Ohio Legislative Service Commission

Bill Analysis

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Sub. S.B. 54

130th General Assembly
(As Reported by S. Medicaid, Health and Human Services)

Sens. Kearney and Eklund, Cafaro, Gentile, Smith, Sawyer, Tavares, Schiavoni, Turner, Lehner, Jones

BILL SUMMARY

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

CONTENT AND OPERATION

Mammography results

Dense breast tissue notice

Federal regulations promulgated by the U.S. Food and Drug Administration pursuant to the Mammography Quality Standards Act of 1992 (MQSA) govern mammography facilities.[1] Under those regulations, a mammography facility must send to each patient who has a mammogram at the facility a summary of the written report containing the results of the patient's mammogram (see "**Written mammography report**," below). The summary must be written in lay terms and be sent to the patient not later than 30 days after the mammogram was performed. If an assessment is "suspicious" or "highly suggestive of malignancy," as defined in federal regulations, the

[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>.

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 in the Revised Code the federal requirement concerning summaries of written mammography reports. In addition, the bill requires the summary to include the following notice if, based on the breast imaging reporting and data system established by the American College of Radiology, the patient's mammogram demonstrates 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 mammography report

Federal regulations require a mammography facility to prepare a written report of the results of each mammogram performed at the facility. 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, and (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 the 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 in federal 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 in the Revised Code the federal requirement concerning written mammography reports. It does this by requiring a mammography facility to

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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).

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

send to the patient's health care provider, if known, a copy of the written report containing the results of the patient's mammogram not later than 30 days after the mammogram was performed.[6]

Bill's legal scope

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

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

--Create 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, as required by the bill.

Definitions

The bill specifies that the terms, "mammogram" and "facility," have the same meanings as in the MQSA,[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 processing of the film, the initial interpretation of the mammogram, and the viewing conditions for that interpretation.)[10]

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[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).

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

HISTORY

ACTION	DATE
Introduced	02-25-13
Reported, S. Medicaid, Health & Human Services	05-14-14

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