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H.B. 371*
134th General Assembly

Bill Analysis

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Version: As Reported by Senate Health

Primary Sponsors: Reps. Schmidt and Denson

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SUMMARY

Screening mammography

- Revises the law governing health insurance and Medicaid coverage of screening mammography.
- Requires health insurers and the Medicaid program to cover supplemental breast cancer screening if certain conditions are met.
- Revises the language a mammography facility must use when notifying a mammography patient in writing of the presence of dense breast tissue.

Temporary certificate of need changes

- For a certificate of need (CON) granted during the period of the COVID-19 state of emergency:
  - Requires the Director of Health to grant a CON holder a 24-month extension to obligate capital expenditures and commence construction for a proposed project;
  - Provides that the transfer of a CON, or transfer of the controlling interest in an entity that holds a CON, prior to completion of the reviewable activity for which the CON was granted, does not void the CON, so long as recognizing the transfer does not violate existing law that prohibits a CON from being approved in various circumstances.

* This analysis was prepared before the report of the Senate Health Committee appeared in the Senate Journal. Note that the legislative history may be incomplete.

- For a CON granted on or before the effective date of the bill, prohibits the Director from imposing a civil penalty against a CON holder for obligating a capital expenditure in an amount between 110% and 150% of the approved project cost.

DETAILED ANALYSIS

Screening mammography

Current Ohio statutory law requires the Medicaid program and the following types of health insurers to cover or provide benefits for the expenses of screening mammography (to detect the presence of breast cancer) and cytologic screening (to detect the presence of cervical cancer): health insuring corporations, sickness and accident insurers, and public employee benefit plans.[1] The bill revises this law in two main ways, first by eliminating certain coverage limits for screening mammography and second, by requiring coverage of supplemental breast cancer screening in specified circumstances. It also makes changes to the law governing written notice to mammography patients regarding dense breast tissue.

Coverage of screening mammography

Under existing law, how often screening mammography must be covered by the Medicaid program and the foregoing insurers depends on the woman's age and risk factors for breast cancer. For instance, if a woman is at least 35 but under 40 years of age, the law requires coverage of one screening mammography, without reference to the timing or frequency of the screening. If a woman is at least 40 but under 50 years of age, one screening mammography is covered every two years, except that if a physician has determined that she has risk factors, one screening mammography is covered every year. Finally, in the case of a woman who is at least 50 but under 65 years of age, one screening mammography is covered every year.

The bill instead requires coverage of one screening mammography every year, regardless of the woman's age or risk factors.[2] It also specifies that the coverage includes digital breast tomosynthesis.

Screening mammography definition

The bill maintains the current law definition of "screening mammography," but specifies that it also includes digital breast tomosynthesis.[3] At present, screening mammography includes the x-ray examination of the breast using equipment that is dedicated specifically for mammography. Digital breast tomosynthesis is a three-dimensional imaging technology that

[1] R.C. 1751.62, 3923.52, 3923.53, and 5164.08.

[2] R.C. 1751.62(C), 3923.52(C), 3923.53(B), and 5164.08(C).

[3] R.C. 1751.62(A)(1), 3923.52(A)(1), and 5164.08(A)(1).

involves acquiring images at multiple angles during a scan. The images are reconstructed into a series of thin high-resolution slices that can be displayed individually or in a dynamic mode.[4]

Coverage of supplemental breast cancer screening

The bill requires the Medicaid program and health insuring corporations, sickness and accident insurers, and public employee benefit plans to cover supplemental breast cancer screening in specified circumstances.[5]

Types of supplemental breast cancer screening

Under the bill, supplemental breast cancer screening means any additional screening method deemed medically necessary by a treating health care provider for proper breast cancer screening in accordance with applicable American College of Radiology Guidelines. Supplemental breast cancer screening includes magnetic resonance imaging (MRI), ultrasound, and molecular breast imaging.[6]

Eligibility

To be eligible for supplemental breast cancer screening coverage under the bill, an adult woman must meet either of the following conditions:

- The woman's screening mammography demonstrates, based on the breast imaging reporting and data system established by the American College of Radiology, that the woman has dense breast tissue; or
- The woman is at increased risk of breast cancer due to family history, prior personal history of breast cancer, ancestry, genetic predisposition, or other reasons as determined by the woman's health care provider.[7]

Reimbursement rates and payment

The bill expands the current law insurance reimbursement limits pertaining to screening mammography to also apply to supplemental breast cancer screening. With respect to benefits provided by health insuring corporations, sickness and accident insurers, and public employee benefit plans, current law limits the total benefit for screening mammography to 130% of the Medicare reimbursement rate in Ohio. However, if there is more than one Medicare reimbursement rate in Ohio, the reimbursement rate is 130% of the lowest Medicare reimbursement rate. The bill applies these provisions to the reimbursement rates for supplemental breast cancer screening. Under the bill, therefore, the reimbursement rates for

[4] *Digital Breast Tomosynthesis*, Technology Assessment Number 9 (reaffirmed 2020), which is available on ACOG's website: https://www.acog.org/.

[5] R.C. 1751.62(B), 3923.52(B), 3923.53(A), and 5164.08(B).

[6] R.C. 1751.62(A)(3), 3923.52(A)(2), and 5164.08(A)(2).

[7] R.C. 1751.62(C), 3923.52(C), 3923.53(B), and 5164.08(C).

supplemental breast cancer screening is limited to 130% of the Medicare reimbursement rate for that supplemental screening and will depend on the type of screening utilized.

