imaging, which would further divide the group into 2 subgroups: a false-positive group (benign findings) or a group diagnosed with breast cancer. CHBRP estimates about 5,477 extra biopsies would occur from those new supplemental screenings or diagnostic images. Based on national data, between 70% and 80% of breast biopsies would result in negative findings. If this assumption is true, this could result in approximately 1,370 breast cancer cases (0.75 x 5,477) being diagnosed earlier due to the removal of breast imaging cost sharing. However, the morbidity and mortality outcomes of these earlier diagnoses as compared with later diagnoses are unknown.

viii) **Long-term impacts.** In the first postmandate year, CHBRP does not anticipate long-term population-level measurable change in the annual number of cancer treatments because 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.** Susan G. Komen, sponsor of this bill, writes that widespread access to preventive screening mammography is available to millions of women as a result of ACA. Unfortunately, if the results of that screening mammogram require a follow-up diagnostic exam (such as an MRI, ultrasound, or diagnostic mammogram) to rule out breast cancer or confirm the need for a biopsy, the patient will likely face hundreds to thousands of dollars in OOP costs, all before they even begin treatment. Aside from follow-up testing, diagnostic imaging is also often recommended as 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. This bill will ensure fair and equitable access to these services by eliminating the OOP costs for medically necessary diagnostic imaging tests.

4) **OPPOSITION.** The California Association of Health Plans, the Association of California Life and Health Insurance Companies, and America's Health Insurance Plans contend that in the face of continued uncertainty and efforts to fragment the market and promote less comprehensive coverage, California needs to protect the coverage gains we've made and stay focused on the stability and long-term affordability of our health care system.

5) **RELATED LEGISLATION.** SB 974 (Portantino) requires a health plan contract, or an individual or group policy of disability insurance that provides hospital, medical, or surgical coverage, or a self-insured employee welfare benefit plan issued, amended, or renewed on or after January 1, 2023, to provide coverage without imposing 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. SB 974 is currently pending in Senate Health Committee.

6) **PREVIOUS LEGISLATION.**

   a) AB 2342 (Burke) of 2018 would have required health plans, health insurers, and DHCS to cover breast and ovarian cancer susceptibility screening as recommended by the USPSTF was vetoed by Governor Brown: "Each of these bills require significant, ongoing general fund commitments. As such, I commend these policies to the budget process where they may be prioritized along with other spending proposals and which begins again on January 3rd."

   b) AB 1860 (Limon), Statutes of 2018, Chapter 427, extends the January 1, 2019 sunset in existing law that requires health plans and health insurers that provide 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, notwithstanding any deductible, 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.

   c) SB 1034 (Mitchell), Statutes of 2018, Chapter 332, extends the January 1, 2019 sunset in existing law that requires a health facility at which a mammography examination is performed to include a prescribed notice on breast density in the summary of the written report that is sent to a patient, if specified circumstances apply.

   d) AB 1386 (Waldron), Chapter 693, Statutes of 2017, requires DHCS to include information relating to breast cancer susceptibility gene mutations in the next revision of a brochure that is provided to cancer patients.

   e) AB 1795 (Atkins), Chapter 608, Statutes of 2016, changes provisions of the EWC and the BCCTP within DHCS regarding eligibility for screenings, period of treatment, and eligibility of coverage after reoccurrence of cancer.

7) **AUTHOR'S AMENDMENTS.** Under the tax law, high deductible health plans (HDHP) must set a minimum deductible and a limit, or maximum, on OOP costs. A health savings account (HSA) is an account that allows individuals to set aside money on a pre-tax basis to pay for qualified medical expenses, as defined in the tax law. The author proposes to add language to ensure that this bill complies with federal law as it relates to HDHPs with HSAs.

REGISTERED SUPPORT / OPPOSITION:

Support

Susan G. Komen (sponsor)
American College of Obstetricians and Gynecologists District Ix
California Academy of Family Physicians
California Life Sciences
California Professional Firefighters
California Radiological Society
California Society of Plastic Surgeons

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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