2015 Regular Session

HOUSE BILL NO. 186

BY REPRESENTATIVES MONTOUCET, ADAMS, BARROW, BILLIOT, WESLEY BISHOP, BOUIE, BROADWATER, BROWN, BURFORD, HENRY BURNS, BURRELL, CARMODY, CHANEY, CONNICK, COX, CROMER, DOVE, EDWARDS, FOIL, GAINES, GISCLAIR, GUILLORY, GUINN, HARRIS, HARRISON, HAVARD, HAZEL, HENRY, HILL, HONORE, HUNTER, JACKSON, JAMES, JEFFERSON, JONES, KLECKLEY, NANCY LANDRY, LEBAS, LEOPOLD, LORUSSO, MIGUEZ, MILLER, MORENO, JAY MORRIS, JIM MORRIS, NORTON, PEARSON, PIERRE, PUGH, PYLANT, REYNOLDS, RICHARD, RITCHIE, ROBIDEAUX, SCHRODER, SMITH, ST. GERMAIN, TALBOT, THIERRY, WHITNEY, PATRICK WILLIAMS, AND WILLMOTT

Prefiled pursuant to Article III, Section 2(A)(4)(b)(i) of the Constitution of Louisiana.

HEALTH/CANCER: Provides for notification to patients concerning supplemental breast cancer screening and access by patients to mammography and ultrasound reports

1	AN ACT
2	To amend and reenact R.S. 40:1300.182 and 1300.183, and to enact R.S. 40:1300.182.1 and
3	1300.182.2, relative to breast cancer screening services; to provide relative to
4	screening mammograms and breast ultrasound examinations; to require healthcare
5	facilities to offer patients the option of receiving mammography and ultrasound
6	reports; to provide for notification concerning supplemental screening; to prescribe
7	language to be included in such notifications; to provide for limitation of liability;
8	to specify an effective date; and to provide for related matters.
9	Be it enacted by the Legislature of Louisiana:
10	Section 1. R.S. 40:1300.182 and 1300.183 are hereby amended and reenacted and
1	R.S. 40:1300.182.1 and 1300.182.2 are hereby enacted to read as follows:

1	§1300.182. Notification of results
2	A. Each patient shall be given the opportunity to name a physician to receive
3	the results of any screening mammogram performed pursuant to this Part without the
4	direction by prescription of a licensed practitioner.
5	B. The report of results mailed to the patient and to the named any physician
6	named pursuant to Subsection A of this Section shall clearly state whether the need
7	for any follow-up care is indicated by the mammogram.
8	§1300.182.1. Notice concerning supplemental screening
9	A. Upon completion of any screening mammogram, regardless of whether
10	the mammogram was directed by prescription of a licensed practitioner, each
11	mammography facility certified by the United States Food and Drug Administration
12	or by a certification agency approved by the United States Food and Drug
13	Administration shall mail to the patient, in addition to any letter or report required
14	by 21 CFR Part 900, the following notice in conspicuous and legible type which is
15	not smaller than twelve-point font:
16	"If your mammogram demonstrates that you have dense breast tissue, which
17	could hide abnormalities, and you have other risk factors for breast cancer that have
18	been identified, you might benefit from supplemental screening tests that may be
19	suggested by your ordering physician.
20	Dense breast tissue, in and of itself, is a relatively common condition.
21	Therefore, this information is not provided to cause undue concern, but rather to
22	raise your awareness and to promote discussion with your physician regarding the
23	presence of other risk factors, in addition to dense breast tissue.
24	A summary of your mammography results will be sent to you, and a full
25	mammography report will be sent to your physician and also to you, if you indicated
26	to the mammography provider that you requested the full report. You should contact
27	your physician if you have any questions or concerns regarding your summary or
28	report of results."

