Henda’s Law

Supplemental screening for women with dense breast tissue and increased risk

The 2011 Texas Legislature passed House Bill 2102 which is effective 1st September 2011. The law is informally known as Henda’s Law, named after Henda Salmeron, a Dallas realtor and breast cancer survivor who was instrumental in organizing the effort to draft and pass the law in Texas. It is based on a similar law passed three years earlier in Connecticut, and requires that mammography providers notify all women with dense breast tissue that the accuracy of their mammograms is less than that of women with lower breast density, and that they may benefit from “supplemental screening” in addition to the annual mammogram, particularly if they have additional risk factors for breast cancer. The mandated language for the notification reads:

“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 report of your mammography results will be sent to you and your physician. You should contact your physician if you have any questions or concerns regarding this report.”

For consistency, the American College of Radiology has 4 grades of breast composition to describe the breast density of all patients using the following patterns:

Grade 1: The breast is almost entirely fat (less than 25% glandular)

Grade 2: There are scattered fibroglandular densities (approximately 25% - 50% glandular)

Grade 3: The breast tissue is heterogeneously dense, which could obscure detection of small masses (approximately 51% - 75% glandular)

Grade 4: The breast tissue is extremely dense. This may lower the sensitivity of mammography (greater than 75% glandular)

For the purposed of this law, women with breast grades 3 or 4 are considered to have “dense breast tissue”.

The fact that dense breast tissue lowers the accuracy of the mammogram has been recognized for several decades, and supplemental screening of high-risk women with difficult mammograms has
been occasionally provided to some patients for many years. This practice, however, has never been formalized nor uniformly practiced by mammography facilities. For women with an average lifetime risk of breast cancer, undergoing supplemental screening is not considered the standard of care, even if they have dense breast tissue. It was Ms. Salmeron’s belief that women deserve to be directly informed if they have **dense breast tissue** and be given the opportunity to be proactive in their choices regarding the early detection of breast cancer. The law, having passed in Texas, requires us now to address the details of implementing the legislation in a responsible manner.

**Limitations of Mammography**

Contrary to popular notions, the majority of cancerous breast tumors are relatively slow-growing and detectable at an early stage in women who are undergoing a regular, annual mammogram – even in those with dense breast tissue. Some tumors, however, may simply be very small at the time of the mammogram or lacking in distinct characteristics, thereby allowing them to be obscured by overlying breast tissues. If these undetected tumors are fast-growing, they may well be detected on breast self-examination (BSE) or on a clinical breast exam (CBE) by your doctor before the next annual mammogram is due. If slow-growing, they may be detected on the mammogram a year or two later, but the opportunity for the earliest detection will have been lost.

**Supplemental Screening**

As stated earlier, limited supplemental screening of the breast has been practiced for many years. One of these methods is screening breast MRI, which is typically recommended in women who have tested positive for one of the “breast cancer genes” (BRCA-positive), regardless of their breast density. However, MRI may prove too expensive for screening women who present with dense breasts as their only elevated risk, and it has not been shown to be beneficial in randomized controlled trials in this group of patients.

More recently, a major study suggested that breast ultrasound can improve the detection of early breast cancer in women with **dense breast tissue**. Breast ultrasound was however shown to be effective, only when performed by an “experienced” physician or breast ultrasound technologist. Unfortunately, there are few radiologists or breast ultrasound technologists with the necessary experience to perform these sophisticated examinations accurately. The reality of offering highly accurate breast ultrasound to a large number of women may prove problematic for many mammography providers, thereby limiting patient’s access to the procedure.

Studies indicate that both breast ultrasound and MRI have a significant rate of “false-positive” examinations which may result in the need for a needle biopsy or other invasive procedures at substantial cost. False positives occur in mammography, as well, but the rate of false positives is dramatically reduced by the advanced training, focus, and exam volume of the radiologist interpreting the examination. False positives in both MRI and breast ultrasound are typically higher than for mammography, even when performed by experienced professionals. When performed and interpreted by inexperienced individuals the false positive rate is significantly higher. This is a critical consideration to remember when choosing a facility for your screening examinations.

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Emerging technologies like automated whole-breast ultrasound (ABUS), digital tomosynthesis and a number of nuclear medicine examinations offer intriguing possibilities, but it may be years before we can determine with certainty if they are effective and practical alternatives. In the absence of adequate scientific data, we will comply with this law using the proven screening tools available: breast ultrasound and MRI.

**Actions to Be Taken By Informed Women**

The mammography provider is responsible for educating women and physicians about the benefits and potential consequences of supplemental screening exams, but the decision to undergo supplemental screening must be a personal one between the woman and her physician. In making these choices, potential benefits and known risks must be carefully weighed. Additionally, an assessment of factors that may increase a woman’s personal risk of breast cancer should be considered, as women of higher risk will likely have a greater chance of benefitting from these tests.

