

I MINA'TRENTAI SINGKO NA LIHESLATURAN GUÅHAN
2019 (FIRST) Regular Session

Bill No. 213-35(LS)

Introduced by:

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**AN ACT TO AMEND § 181003(b) OF ARTICLE 10,
CHAPTER 18, OF TITLE 22 GUAM CODE ANNOTATED
AND § 2208.1 OF ARTICLE 2, CHAPTER 2, TITLE 10,
GUAM CODE ANNOTATED RELATIVE TO BREAST
CANCER SCREENING USING DIGITAL BREAST
TOMOSYNTHESIS.**

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BE IT ENACTED BY THE PEOPLE OF GUAM:

Section 1. Legislative findings and intent. *I Liheslaturan Guåhan* finds that the *Food and Drug Administration* (FDA) approved digital breast tomosynthesis (DBT) as a breast cancer diagnostic modality in 2011 and as a screening modality in 2017. Since its adoption as a screening modality, healthcare providers that offer DBT have found it difficult to get insurance companies to pay for the mammograms. The apparent cause of this difficulty is that many insurance companies do not recognize DBT as a screening modality but as an “add-on diagnostic procedure” to a 2-D mammogram because of the lack of a standardized billing code for standalone DBT mammograms. Since the *Affordable Care Act* (ACA) mandate allows for a single mammogram each screening period, claims for the DBT as an add-on are determined to be diagnostic and denied coverage when performed with a screening exam. The health insurance benefits for mammograms

1 and other screening exams are part of the *Affordable Care Act's* Essential Benefits
2 and include preventive services. These screening exams are covered by compliant
3 health insurance policies without the subscriber having to pay copayments or meet
4 deductibles.

5 *I Liheslatura* further finds that the *American Society of Breast Surgeons*
6 (ASBrS), *breastcancer.org* and the *American College of Radiology* (ACR) have
7 concluded that digital breast tomosynthesis (DBT) is the preferred mode of
8 mammography screening for women in all risk categories. Since the FDA
9 approval as a diagnostic modality in 2011 and as a screening modality in 2017,
10 DBT or 3-D mammography is rapidly becoming the standard for breast cancer
11 diagnostics and screening.

12 An article in *breastcancer.org* published on March 18, 2019 stated:

13 *"The issue for women ages 40 to 49 is that with conventional 2D mammography*
14 *there are clearly too many false positives," said Emily Conant, M.D., chief of*
15 *breast imaging and professor of radiology at the University of Pennsylvania*
16 *Medical Center and member of the Breastcancer.org Professional Advisory Board.*
17 *"At the same time, we can't even find some of the cancers on 2D mammography.*
18 *Many of the false positives in this age group are because the mammogram is their*
19 *first, or 'baseline,' with no earlier mammograms to compare it to so the*
20 *radiologist can say, 'Oh, that is the way her breasts have always been — this is*
21 *just normal for her."*

22 The Article further notes that *"Conant was one of the authors of a 2016 study that*
23 *found the benefits of 3D mammograms last over time. "The findings reaffirmed*
24 *that 3D mammography is a better mammogram for breast cancer screening," she*
25 *said."*

26 The ASBrS guidelines recommend (published May 10, 2019 on
27 *breastcancer.org*):

- 1 • All women should have a formal breast cancer risk assessment done by their
2 doctors between age 25 and 30. This assessment should be updated at
3 regular intervals.
- 4 • All women should have screening with 3D mammograms (also called digital
5 breast tomosynthesis, digital tomosynthesis, or just tomosynthesis), which
6 create a 3D picture of the breast using X-rays. Several low-dose images from
7 different angles around the breast are used to create the 3D picture.
- 8 • Women at average risk of breast cancer should receive annual screening
9 mammograms starting at age 40. Women at average risk with dense breasts
10 should consider supplemental imaging.
- 11 • Women with a higher-than-average risk of breast cancer because of a known
12 genetic mutation or radiation to the chest wall earlier in life should receive
13 an annual screening MRI starting at age 25 and annual screening
14 mammograms starting at age 30.
- 15 • Women with a higher-than-average risk of breast cancer because of a strong
16 family history of breast cancer or who have a lifetime risk of breast cancer
17 that is greater than 20% as calculated by a standard risk model should
18 receive an annual screening mammogram starting at age 35 and
19 supplemental imaging as recommended by their doctors.
- 20 • Women age 50 or older with a history of breast cancer who have non-dense
21 breasts should have a mammogram every year.
- 22 • Women younger than 50 with a history of breast cancer, or who have dense
23 breasts, should have a mammogram every year and supplemental imaging as
24 recommended by their doctors.
- 25 • Women should continue having annual mammograms until their life
26 expectancy is less than 10 years.

