SENATE COMMITTEE ON HEALTH
Senator Dr. Richard Pan, Chair

BILL NO: AB 2024
AUTHOR: Friedman
VERSION: June 15, 2022
HEARING DATE: June 29, 2022
CONSULTANT: Teri Boughton

SUBJECT: Health care coverage: diagnostic imaging.

SUMMARY: Requires a health plan, health insurer or self-insured employee welfare benefit plan to cover screening mammography, medically necessary diagnostic or supplemental breast examinations, or tests for screening or diagnostic purposes upon the referral of a participating providers, as specified, and, prohibits a plan contract or insurance policy from imposing a deductible, coinsurance, copayment, or any other cost-sharing requirement for screening mammography, medically necessary diagnostic or supplemental breast examinations, or testing.

Existing law:

1) Establishes the Department of Managed Health Care (DMHC) to regulate health plans under the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene Act); California Department of Insurance (CDI) to regulate health and other insurance; and, the Department of Health Care Services (DHCS) to administer the Medi-Cal program. [HSC §1340, et seq., INS §106, et seq., and WIC §14000, et seq.]

2) Requires health plans, except a specialized health plan contract, to provide coverage for mammography for screening or diagnostic purposes upon referral by 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. [HSC §1367.65]

3) Requires an individual or group policy of disability insurance or self-insured employee welfare benefit plan to be deemed to provide coverage as described in 2) above upon referrals as described in 2) above. Excludes specialized health insurance, Medicare, CHAMUS, and TRI-CARE supplement insurance, hospital indemnity, accident-only, or specified disease insurance.[INS §10123.81]

4) Indicates that 2) above does not prevent application of copayment or deductible provisions in a plan, nor does it require a plan or policy be extended to cover any other procedures under an individual or a group health plan contract or health insurance policy, and it does not authorize a plan enrollee or insured to receive services furnished by a nonparticipating provider, unless the plan 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]

5) Requires a health plan contract and health insurance policy, except for a specialized health plan contract and policy, to be deemed to provide coverage for all generally medically accepted cancer screening tests, subject to all terms and conditions that would otherwise apply. [HSC §1367.665 and INS §10123.20]

6) Requires a group or individual nongrandfathered health plan contract or health insurance policy, 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;
   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 (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);
   d) With respect to women, those additional preventive care and screenings as provided for in comprehensive guidelines supported by the HRSA; and,
   e) 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. [HSC§ 1367.002 and INS 10112.2]

7) Establishes health savings accounts (HSAs), as an account used exclusively for the purpose of paying the qualified medical expenses of the account beneficiary, but only if the written governing instrument creating the trust meets specified requirements. Establishes high deductible health plans (HDHPs), which are plans with deductibles not less than $1,000 for an individual and $5,000 for a family, as specified.[26 USC § 223]

8) Allows an annual tax deduction in an amount equal to the aggregate amount paid in cash by or on behalf of an individual, to an HSA [26 USC § 223]

9) Prohibits a plan from failing to be treated as an HDHP by reason of failing to have a deductible for preventive care, as specified. [26 USC § 223]

This bill:

1) Requires a health plan contract, a health insurance policy, or a self-insured employee welfare benefit plan 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 the scope of practice provided under existing law.

2) Prohibits a plan contract or insurance policy 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) Applies 2) above only to a health plan contract or insurance policy that meets the definition of a "high deductible health plan" (HDHP) set forth under federal law after an enrollee's or insured's deductible has been satisfied for the year.

4) Establishes the following definitions:

a) "Breast magnetic resonance imaging" means 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" means a noninvasive diagnostic tool that uses high-frequency sound.
c) "Cost-sharing" means 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" means a medically necessary and appropriate examination of the breast, including an examination using diagnostic mammography, breast magnetic resonance imaging (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.
    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" means a diagnostic tool that uses x-ray and is designed to evaluate an abnormality in the breast.
f) "Supplemental breast examination" means 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.
    ii) Necessary based on personal or family medical history or additional factors that may increase the individual's risk of breast cancer.

