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Final Analysis

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Primary Sponsors: Reps. Schmidt and Denson

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UPDATED VERSION*

SUMMARY

Screening mammography

- Revises the law governing health insurance and Medicaid coverage of screening mammography by (1) requiring coverage for one screening mammography every year and (2) specifying that screening mammography includes digital breast tomosynthesis.
- 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 continuing law that prohibits a CON from being approved in various circumstances.

* This version updates the effective date.

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

DETAILED ANALYSIS

Screening mammography

The act revises Ohio statutory law that requires the Medicaid program and the following types of health insurers to cover or provide benefits for the expenses of screening mammography (to detect breast cancer) and cytologic screening (to detect cervical cancer): health insuring corporations, sickness and accident insurers, and public employee benefit plans.[1] The two main changes are (1) eliminating certain coverage limits for screening mammography and (2) requiring coverage of supplemental breast cancer screening in specified circumstances. The act also modifies the wording of the written notice that is sent to mammography patients regarding dense breast tissue.

Coverage of screening mammography

The act 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 (described below).

This replaces prior law, under which a woman's age and risk factors for breast cancer determined how often screening mammography was covered. Under prior law, if a woman was at least 35 but under 40 years old, coverage was required for one screening mammography, without reference to the timing or frequency of the screening. If a woman was at least 40 but under 50, one screening mammography was covered every two years, except that if risk factors were present, one screening mammography was covered every year. Finally, in the case of a woman who was at least 50 but under 65, one screening mammography was covered every year.

Screening mammography definition

The act adds digital breast tomosynthesis to the otherwise maintained definition of "screening mammography," which includes the x-ray examination of the breast using equipment that is dedicated specifically for mammography.[3] Digital breast tomosynthesis is a three-dimensional imaging technology that involves acquiring images at multiple angles during

[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).

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

In addition to the coverage discussed above, the act 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] 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 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 act, 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 act expands the 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, continuing 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 rate. The act applies these provisions to reimbursement rates for supplemental breast cancer screening. Therefore, the reimbursement rates for supplemental breast cancer screening are limited to 130% of the Medicare reimbursement rate for that supplemental screening and will depend on the type of screening utilized.[8]

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[4] American College of Obstetricians and Gynecologists (ACOG), *Digital Breast Tomosynthesis*, Technology Assessment Number 9 (reaffirmed 2020), which is available on ACOG's website: acog.org.

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

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

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

[8] R.C. 1751.62(D)(2), 3923.52(D)(2), and 3923.53(C)(2).

Location of supplemental breast cancer screening

As a condition of coverage, the act 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.[9] This same condition also applies under continuing law to the coverage of screening mammography.

Exemption from review by the Secretary of Insurance

Under continuing law unchanged by the act, 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),[10] and to employee benefit plans established or modified by the state or any of its political subdivisions.[11] The act exempts its requirements from this restriction.[12]

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.[13] The summary must be written in lay terms and sent to the patient within 30 days after the mammogram was performed, or sooner if the findings are "suspicious" or "highly suggestive of malignancy."[14]

In general, Ohio law has codified federal law concerning summaries of written mammography reports. In addition, it requires a summary to include notice if a patient's mammogram demonstrates, based on American College of Radiology Standards, that the patient has dense breast tissue. The act revises the content of the notice and directs that it read as follows:[15]

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

[10] 29 United States Code 1001 *et seq.*, not in the act. ERISA is a comprehensive federal statute governing employee benefit plans. ERISA generally precludes state regulation of benefits offered by private employers that self-insure their benefit programs.

[11] R.C. 3901.71, not in the act.

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

[13] 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: fda.gov.

[14] 21 Code of Federal Regulations 900.12(c)(2).

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

> 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 continuing 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 to the facility by the Director of Health.[16] The act 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):

- 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, before 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 continuing law that prohibits a CON from being approved in various circumstances.[18]

The act also makes a third temporary change regarding CONs, for CONs granted on or before September 23, 2022, the act's effective date. For 24 months, it 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

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

[17] Section 4(A).

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

[19] Section 5(A).

administrative rules that permit a monetary penalty for obligating more than 110% of the approved project cost.[20]

The civil penalty prohibition applies to any CON that was granted on or before September 23, 2022, 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
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Passed Senate (31-1)	06-01-22
House concurred in Senate amendments (88-1)	06-01-22

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[20] Ohio Administrative Code 3701-12-18; see also R.C. 3702.52(C)(8), not in the act, 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 act.