1 The ACR, which is approved by the FDA to accredit labs and clinics to use
2 DBT, recognizes the following advantages of DBT over full-field digital
3 mammography (FFDM or 2D):

- 4 • Imaging of the breast allows detection of small tumors. When cancers are
5 small, the woman has more treatment options.
- 6 • The use of screening mammography increases the detection of small
7 abnormal tissue growths confined to the milk ducts in the breast, called
8 ductal carcinoma in situ (DCIS). These early tumors rarely harm patients if
9 they are removed at this stage and mammography is an excellent way to
10 detect these tumors. It is also useful for detecting all types of breast cancer,
11 including invasive ductal and invasive lobular cancer.
- 12 • No radiation remains in a patient's body after an x-ray examination.
- 13 • X-rays usually have no side effects in the typical diagnostic range for this
14 exam.
- 15 • Large population studies have shown that screening with breast
16 tomosynthesis results in improved breast cancer detection rates and fewer
17 "call-backs," instances where women are called back from screening for
18 additional testing because of a potentially abnormal finding.
- 19 • Breast tomosynthesis may also result in:
 - 20 ○ earlier detection of small breast cancers that may be hidden on a
 - 21 conventional mammogram
 - 22 ○ greater accuracy in pinpointing the size, shape and location of breast
 - 23 abnormalities
 - 24 ○ fewer unnecessary biopsies or additional tests
 - 25 ○ greater likelihood of detecting multiple breast tumors
 - 26 ○ clearer images of abnormalities within dense breast tissue

1 *I Liheslatura* further finds that patients are allowed, by federal law, to self-
2 refer themselves for screening mammography. Self-referred patients are not
3 required to have a primary or attending physician. Federal law mandates coverage
4 for self-referred patients as part of the effort to maximally reduce the barriers some
5 women face getting access to screening mammograms -- including FFDM and
6 DBT. Patients often arrive at mammography lab or clinic with a referral that does
7 not specify the type of mammogram they want to be completed. The choice to use
8 or not to use DBT is then left to the radiologist to decide. Many primary care
9 providers prefer that a breast radiologist make that determination.

10 *I Liheslatura* further finds that DBT mammograms costs about \$50 per
11 screening more than traditional 2D mammograms. But since callbacks with 2D
12 mammograms are about 15% and DBT reduces callbacks by 90%, the increased
13 cost is nearly negated. The national trend is to gradually replace FFDM with DBT
14 as the standard breast cancer screening modality for women of average risk.

15 *I Liheslatura* further finds that by enacting PL 31-243 in December of 2012,
16 recognized the advantages of 2-D mammography over film mammography for
17 breast cancer screening of women with dense breasts and required that women
18 diagnosed with dense breast be given a notice advising them of the advantages of
19 that screening modality. Since the enactment of PL 31-243, all mammogram
20 providers have switched from film technology and computed tomography to
21 FFDM.

22 It is the intent of *I Liheslatura* to clarify the provision of PL 34-109
23 regarding breast screening requirements to include DBT as a stand-alone screening
24 modality that is covered without subscriber copayments or deductibles and to
25 update the notice requirements enacted by PL 31-243.

1 **Section 2** §181003(b) of Article 10, Chapter 18, Title 22, Guam Code Annotated is
2 *amended* to read:

3 “(b) The term, “low-dose mammography” means the x-ray examination of the
4 breast using equipment dedicated specifically for mammography, including, but
5 not limited to, ~~the x-ray tube, filter, compression device, screens, films, and~~
6 ~~cassettes, with an average radiation exposure delivery of less than one (1) rad mid-~~
7 ~~breast, with two (2) views for each breast, or by~~ digital breast tomosynthesis
8 (DBT); or full-field digital mammography (FFDM). The choice to use FFDM or
9 DBT is to be determined by an attending, primary or referring physician; a
10 radiologist or an attending or referring advanced practice registered nurse or
11 physician’s assistant.

12 (1) Digital breast tomosynthesis (DBT) is a form of breast imaging, or
13 mammography, that uses a low-dose x-ray system and computer reconstructions to
14 create three-dimensional (3-D) images of the breasts. Notwithstanding any other
15 provision of law, health insurance, Medicaid and Medically Indigent Program shall
16 create a billing code for DBT as a stand-alone screening procedure in the event
17 that no Current Procedural Terminology (CPT) or Healthcare Common Procedure
18 Coding System (HCPCS) or other standard billing codes exists. No person who is
19 eligible for breast cancer screening herein, shall be denied coverage for DBT, as a
20 breast cancer screening modality, based on the lack of a stand-alone screening
21 billing code.

22 (2) Full-field digital mammography (FFDM) is a mammography system in which
23 the x-ray film is replaced by electronics that convert x-rays into mammographic
24 pictures (two-dimensional (2-D) of the breast.”

25
26 **Section 3** § 2208.1 of Article 2, Chapter 2, Title 10, Guam Code Annotated is
27 *amended* to read:

1 **“§ 2208.1. Dense Breast Screening Notice to Patients.**

2 If a mammography examination reveals a patient is categorized as having
3 heterogeneously dense breasts or extremely dense breasts, based on the Breast
4 Imaging Reporting and Data System established by the American College of
5 Radiology, the health facility shall include in the summary of the written report
6 that is sent to the patient, as required by federal law, the following notice:

7 “Your mammogram shows that your breast tissue is dense. Dense breast tissue is
8 common and is not abnormal. However, dense breast tissue can make it harder to
9 evaluate the results of your mammogram and may also be associated with an
10 increased risk of breast cancer. Your exam was completed using a film-based
11 system or full field digital mammography (two-dimensional 2-D mammography).
12 You are advised to consider digital breast tomosynthesis (three dimensional 3-D
13 digital mammography) as it has been shown to be more effective for the detection
14 of breast cancer in women with dense breasts when compared to mammography
15 using a film-based system or full field digital mammography (two-dimensional 2-
16 D mammography). This information about the results of your mammogram is
17 given to you to raise your awareness and should be discussed with your health care
18 provider. Together, you can decide which screening options are right for you. A
19 report of your results was sent to your physician.””