HB 1006

Department of Legislative Services

Maryland General Assembly
2016 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 1006 (Delegate Sample-Hughes, *et al.*)
Health and Government Operations

Health Insurance - Coverage for Digital Tomosynthesis

This emergency bill expands the current health insurance mandate for coverage of breast cancer screenings to include coverage for "digital tomosynthesis" that the treating physician determines is medically appropriate and necessary. A carrier may not impose a copayment or coinsurance requirement for digital tomosynthesis that is greater than one for other breast cancer screenings for which coverage is required. "Digital tomosynthesis" means a radiologic procedure that involves the acquisition of projection images over the stationary breast to produce cross-sectional digital three-dimensional images.

The bill applies to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after January 1, 2017.

Fiscal Summary

State Effect: Minimal increase in special fund revenues for the Maryland Insurance Administration (MIA) in FY 2017 from the $125 rate and form filing fee. Review of filings can likely be handled with existing MIA resources. No impact on the State Employee and Retiree Health and Welfare Benefits Program, as all participating carriers currently provide coverage as required under the bill.

Local Effect: Potential increase in expenditures for local governments that purchase fully insured health benefit plans.

Small Business Effect: Minimal; however, health insurance expenditures may increase for small businesses.

Analysis

Current Law: Under Maryland law, there are 49 mandated health insurance benefits that certain carriers must provide to their enrollees, including coverage for breast cancer screenings. A carrier must cover breast cancer screenings in accordance with the latest screening guidelines issued by the American Cancer Society (ACS). A deductible may not be imposed. A carrier is not required to cover breast cancer screenings used to identify breast cancer in asymptomatic women that are provided by a facility that is not accredited by the American College of Radiology or certified or licensed in Maryland.

The federal Patient Protection and Affordable Care Act requires nongrandfathered health plans to cover 10 essential health benefits, including preventive and wellness services and chronic disease management. Coverage of mammograms for breast cancer screening, without a copayment or deductible, is mandated as a preventive service.

Background: Digital tomosynthesis was approved by the U.S. Food and Drug Administration (FDA) in 2011 to be used in combination with standard digital mammography. In tomosynthesis, a machine takes low-dose X-rays as it moves over the breast. These images can be combined into a three-dimensional picture, which may allow a radiologist to see inside the breast more clearly. Total radiation dose with tomosynthesis is about twice that of digital mammography, but the dose remains below the limits defined by FDA.

According to the American College of Radiology, digital tomosynthesis has shown to be an advance over digital mammography, with higher cancer detection rates and fewer patient recalls for additional testing. In a multicenter study published in the *Journal of the American Medical Association* in 2014, researchers found that digital mammograms with tomosynthesis were associated with an increase in the cancer detection rate (1 additional cancer detected for every 1,000 scans) and a 15% decrease in patient recall rates. The study did not have a randomized design, nor did it assess clinical outcomes.

In its February 2016 final recommendations on breast cancer screening, the U.S. Preventive Services Task Force (USPSTF) found inadequate evidence on the benefits and harms of digital breast tomosynthesis (DBT) as a primary screening method for breast cancer. Similarly, USPSTF found inadequate evidence on the benefits and harms of adjunctive screening for breast cancer using breast ultrasonography, magnetic resonance imaging, DBT, or other methods in women identified to have dense breasts on an otherwise negative screening mammogram. In both cases, while there is some information about the accuracy of these methods, USPSTF concluded that there is no information on the effects of their use on health outcomes, such as breast cancer incidence, mortality, or overdiagnosis rates.

In 2015, Illinois enacted legislation that requires carriers to allow covered mammogram procedures to include digital tomosynthesis.

In October 2015, ACS released new guidelines for breast cancer screening. Under the new recommendations, women with an average risk of breast cancer should begin yearly mammograms at age 45. At age 55, women should have mammograms every other year, though women who want to keep having yearly mammograms should be able to do so. Regular mammograms should continue for as long as a woman is in good health. Breast exams, either from a medical provider or self-exams, are no longer recommended. Women at high risk for breast cancer due to family history, a breast condition, or another reason should begin screening earlier and/or more often according to their health care provider.

Small Business Effect: Per MIA, the bill appears to apply to any nongrandfathered health benefit plan purchased by a small employer.

Additional Information

Prior Introductions: None.

Cross File: SB 648 (Senator Mathias) - Finance.

Information Source(s): American Cancer Society; American College of Radiology; *Breast Cancer Screening Using Tomosynthesis in Combination with Digital Mammography*, JAMA, 2014; 311 (24): 2499-2507; *Final Recommendation Statement: Breast Cancer: Screening*, U.S. Preventive Services Task Force, February 2016; Maryland Health Benefit Exchange; Maryland Insurance Administration; Department of Budget and Management; Department of Legislative Services

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kb/ljm

Analysis by: Jennifer B. Chasse

Direct Inquiries to:
(410) 946-5510
(301) 970-5510