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OFFICE OF THE DIRECTOR
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS**

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Testimony of the Department of Commerce and Consumer Affairs

**Before the
House Committee on Health
Tuesday, January 29, 2019
8:30 a.m.
State Capitol, Conference Room 329**

**On the following measure:
H.B. 481, RELATING TO INSURANCE**

Chair Mizuno and Members of the Committee:

My name is Colin Hayashida, and I am the Insurance Commissioner for the Department of Commerce and Consumer Affairs' (Department) Insurance Division. The Department offers comments on this bill.

The purpose of this bill is to clarify that the existing health insurance mandate for coverage of low-dose mammography includes coverage for digital mammography and breast tomosynthesis.

This bill purports to mandate digital mammography and breast tomosynthesis, and this may be viewed as a new mandate. The addition of new mandated coverage may trigger section 1311(d)(3) of the federal Patient Protection and Affordable Care Act (PPACA), which requires states to defray the additional cost of any benefits in excess of the essential health benefits of the State's qualified health plan under the PPACA.

Testimony of DCCA

H.B. 481

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Additionally, any proposed mandate providing coverage for care requires the passage of a concurrent resolution requesting the State Auditor to prepare and submit a report assessing the social and financial impacts of the proposed mandate, pursuant to Hawaii Revised Statutes section 23-51.

Thank you for the opportunity to testify on this bill.



HAWAII RADIOLOGICAL SOCIETY
Chapter of the American College of Radiology

LETTER OF SUPPORT

January 26, 2019

To the Honorable John M. Mizuno, the Honorable Bertrand Kobayashi and members of the HLT Committee:

WITH REGARD TO **HB 481** which clarifies that the existing health insurance mandate for coverage of low-dose mammography includes coverage for digital mammography and breast tomosynthesis,

the Hawaii Radiological Society (HRS) supports this measure.

A woman in the United States has a one in eight risk, over the course of her lifetime, of being diagnosed with breast cancer. We are sure that the HLT Committee understands the importance of screening to detect breast cancer in women, beginning at age 40.

3D mammography, or digital breast tomosynthesis (DBT), acquires a volumetric picture of the breast such that the Radiologist can scroll through the breast tissue in very thin slices. Because of this technique, the Radiologist can better “see through” dense breast tissue, allowing for detection of at least 2-3 additional cancers per 1000 women screened, and more importantly, recall about 30-50% fewer women for additional imaging from screening for a possible abnormality.

Several studies have shown significant financial savings to the healthcare system when tomosynthesis is incorporated into routine screening, with a recent model showing savings of over \$207,000 per year for a typical state Medicaid plan¹. As of 2015, Medicare and Medicaid have covered the cost of tomosynthesis. Despite the advantages of increased cancer detection, lower recall rates from screening, and cost savings, it is not universally covered by private insurers. Currently this imaging modality is offered only at a limited number of imaging centers here in Hawaii. In the best interest of our patients, many Hawaii radiology practices have opted to provide the service recognizing that they will likely not get paid; however, this is not sustainable financially nor is it appropriate that patients be denied these proven benefits.

On behalf of Hawaii Radiology physicians and our patients, we ask you to pass this bill, and allow **all** women in Hawaii to gain access to the best care by mandating insurance coverage of breast cancer screening to include Digital Breast Tomosynthesis.

Please contact us with any concerns or questions.
Mahalo for your thoughtful consideration of these issues.

With Warmest Aloha,

Elizabeth Ann Ignacio MD
President, Hawaii Radiological Society
808.250.7058

¹ Miller JD et al, Value analysis of digital breast tomosynthesis for breast cancer screening in a U.S. Medicaid Population. JACR 2017;14:467-474.

January 28, 2019

Dear Chair and members of the Committee,

The American College of Radiology appreciates the opportunity to provide testimony for coverage of digital breast tomosynthesis (DBT). Coverage is already provided for full-field digital mammography (FFDM), based on its ability to improve interpretive performance compared with standard film-screen mammography.¹ The evidence described and cited below documents that DBT shows an even greater improvement in cancer detection than that found for FFDM, with the additional benefit of reducing the frequency of false-positive examinations.

Conventional mammography (either film-screen or FFDM) produces planar images, in which overlapping tissue can result both in unnecessary recalls from screening mammograms (false positive studies) and in missed cancers (false negative studies). Approximately 10%-20% of the cases in which a woman must be recalled from screening mammography are due to superimposed normal tissue simulating a lesion.² This additional imaging causes patient anxiety, inconvenience, and increased cost. In addition, overlying tissue can obscure cancers, with as many as 20%-30% of cancers being missed by conventional planar mammography^{3,4}.