1	B. The notice provided for in this Section may be transmitted to the patient
2	by either regular mail or certified mail via the United States Postal Service, or by any
3	other commercial mail delivery service.
4	C. Notwithstanding any other law, compliance with this Section does not
5	create a cause of action or create a standard of care, obligation, or duty that provides
6	a basis for a cause of action.
7	§1300.182.2. Mammography and ultrasound reports; option for patients to obtain
8	A. Each mammography facility certified by the United States Food and Drug
9	Administration or by a certification agency approved by the United States Food and
10	Drug Administration and every healthcare facility that performs breast ultrasound
11	examinations shall establish and provide to each mammography and ultrasound
12	patient a form on which the patient may easily elect to receive either of the
13	following, as appropriate to the procedure performed:
14	(1) A copy of the patient's mammography report, as defined in 21 CFR
15	900.12(c), issued by the facility to the patient's referring physician.
16	(2) A copy of the patient's full narrative radiology report of ultrasound
17	findings.
18	B. The reports provided for in Subsection A of this Section may be
19	transmitted by any of the following methods:
20	(1) Regular mail via the United States Postal Service.
21	(2) Certified mail via the United States Postal Service.
22	(3) A commercial mail delivery service other than the United States Postal
23	Service.
24	C. In addition to facilitating provision of reports to patients in accordance
25	with Subsection A of this Section, a healthcare facility may provide such reports
26	electronically through an electronic patient portal that meets applicable standards
27	provided in federal law and regulation.

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§1300.183. Limitation of liability

2 A. Any liability or responsibility for any subsequent or follow-up care and 3 treatment of an individual who receives a screening mammogram pursuant to this 4 Part R.S. 40:1300.181 on the part of the performer of that screening mammogram or 5 any physician performing an assessment of a screening mammogram shall cease 6 upon delivery of the results or report of such screening mammogram to the screened 7 or tested individual and to any physician named by the patient to receive such results. 8 These results shall be sent by certified mail, return receipt requested, and shall 9 comply with the reporting requirements for mammography results in the federal 10 Mammography Quality Standards Act, 42 USC U.S.C. 263b, and any regulations 11 promulgated pursuant thereto, including 21 CFR 900.1 et seq.

B. The liability of a supervising licensed practitioner for follow-up of patients following a screening mammogram shall be limited to informing the patient and a designated physician in accordance with the guidelines issued under the Mammography Quality Standards Act, 42 USC U.S.C. 263b, and any regulations promulgated pursuant thereto, including 21 CFR 900.1 et seq.

Section 2.(A) The legislature hereby declares that early detection of breast cancer
saves lives, and that facilitating early detection of all forms of cancer is a public health
priority of this state.

20 (B) This Act shall be known as the "Monica Landry Helo Early Detection Act".

Section 3. The Louisiana State Law Institute is hereby authorized to redesignate the
number of any Section of statute enacted by this Act in a manner that comports with the
technical recodification provisions of House Concurrent Resolution No. 84 of this 2015
Regular Session of the Legislature.

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Section 4. This Act shall become effective on January 1, 2016.

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DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

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Abstract: Requires that a notification concerning supplemental breast cancer screening be transmitted to patients pursuant to screening mammograms, and that healthcare facilities offer to patients the reports of results of their mammograms and breast ultrasound examinations.

<u>Present law</u> relative to access to mammograms provides that any person who may legally perform a mammography in this state may perform a screening mammography without the direction to do so by prescription of a licensed practitioner. Provides for notification to patients of results of screening mammograms.

<u>Proposed law</u> retains <u>present law</u>, and adds thereto a requirement that, in addition to any letters or reports to patients pursuant to screening mammograms as may be required by federal law, the following notice be transmitted to all patients pursuant to such procedures, regardless of whether the procedure was directed by prescription or performed pursuant to self-referral:

"If your mammogram demonstrates that you have dense breast tissue, which could hide abnormalities, and you have other risk factors for breast cancer that have been identified, you might benefit from supplemental screening tests that may be suggested by your ordering physician.

Dense breast tissue, in and of itself, is a relatively common condition. Therefore, this information is not provided to cause undue concern, but rather to raise your awareness and to promote discussion with your physician regarding the presence of other risk factors, in addition to dense breast tissue.