FISCAL EFFECT: According to the Assembly Appropriations Committee:

1) The California Health Benefits Review Program (CHBRP) estimates aggregate premiums for commercial and California Public Employees' Retirement System (CalPERS) health plans and insurance policies would increase by $5,386,000 annually, and total net annual expenditures by $43,742,000, or 0.0293%, for commercial enrollees in plans regulated by the DMHC and policies regulated by the CDI.
2) CHBRP estimates aggregate premiums for all persons purchasing individual market plans and policies through Covered California would increase by $25,687,000.
3) CHBRP states no effect would be expected on the premiums paid to enroll Medi-Cal beneficiaries in DMHC-regulated plans, because their coverage generally includes no cost sharing.
4) Estimated costs to CDI in the thousands to low tens of thousands of dollars per year in fiscal years (FY) 2022-23 and 2023-24 (Insurance Fund).
5) Estimated costs to DMHC in the hundreds of thousands of dollars per year in FYs 2022-23 and 2023-24 (Managed Care Fund).

COMMENTS:

1) *Author's statement.* According to the author, thanks to the Affordable Care Act (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 out-of-pocket costs, even with health insurance, all before they even begin treatment. A recent Susan G. Komen-commissioned study found the out-of-pocket 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. Reducing out-of-pocket costs for diagnostic imaging improves access to care and will lead to more patients receiving early detection services and critical follow-up care.

2) *ACA.* Under the ACA, non-grandfathered group and individual health insurance plans and policies must cover certain preventive services without cost-sharing when delivered by in-network providers. The ACA prohibits copayments, coinsurance, and deductibles for preventive services that are determined based on recommendations by specified federally recognized groups and federal agencies, and must be covered without cost-sharing when provided in-network as soon as 12 months after a recommendation appears. For breast cancer screening, the recommendations are:

   a) After an appropriate brief familial risk assessment, women with a positive result should receive genetic counseling followed by genetic testing for BRCA1 or BRCA2, if indicated; and,
   b) Women ages 50 to 74 years should receive biennial mammography screening. However, HRSA recommends this beginning at age 40, so the preventive services mandate prohibits cost-sharing for women aged 40 to 74.

3) *Internal Revenue Service (IRS) Preventive Services.* Among the requirements to qualify as an HSA, an individual must be covered under an HDHP with no disqualifying health coverage. An HDHP is a health plan that satisfies certain requirements with respect to minimum deductibles and maximum out-of-pocket expenses. Generally, under federal law, an HDHP may not provide benefits for any year until the minimum deductible for that year is satisfied. However, the law provides a safe harbor for the absence of a deductible for preventive care. Therefore, an HDHP may provide preventive care benefits without a deductible. To be a preventive care benefit, the benefit must either be described as preventive care under the ACA or for purposes of the Social Security Act or determined to be preventive care in guidance issued by the Department of the Treasury (Treasury Department) and the IRS.

4) *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, and reviewed this bill. Key findings include:

   a) *Screening guidelines.* Primary and supplemental screening guidelines are generally organized according to lifetime risk of breast cancer. Guidelines generally recommend primary screening mammography for women beginning at age 40 years (with provider consultation) or age 50 and continuing through age 74.There is less consensus on supplemental screening. Most guidelines recommend supplemental screening for women at highest risk, but guidelines differ as to which category of risk, as well as to the frequency of and which types of breast imaging that should be used. Guidelines generally recommend against supplemental screening for people with dense breast tissue. The types of breast imaging used include mammography, breast MRI, digital breast tomosynthesis (DBT), and breast ultrasound.

b) *Coverage impacts and 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 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. The bill was amended on June 15, 2022, CHBRP indicates the amended language would allow cost sharing for some – or perhaps all - enrollees in plans or policies with an annual deductible of $1,400 or more per year. CHBRP's fiscal and public health analysis remains directionally correct. However, if the amended language would exempt all HDHPs, impacts could be lower for 22% of commercial enrollees. If the amended language would exempt only HDHPs associated with health savings accounts (HSAs), impacts would be lower for 6% of commercial enrollees. All other portions of CHBRP's analysis remain relevant. The amended language also adds an Insurance Code reference to self-insured employee welfare benefit plans. As CDI does not regulate such plans, the impact of the addition is unclear.

c) *Medical effectiveness.* Although primary screening is not the focus of this analysis, it seems appropriate to note 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.

d) *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.

e) *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 and so is compliant with this bill.

f) *Impact on expenditures.* 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 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.

g) *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. 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.

h) *Essential health benefits*. As this bill would not require coverage for a new benefit, the bill appears not to exceed the definition of essential health benefits in California

5) *Related legislation.* SB 974 (Portantino) requires coverage without cost-sharing for screening mammography and medically necessary diagnostic breast imaging, including diagnostic breast imaging following an abnormal mammography result and for a patient indicated to have a risk factor associated with breast cancer, including family history or known genetic mutation. Includes breast MRI, breast ultrasound, and other clinically indicated diagnostic testing. *SB 974 is set for hearing in the Assembly Health Committee on June 28, 2022.*

6) *Prior legislation.* SB 406 (Pan, Chapter 302, Statutes of 2020) among other things, rewrites existing law that requires health plan contracts to cover preventive services without cost-sharing by deleting federal statutory citations and replacing those citations with the actual federal provisions that impose the requirements.