The latest advancement in mammography – digital breast tomosynthesis (DBT) – helps address the problem of overlapping tissues in planar FFDM and reduces interpretation inaccuracy. DBT is a mammography-based system that acquires low-dose images of the breast at multiple angles during a short scan time. The individual images are then reconstructed into a series of thin, high-resolution slices. This provides a clearer depiction of the internal architecture of the breast, making underlying breast cancers more easily perceptible and facilitating confirmation that superimposed normal glandular tissue does not represent an abnormality. Conventional, planar mammographic images are still necessary to demonstrate the anatomic distribution of findings and to characterize calcifications. Furthermore, DBT cannot produce magnification images, still useful for some mammographically-detected lesions in determining which do and do not require biopsy.

DBT was approved by the U.S. Food & Drug Administration (FDA) on February 11, 2011 for the same indications as planar FFDM. This includes breast cancer screening, diagnosis, and intervention. On August 26, 2014, a second vendor received FDA approval for DBT. Other vendors are expected to apply for approval. Since receiving FDA approval, there have been numerous published studies demonstrating the clinical benefits of DBT. These studies consistently report substantial decreases in the recall rate from screening (reduced false positives) and substantial increases in the cancer detection rate (increased true positives).

The first prospective screening trial to compare DBT to planar FFDM was published by Skaane et al⁵. Researchers compared FFDM+DBT to FFDM alone, in **12,631 screening examinations**. Skaane's study demonstrated increased sensitivity in the detection of breast cancer without compromising specificity or increasing the rate of false positive results. In an interim analysis, they found that the addition of DBT resulted in a:

- **40% statistically significant increase in the detection of invasive breast cancers.**
- **27% statistically significant increase in the detection of all cancers** (invasive and in situ cancers combined)
- **15% statistically significant decrease in false-positive rates.**

¹ Pisano, ED et al. Diagnostic Performance of Digital versus Film Mammography for Breast-Cancer Screening. N Engl J Med 2005 353: 1773-1783.

² Rosenberg RD, Yankaskas BC, Abraham LA, Sickles EA, Lehman CD, Geller BM, Carney PA, Kerlikowske K, Buist DS, Weaver DL, Barlow WE, Ballard-Barbash R. Performance benchmarks for screening mammography. Radiology. 2006 Oct;241(1):55-66. Erratum in: Radiology. 2014 May;271(2):620.

³ Schell MJ et al. Evidence-based target recall rates for screening mammography. Radiology, June 2007; 243: 681-689.

⁴ Holland R, Mravunac M, Hendriks JH, Bekker BV. So-called interval cancers of the breast: pathologic and radiologic analysis of sixty-four cases. Cancer 1982;49(12):2527-2533.

⁵ Skaane P, Bandos AI, Gullien R, et al. Comparison of Digital Mammography Alone and Digital Mammography Plus Tomosynthesis in a Population-based Screening Program. Radiology 2013, Apr; 267(1): 47-56.

HEADQUARTERS

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The Screening with Tomosynthesis Or Routine Mammography (STORM) trial⁶ was a prospective comparative study of **7292 women** from two institutions. The **cancer detection rate was 51% higher** for FFDM+DBT than FFDM alone, while FFDM+DBT was also associated with a **17% statistically significant reduction in false positive recalls**.

Haas et al.,⁷ in a study of **6100 women** receiving FFDM+DBT, reported a **30% statistically significant reduction in recall rate with DBT screening**. Rose et al.,⁸ in a study of **9499 women** receiving FFDM+DBT, reported a **53% increase in the detection of invasive cancers** and a statistically significant increase in the positive predictive value for screening recalls (PPV₁) with FFDM+DBT compared to FFDM alone.

The largest study to date, by Friedewald et al, was published in 2014 in the Journal of the American Medical Association.⁹ This multi-center trial compared 281,187 conventional mammograms to **173,663 DBT exams**. The study reported the following findings:

- A **41% statistically significant increase** in the **detection** of invasive breast cancers.
- A **29% statistically significant increase** in the **detection** of all breast cancers.
- A **15% statistically significant decrease** in women **recalled** for additional imaging.
- A **49% statistically significant increase** in **positive predictive value for recall (PPV₁)**.
- A **21% statistically significant increase** in **positive predictive value for biopsy (PPV₃)**.

Given the above information, CMS decided to add additional reimbursement for Medicare patients receiving DBT, beginning in January of 2015.