A summary of your mammography results will be sent to you, and a full mammography report will be sent to your physician and also to you, if you indicated to the mammography provider that you requested the full report. You should contact your physician if you have any questions or concerns regarding your summary or report of results."

<u>Proposed law</u> provides that the notification concerning supplemental screening required by <u>proposed law</u> may be transmitted by either regular mail or certified mail via the U.S. Postal Service, or by any other commercial mail delivery service.

<u>Proposed law</u> provides that compliance with <u>proposed law</u> and <u>present law</u> does not create a cause of action or create a standard of care, obligation, or duty that provides a basis for a cause of action.

<u>Proposed law</u> requires each mammography facility and every healthcare facility that performs breast ultrasound examinations to establish and provide to each patient a form on which the patient may easily elect to receive either of the following:

- (1) A copy of the patient's mammography report issued by the facility to the patient's referring physician.
- (2) A copy of the patient's full narrative radiology report of ultrasound findings.

<u>Proposed law</u> provides that the mammography and ultrasound reports which patients may elect to receive pursuant to <u>proposed law</u> may be transmitted by either regular mail or certified mail via the U.S. Postal Service, or by any other commercial mail delivery service.

<u>Proposed law</u> provides that in addition to facilitating provision of mammography and ultrasound reports to patients in accordance with <u>proposed law</u>, healthcare facilities may provide such reports electronically through electronic patient portals that meet applicable federal standards.

<u>Proposed law</u> provides a legislative declaration indicating that early detection of breast cancer saves lives, and that facilitating early detection of all forms of cancer is a public health priority of this state.

Proposed law shall be known as the "Monica Landry Helo Early Detection Act".

Effective Jan. 1, 2016.

(Amends R.S. 40:1300.182 and 1300.183; Adds R.S. 40:1300.182.1 and 1300.182.2)

Summary of Amendments Adopted by House

The Committee Amendments Proposed by <u>House Committee on Health and Welfare to</u> the <u>original</u> bill:

- 1. Specify that the notification concerning supplemental screening required by <u>proposed law</u> shall be transmitted to patients pursuant to any screening mammogram or breast ultrasound examination, regardless of whether the procedure was directed by prescription or performed pursuant to self-referral by a patient.
- 2. Provide that the notification concerning supplemental screening required by <u>proposed law</u> may be transmitted by either regular mail or certified mail via the U.S. Postal Service, or by any other commercial mail delivery service.
- 3. Delete <u>proposed law</u> providing that the information concerning supplemental screening required by <u>proposed law</u> or evidence that a person violated the provisions of <u>proposed law</u> is not admissible in a civil, judicial, or administrative proceeding.
- 4. Make technical changes.

The House Floor Amendments to the engrossed bill:

- 1. Delete <u>proposed law</u> authorizing breast ultrasound examinations as procedures which may be performed without direction to do so by prescription of a licensed practitioner.
- 2. Delete the requirement that the notification concerning supplemental screening provided for in <u>proposed law</u> be transmitted to patients pursuant to breast ultrasound examinations.
- 3. Add the following language to the notification concerning supplemental screening provided for in proposed law:

"A summary of your mammography results will be sent to you, and a full mammography report will be sent to your physician and also to you, if you indicated to the mammography provider that you requested the full report. You should contact your physician if you have any questions or concerns regarding your summary or report of results."

4. Add a requirement that each mammography facility and every healthcare facility that performs breast ultrasound examinations establish and provide to each patient a form on which the patient may easily elect to receive either of the following:

(a) A copy of the patient's mammography report issued by the facility to the patient's referring physician.

(b) A copy of the patient's full narrative radiology report of ultrasound findings.

- 5. Provide that the mammography and ultrasound reports which patients may elect to receive pursuant to <u>proposed law</u> may be transmitted by either regular mail or certified mail via the U.S. Postal Service, or by any other commercial mail delivery service.
- 6. Provide that in addition to facilitating provision of mammography and ultrasound reports to patients in accordance with <u>proposed law</u>, healthcare facilities may provide such reports electronically through electronic patient portals that meet applicable federal standards.
- 7. Make technical changes.