   AB 137 (Portantino, Chapter 436, Statutes of 2013) requires every individual or group health plan or policy of health insurance to provide coverage for mammography, for screening or diagnostic purposes, upon the referral by a participating nurse practitioner, participating certified nurse-midwife, participating physician assistant, or participating physician, as specified, based on medical need regardless of age.

7) *Support.* This bill's sponsor, Susan G. Komen, writes unfortunately, if the results of the 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 out-of-pocket 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 would ensure fair and equitable access to these services by eliminating the out-of-pockets costs for medically necessary diagnostic imaging tests. A recent Komen-commissioned study found the out-of-pocket costs for patients to be high, with much variation for diagnostic breast imaging. For example, average patient cost for a mammogram is $265, and for a breast MRI, $3,000. The study found also that the inconsistency in cost and coverage is a recognized concern among patients, and health care providers, which may lead to additional stress and confusion for women who are already dealing with the daunting possibility of a breast cancer diagnosis. The use of breast cancer screening and follow-up diagnostics have led to significant increases in the early detection of breast cancer in the past 30 years. However, evidence shows that commercially insured Black breast cancer patients were diagnosed at a later stage and had a higher mortality rate when compared with their white counterparts with the same insurance status. Unfortunately, we often receive calls and emails from women who are unable to afford the out-of-pocket costs for their follow-up

diagnostic imaging services. Without some assistance, many of these women will simply delay or forego their follow-up screenings, leading to later diagnoses. This delay can mean that woman will not seek care until the cancer has spread making it much deadlier and much more costly to treat. Breast cancer can be up to five times more expensive to treat when it has spread beyond the breast to other parts of the body. Additionally, COVID-19 has created significant delays in annual breast cancer screenings and experts have warned that the "missed" cancers might be larger and more advanced once ultimately detected, often requiring the use of diagnostic imaging. In recent years, several other states have passed and implemented this vitally important legislation, including Arkansas, Colorado, Illinois, Louisiana, New York and Texas. This session, Georgia and Oklahoma have passed similar legislation ensuring access to diagnostic imaging.

8) *Opposition.* The California Association of Health Plans, the Association of California Life and Health Insurance Companies, and America's Health Insurance Plans states that this bill, taken together with AB 1859 (Levine, related to mental health treatment) and AB 2516 (Aguiar-Curry, related to HPV), will increase premiums on Californians by nearly $123 million. California has been a national leader in maintaining a stable market despite rising costs and uncertainty at the federal level over the individual and employer market. Opponents write that now is not the time to inhibit competition with proscriptive mandates that reduce choice and increase costs. California needs to protect the coverage gains made and stay focused on the stability and long-term affordability of our health care system. Benefit mandates impose a one-size-fits-all approach to medical care and benefit design driven by the legislature, rather than consumer choice. 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. These bills will lead to higher premiums, harming affordability and access for small businesses and individual market consumers. The California Chamber of Commerce writes employer-based health care coverage is usually one of the most formidable expenses a business experiences and, while the bill is well-intentioned, it will unintentionally exacerbate health care affordability issues. 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 concluded that if the mandate went into effect, it would increase employer health care premiums over $55 million. Employee premiums would also increase over $23 million. California businesses are already facing tremendous adversity in rebuilding and any added costs will likely prove unmanageable.

9) *Amendment request.* The Chair is requesting that the coverage of supplemental breast examinations, or tests for screening or diagnostic purposes is covered to the extent it is consistent with nationally recognized evidence-based clinical guidelines.

SUPPORT AND OPPOSITION:

Support: Susan G. Komen (sponsor)
American Association of University Women California
American Association of University Women San Jose
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
NextGen California
Planned Parenthood Affiliates of California

Oppose: America's Health Insurance Plans
Association of California Life and Health Insurance Companies
California Association of Health Plans
California Chamber of Commerce

-- END --