Location of supplemental breast cancer screening

As a condition of coverage, the bill requires the supplemental breast cancer screening to be performed either in a facility or mobile mammography screening unit that is accredited by the American College of Radiology or in a hospital.[8] This same condition also applies under current law to the coverage of screening mammography.

Exemption from review by the Secretary of Insurance

It could be argued that by requiring health insurers to cover supplemental breast cancer screening in accordance with the bill's provisions, the bill might establish a mandated health benefit. Under current law, if the General Assembly enacts a mandated health benefit, it cannot be applied to any health benefit plan until the Superintendent of Insurance determines that the benefit also can be applied fully and equally in all respects to employee benefit plans subject to the federal "Employee Retirement Income Security Act of 1974" (ERISA),[9] and to employee benefit plans established or modified by the state or any of its political subdivisions.[10] The bill exempts its requirements from this restriction.[11]

Dense breast tissue notice to patients

Federal law requires a mammography facility to send to each patient who has a mammogram performed at the facility a summary of the written report of the mammogram results.[12] The summary must be written in lay terms and sent to the patient not later than 30 days after the mammogram was performed. If the written report's overall final assessment of findings is "suspicious" or "highly suggestive of malignancy," as defined by federal law, the facility must make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.[13]

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[8] R.C. 1751.62(E), 3923.52(E), 3923.53(D), and 5164.08(D).

[9] 29 United States Code 1001 *et seq.*, not in the bill. ERISA is a comprehensive federal statute governing the administration of employee benefit plans. ERISA generally precludes state regulation of benefits offered by private employers that self-insure their benefit programs. Larger employers frequently choose to establish their own health insurance plans for their employees in lieu of purchasing coverage from a sickness and accident insurer or health insuring corporation.

[10] R.C. 3901.71, not in the bill.

[11] R.C. 1751.62(B), 3923.52(B), and 3923.53(A).

[12] Public Law 102-539. The Mammography Quality Standards Act of 1992 was reauthorized by Congress in 1998 and 2004, with some changes to the law. See U.S. Food and Drug Administration, *Radiation-Emitting Products: About Mammography Quality Standards Act (MQSA)*, which is available on the FDA's website: https://www.fda.gov/fda.gov.

[13] 21 Code of Federal Regulations 900.12(c)(2).

In general, Ohio law has codified federal law concerning summaries of written mammography reports. In addition, it requires a summary to include the following notice if a patient's mammogram demonstrates, based on American College of Radiology Standards, that the patient has dense breast tissue:[14]

> Your mammogram demonstrates that you have dense breast tissue, which could hide abnormalities. Dense breast tissue, in and of itself, is a relatively common condition. Therefore, this information is not provided to cause undue concern; rather, it is to raise your awareness and promote discussion with your health care provider regarding the presence of dense breast tissue in addition to other risk factors.

The bill revises the foregoing notice and directs that it read as follows:[15]

> Your mammogram shows that your breast tissue is dense. Dense breast tissue is very common and is not abnormal. However, dense breast tissue can make it harder to find cancer on a mammogram and also may increase your risk of developing breast cancer. Because you have dense breast tissue, you could benefit from additional imaging tests such as a screening breast ultrasound or breast magnetic resonance imaging. This information about your breast density is being provided to you to raise your awareness. It is important to continue routine screening mammograms and use this information to speak with your health care provider about your own risk for breast cancer. At that time, ask your health care provider if more screening tests might be useful based on your risk. A report of your mammogram results was sent to your health care provider.

Temporary certificate of need changes

Under current law, certain activities involving long-term care facilities, such as constructing a new facility or increasing bed capacity, may be conducted only if a certificate of need (CON) has been granted by the Director of Health.[16] The bill makes the following two changes regarding certificates of need that were granted during the COVID-19 state of emergency (from March 9, 2020 through June 18, 2021):

[14] R.C. 3702.40(B).

[15] R.C. 3702.40(B).

[16] R.C. 3702.51 through 3702.62, not in the bill.

- First, it grants a CON holder a 24-month extension to obligate capital expenditures and commence construction for the proposed project and requires the Director to notify the CON holder of the date the extension expires.[17]
- Second, it provides that the transfer of a CON, or transfer of the controlling interest in an entity that holds a CON, prior to completion of the reviewable activity for which the CON was granted, does not void the CON, so long as recognizing the transfer does not violate existing law that prohibits a CON from being approved in various circumstances.[18]

The bill also makes a third temporary change regarding CONs, and that change applies to CONs granted on or before the effective date of the bill. For 24 months, the bill prohibits the Director from imposing a civil penalty against a CON holder for obligating a capital expenditure in an amount between 110% and 150% of the approved project cost.[19] This will temporarily override current administrative rules that permit a monetary penalty for obligating more than 110% of the approved project cost.[20]

The above provision applies to any CON that was granted on or before the effective date of the bill and for which the Director is still monitoring the activities of the person granted the CON.[21]

HISTORY

Action	Date
Introduced	07-07-21
Reported, H. Families, Aging, & Human Services	11-01-21
Passed House (89-2)	11-18-21
Reported, S. Health	---

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[17] Section 4(A).

[18] Section 4(B); reasons for which a CON must be denied under current law can be found in R.C. 3702.59, not in the bill.

[19] Section 5(A).

[20] Ohio Administrative Code 3701-12-18; see also R.C. 3702.52(C)(8), not in the bill, which requires the Director, in granting a CON, to specify as the maximum capital expenditure that may be obligated under the CON a figure equal to 110% of the approved project cost.

[21] Section 5(B); see R.C. 3702.52(E), not in the bill.