In conclusion, the American College of Radiology affirms that:

- DBT addresses a primary limitation of planar FFDM in the detection of breast cancer.
- DBT is not investigational. The term investigational implies that studies have not been performed demonstrating improved performance compared with FFDM. Numerous large-scale studies of DBT already have demonstrated this benefit.
- Demonstrated benefits of DBT, compared to FFDM alone, include significant increase in detection of invasive breast cancer and significant reduction in unnecessary recall from screening mammography. Additional benefits include decreased patient anxiety and inconvenience.
- DBT leads to improved detection of early breast cancer. Smaller cancers require fewer and/or less invasive surgical procedures, less frequent and less toxic chemotherapy, and more frequent use of breast preservation surgery, all of which can result in improved patient outcomes.

Therefore, the American College of Radiology **recommends** coverage of digital breast tomosynthesis as a medically necessary screening and diagnostic mammography service. Thank you for your consideration and please feel free to contact us if you have any questions or require any additional information.

Respectfully,



Kelly W. Biggs, MD
Chair, Government Relations Committee of ACR's Breast Imaging Commission

⁶ Ciatto S, Houssami N, Bernardi D, Caumo F, Pellegrini M, Brunelli S, Tuttobene P, Bricolo P, Fantò C, Valentini M, Montemezzi S, Macaskill P. Integration of 3D digital mammography with tomosynthesis for population breast-cancer screening (STORM): a prospective comparison study. *Lancet Oncol.* 2013 Jun;14(7):583-9.

⁷ Haas BM, Kaira V, Geisel J, Raghy M, Durand M, Philpotts LE. Comparison of tomosynthesis plus digital mammography and digital mammography alone for breast cancer screening. *Radiology* 2013; 269:694-700

⁸ Rose SL, Tidwell AL, Bujnoch LJ, Kushwaha AC, Nordmann AS, Sexton R. Implementation of breast tomosynthesis in a routine screening practice: an observational study. *AJR* 2013; 200:1401-1408

⁹ Friedewald S M, Rafferty E A, Rose S L, Durand M A, Plecha D M, Greenberg J S, Hayes M K, Copit D S, Carlson K L, Cink T M, Barke L D, Greer L N, Miller D P, Conant E F Breast Cancer Screening Using Tomosynthesis in Combination with Digital Mammography, *JAMA.* 2014;311(24):2499-2507



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To:

HOUSE COMMITTEE ON HEALTH

Rep. John Mizuno, Chair

Rep. Bertrand Kobayashi, Vice Chair

Date: January 29, 2019

Time: 8:30 a.m.

Place: Room 329

From: Hawaii Medical Association

Jerry Van Meter, MD, President

Christopher Flanders, DO, Executive Director

Re: HB 481 – Relating to Insurance

Position: SUPPORT

On behalf of Hawaii's physician and student members, the HMA strongly supports HB 481 requiring coverage by insurers of digital breast tomosynthesis (DBT).

Use of 3-D imaging through DBT improves both sensitivity and specificity in screening for breast cancers, particularly in women with dense breast tissue. This is especially important for Hawaii, in that dense breast tissue is more common in those of Asian descent, of which comprise the majority of Hawaii's females. DTB permits better recognition of malignant and pre-malignant lesions, as well as fewer false positive interpretations, leading to potentially fewer unnecessary breast biopsies.

As an evolution of traditional mammography, it is the belief of the HMA that the original intent of the legislature to require coverage was not limited to a specific study technique, but rather to a commitment for women's health in making state-of-the-art breast cancer screening available to all women. As such, a mandate for DTB is appropriate.

Thank you for allowing testimony on this issue.

HMA OFFICERS

President – Jerry Van Meter, MD President-Elect – Michael Champion, MD Secretary – Thomas Kosasa, MD

Immediate Past President – William Wong, Jr., MD Treasurer – Elizabeth A. Ignacio, MD

Executive Director – Christopher Flanders, DO

January 27, 2019

Dear Dr. Sir or Madam,

I respectfully request that Hawaii Medical Services Association(HMSA) provide benefit coverage of digital breast tomosynthesis (DBT). The rationale behind this request is that coverage is already provided for full-field digital mammography (FFDM), based on its ability to improve interpretive performance compared with standard film-screen mammography. Digital breast tomosynthesis shows an even greater improvement in cancer detection than that found for FFDM, with the additional benefit of reducing the frequency of false-positive examinations.

