

**Final Rule**

LSA Document #15-299(F)

**DIGEST**

Adds [844 IAC 16](#) to establish an education program to be used to educate women with high breast density and standards for providing an annual screening or diagnostic test for a woman who is at least 40 years of age and who has been determined to have high breast density. Effective 30 days after filing with the Publisher.

**[844 IAC 16](#)**

SECTION 1. [844 IAC 16](#) IS ADDED TO READ AS FOLLOWS:

**ARTICLE 16. HIGH BREAST DENSITY GUIDELINES**

**Rule 1. High Breast Density Guidelines**

**[844 IAC 16-1-1](#) Scope**

Authority: [IC 25-22.5-2-7](#)

Affected: [IC 25-22.5](#)

**Sec. 1. This rule establishes an education program to be used to educate women with high breast density and standards for providing an annual screening or diagnostic test for a woman who is at least forty (40) years of age and who has been determined to have high breast density.**

*(Medical Licensing Board of Indiana; [844 IAC 16-1-1](#); filed Sep 23, 2016, 9:04 a.m.: [20161019-IR-844150299FRA](#))*

**[844 IAC 16-1-2](#) Definitions**

Authority: [IC 25-22.5-2-7](#)

Affected: [IC 25-22.5-2-7](#); [IC 25-22.5-13.2](#)

**Sec. 2. (a) The definitions in this section apply throughout this rule.**

**(b) "Extremely dense" means the breast has a lot of fibrous and glandular tissue making it harder to find a cancer that may be present, as it can blend in with normal breast tissue.**

**(c) "Heterogeneously dense" means the breast has more areas of fibrous and glandular tissue that are found throughout the breast, making it difficult to see small masses.**

**(d) "High breast density" has the meaning set forth in [IC 25-22.5-2-7\(a\)\(11\)](#). Both extremely dense and heterogeneously dense breast tissues are breast tissues with high breast density.**

*(Medical Licensing Board of Indiana; [844 IAC 16-1-2](#); filed Sep 23, 2016, 9:04 a.m.: [20161019-IR-844150299FRA](#))*

**[844 IAC 16-1-3](#) Education program**

Authority: [IC 25-22.5-2-7](#)

Affected: [IC 25-22.5](#); [IC 25-22.5-13.2-1](#)

**Sec. 3. (a) The medical licensing board of Indiana shall maintain on its website informational resources on high breast density for use by the public for the purpose of educating women about high breast density.**

(b) If notification of high breast density was provided pursuant to [IC 25-22.5-13.2-1](#), then the physician interpreting the mammography report shall consult with the physician ordering the mammography examination and the patient to determine what follow-up care or testing is appropriate, in accordance with section 4 of this rule.

(Medical Licensing Board of Indiana; [844 IAC 16-1-3](#); filed Sep 23, 2016, 9:04 a.m.: [20161019-IR-844150299FRA](#))

#### [844 IAC 16-1-4](#) Screening and testing protocols

Authority: [IC 25-22.5-2-7](#)

Affected: [IC 25-22.5](#)

**Sec. 4. (a)** This section establishes protocols for the provision of annual screening or diagnostic testing for a woman who is at least forty (40) years of age and who has been determined to have high breast density.

(b) Follow-up care or testing may include, but is not limited to, the following:

- (1) Completion of a breast cancer risk assessment using a cancer risk assessment program or performed by a physician with experience in breast cancer risk model selection and interpretation.
- (2) Educating the patient about the risks, benefits, and costs of additional screening options using magnetic resonance imaging (MRI), ultrasound, tomosynthesis, or other screening modalities.
- (3) Any recommendations on follow-up care or testing for women over forty (40) years of age with high breast density recommended by:
  - (A) the American College of Radiology;
  - (B) the American Cancer Society;
  - (C) the American Medical Association;
  - (D) the American Society of Clinical Oncology;
  - (E) the United States Preventative Services Taskforce;
  - (F) the Society of Breast Imaging; or
  - (G) a like professional medical society.

(4) Any other actions that are clinically indicated as determined by the physician using the physician's professional judgment.

(c) Nothing in this section should be construed to replace routine mammogram screenings.

(d) Nothing in this section should be construed to mandate a particular course of follow-up care or testing.

(e) A physician shall not be required to proceed with any course of follow-up care or testing that may be harmful or not beneficial to the patient in the physician's professional judgment.

(Medical Licensing Board of Indiana; [844 IAC 16-1-4](#); filed Sep 23, 2016, 9:04 a.m.: [20161019-IR-844150299FRA](#))

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