Ohio Legislative Service Commission

Bill Analysis

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Sub. S.B. 54

130th General Assembly
(As Passed by the Senate)

Sens. Kearney and Eklund, Cafaro, Gentile, Smith, Sawyer, Tavares, Schiavoni, Turner, Lehner, Jones, Bacon, Balderson, Beagle, Burke, Coley, Faber, Gardner, Hite, Hughes, LaRose, Manning, Obhof, Oelslager, Patton, Peterson, Schaffer, Seitz, Skindell, Uecker, Widener

BILL SUMMARY

- Requires a mammography facility to include certain information in a patient's mammogram summary if the patient's mammogram demonstrates the presence of dense breast tissue.

CONTENT AND OPERATION

Mammogram results

Dense breast tissue notice to patients

Federal law requires a mammography facility to send to each patient who has a mammogram performed there a summary of the written report of the results of the patient's mammogram (see "**Written report to health care providers**," below).[1] 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,

[1] 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)* (last updated November 6, 2012), available at <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActand Program/AbouttheMammographyProgram/default.htm>.

the facility must make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.[2]

In general, the bill codifies federal law concerning summaries of written mammography reports. In addition, the bill 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:[3]

> 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.

Written report to health care providers

Federal law requires a mammography facility to (1) prepare a written report of the results of each mammogram performed there and (2) send the report to a patient's health care provider. In general, the report must contain the following information:[4]

(1) The name of the patient and an additional patient identifier;

(2) The date of examination;

(3) The name of the physician who interpreted the mammogram;

(4) An overall final assessment of findings, classified in one of five categories: negative, benign, probably benign, suspicious, or highly suggestive of malignancy;

(5) Recommendations to the health care provider about what additional actions, if any, should be taken.

When a patient has a referring health care provider or the patient has named a health care provider, the facility must send the report to that provider as soon as possible, but not later than 30 days after the mammogram was performed. If an assessment is "suspicious" or "highly suggestive of malignancy," as defined by federal

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[2] 21 Code of Federal Regulations (C.F.R.) 900.12(c)(2).

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

[4] 21 C.F.R. 900.12(c)(1).

law, the facility must make reasonable attempts to communicate with the health care provider as soon as possible or, if the health care provider is unavailable, to a responsible designee of the health care provider.[5]

The bill largely codifies federal law concerning written mammography reports, by requiring a facility to send to the patient's health care provider, if known, a copy of the written report containing the results of the patient's mammogram. The report must be sent not later than 30 days after the mammogram was performed.[6]

Scope of the bill

The bill specifies that its provisions do not create either of the following:[7]

--A new cause of action or substantive legal right against a person, facility, or other entity; or

--A standard of care, obligation, or duty for a person, facility, or other entity that would provide the basis for a cause of action or substantive legal right, other than the duty to send the summary and written report described above.

Definitions

The bill specifies that the terms, "mammogram" and "facility," have the same meanings as in federal law,[8] which are:

"**Mammogram**" – A radiographic image produced through mammography. ("Mammography" is radiography of the breast.)[9]

"**Facility**" – Any of the following that conducts breast cancer screening or diagnosis through mammography activities: a hospital, outpatient department, clinic, radiology practice, or mobile unit; an office of a physician; or another facility determined by the U.S. Secretary of Health and Human Services. The term does not, however, include a facility of the U.S. Department of Veterans Affairs. ("Mammography activities" include the operation of equipment to produce the mammogram, the

[5] 21 C.F.R. 900.12(c)(3).

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

[7] R.C. 3702.40(C).

[8] R.C. 3702.40(A).

[9] 42 United States Code (U.S.C.) 263b(a)(5) and (6).

processing of the film, the initial interpretation of the mammogram, and the viewing conditions for that interpretation.)[10]

HISTORY

ACTION	DATE
Introduced	02-25-13
Reported, S. Medicaid, Health & Human Services	05-14-14
Passed Senate (32-0)	05-28-14

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[10] 42 U.S.C. 263b(a)(3).