Should a woman choose to undergo supplementary screening, we strongly urge that she seek care from an experienced dedicated breast imaging specialist. Many facilities, particularly facilities that do not focus on mammography, may feel compelled to provide these services even if they lack the needed experience and expertise to perform them accurately. As studies have shown with screening mammography, less focused, lower volume facilities have significantly higher false positives, leading to unnecessary biopsies and undue patient anguish.

Unfortunately, one should also anticipate that less scrupulous providers and diagnostic equipment vendors will attempt to capitalize on this law by offering questionable and unproven “dense breast” screening products and procedures.

The most important, pro-active effort the informed woman should make is the decision to get a **regular, annual screening mammogram**. The screening mammogram remains the best means of early detection for the majority of women, including the diagnosis of many cancers not easily detected by the supplemental screening procedures discussed. Even with the breast cancer awareness in the media today, the national compliance rate for screening mammography is less than 60% of eligible women.

**Does “dense breast tissue” alone equate to an increase risk of breast cancer?**

This has been a topic of considerable scientific discussion. There is some evidence that suggests the presence of “dense breast tissue” may, by itself, be an indicator of increased breast cancer risk. Unfortunately, the data is not definitive and is questioned by many in the scientific community. It will likely be some time before we can be certain what additional risk, if any, dense breast tissue alone may present. In the meantime, it will be our position that “dense breast tissue” may indeed be an important risk factor and we have designed our policies accordingly.

**Does breast density change?**

The simple answer is “yes”. Aging, hormonal changes, weight gain and loss and a number of other factors can result in a change in breast density over time. The assignment of a breast density
grade by the radiologist when your mammogram is interpreted is often a “subjective” determination and could change from year-to-year with little actual change in density. Don’t be confused or concerned if this happens. It actually suggests that you have “mid-density” breast tissue and your mammogram is not particularly difficult to accurately interpret.

Our Policy on Supplemental Screening

**Education:** It is an important element of our policy that all Solis patients and referring physicians be fully informed regarding the potential benefits and risks associated with supplemental screening in order to facilitate appropriate decision-making.

**Recommended guidelines:** All women who are eligible for screening mammography under the guidelines of the American Cancer Society (ACS), who have had a mammogram within the past 12 months and have a breast density grade of 3 or 4 (dense breast tissue), will be a candidate for supplementary screening regardless of any additional risk factors for breast cancer.

**Screening modalities:** Solis will provide breast ultrasound performed by experienced sonographers and/or breast radiologists as the primary supplemental screening modality. In some instances of exceptional risk, we may recommend MRI examinations alone or in conjunction with the breast ultrasound.

**Ordering requirements:** Any woman meeting the eligibility requirements above may schedule a breast ultrasound with an order from her doctor. It is likely that many insurance plans will cover the costs of a breast ultrasound for women with dense breast tissue, but unlike screening mammography, insurance coverage for this test will require an “order” from the woman’s doctor and will most likely be applied to an insurance deductible.

**Scheduling:** Breast ultrasounds for dense breast are scheduled at all Solis diagnostic centers in the Dallas-Fort Worth area. These procedures are performed by breast ultrasound technologists and/or breast radiologists in approximately 15-20 minutes. At this time, a patient will need an order from their referring physician for a breast ultrasound for dense breast. The ICD 9 code for this procedure is 793.82.

**Patients New to Solis:** Patients who may have had a mammogram at another facility, but are coming to Solis for a screening breast ultrasound will need to provide a copy of their last mammogram at the time-of-service.

**Additional Risk Factors for Breast Cancer**

The principal risk factors for breast cancer are gender and age. The fact that a patient is a woman and getting older are the major contributors to the “1 in 8” lifetime risk that most women share. Additionally, there are many minor risks conferred by behavioral or environmental factors. Below we have listed well-recognized and generally-accepted “additional risk factors” that you should consider in your decision-making with regard to screening mammography and supplemental screening tests:

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1. Inherited genetic mutations (positive for one of the BRCA cancer genes)
2. A personal history of breast cancer
3. An immediate family history of breast, ovarian or prostate cancer
4. Dense breast tissue
5. A history of previous breast biopsies, particularly if any biopsies showed precancerous disease
6. Early onset of menstrual periods (early menarche)
7. Late birth of first child or “nulliparity” (no children)
8. Long-term hormone replacement therapy

Additional risk factors and an excellent discussion surrounding these factors and their importance are available at the Solis Women’s Health website.

Solis Women’s Health provides breast imaging and diagnostic services with fellowship trained breast radiologists and registered breast ultrasound technologists who focus only on breast screening and diagnostic breast care. Clinical research clearly substantiates that, regardless of technology, interpretation is most accurate when the exams are interpreted by a breast fellowship trained radiologist, in a dedicated breast imaging center, interpreting a high volume of both screening and diagnostic exams (>5000 annually). In this model, false positives are significantly lower, and the detection of early stage cancers is greater.