Conventional mammography (either film-screen or FFDM) produces planar images, in which overlapping tissue can result both in unnecessary recalls from screening mammograms (false positive studies) and in missed cancers (false negative studies). The latest advancement in mammography – digital breast tomosynthesis (DBT) – helps address the problem of overlapping tissues and dense breasts in conventional mammography and reduces interpretation inaccuracy. DBT is a mammography-based system that acquires low-dose images of the breast similar to a CT scan. The individual images are then reconstructed into a series of thin, high-resolution slices. This provides a clearer depiction of the internal architecture of the breast, making underlying breast cancers more easily perceptible and facilitating confirmation that superimposed normal glandular tissue does not represent an abnormality.

DBT was approved by the U.S. Food & Drug Administration (FDA) on February 11, 2011 for the same indications as planar FFDM. This includes breast cancer screening, diagnosis, and intervention.

Thank you for considering this bill which will especially help the women of Hawaii who have a higher incidence of dense breasts.

David W. Camacho, Jr., MD

HB-481

Submitted on: 1/28/2019 7:49:54 AM

Testimony for HLT on 1/29/2019 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Erin Capps	Individual	Support	No

Comments:

With conventional mammography, overlapping tissue can result both in unnecessary recalls from screening mammograms (false positive studies) and in missed cancers (false negative studies). Approximately 10%-20% of the cases in which a woman must be recalled from screening mammography are due to superimposed normal tissue simulating a lesion. This additional imaging causes patient anxiety, inconvenience, and increased cost. In addition, overlying tissue can obscure cancers, with as many as 20%-30% of cancers being missed by conventional planar mammography.

Digital breast tomosynthesis (DBT) helps to address the problem of overlapping tissues and reduces interpretation inaccuracy.

Since receiving FDA approval in 2011, there have been numerous published studies demonstrating the clinical benefits of DBT. These studies consistently report substantial decreases in the recall rate from screening (reduced false positives) and substantial increases in the cancer detection rate (increased true positives):

- 40% statistically significant increase in the detection of invasive breast cancers.
- 25-30% statistically significant increase in the detection of all cancers (invasive and in situ cancers combined)
- 15% statistically significant decrease in false-positive rates.

DBT is not investigational. Numerous large-scale studies of DBT already have demonstrated this benefit.

The American College of Radiology has developed Appropriateness Guidelines which are evidence-based imaging guidelines that follow Protecting Access to Medicare Act development requirements and robust methodology that includes thorough literature search and strength-of-evidence, expert authorship, and multilevel committee review. The ACR Appropriateness Guidelines for breast cancer screening outline that for average-risk women, mammography and DBT receive the highest rating and recommend that screening commence at age 40.

DBT leads to improved detection of early breast cancer. Smaller cancers require fewer and/or less invasive surgical procedures, less frequent and less toxic chemotherapy,

and more frequent use of breast preservation surgery, all of which can result in improved patient outcomes.

As a breast imager, I have personally seen the advantages of breast tomosynthesis and its impact on patients' lives. It is not uncommon for a small invasive cancer to be detected on DBT only, meaning that it would have been missed on standard 2D mammography. This earlier detection allows for less invasive treatment and improved chance for cure. The added accuracy and confidence provided by DBT allows for fewer false positives and fewer recalls; this has a significant impact on patients. When a woman is recalled for additional imaging, there is significant anxiety and stress during the time between screening and the diagnostic exam. DBT should be the standard of care for breast cancer screening and coverage for this technology should be available for all women.

Therefore, I am in support of coverage of digital breast tomosynthesis as a medically necessary screening and diagnostic mammography service.

Sincerely,

Erin Capps MD

HB-481

Submitted on: 1/28/2019 8:30:11 AM

Testimony for HLT on 1/29/2019 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Laeton J Pang	Individual	Support	No

Comments:

NCI research documents the denser breast tissue of Asian women on mammography, which limits the sensitivity of mammography. Asian women also tend to have an earlier onset of breast cancer, and cancers in young women are often more aggressive than older women. (<https://dceg.cancer.gov/research/cancer-types/breast-cancer/breast-asian-women>).

Hawaii has the highest percentage of Asian women, and therefore the larger percentage of women with mammographically dense breasts. Our patients in Hawaii would benefit more from tomosynthesis, than any other state, and yet our state has amongst the worse coverage of tomosynthesis of any state in the U.S. Many other states already have similar mandates that have been passed.

I am writing in support of HB 481 - RELATING TO INSURANCE - Clarifies that the existing health insurance mandate for coverage of low-dose mammography includes coverage for digital mammography and breast tomosynthesis - a bill scheduled for hearing with the House HLT Committee Tuesday Jan 29, 2019 8:30am.

As a actively practicing radiation oncologist, I have seen many women with breast cancers not detected earlier due to the density of their breasts. Increased breast density is also associated with a higher risk of developing breast cancer. Early detection saves lives.

I've attached a letter from the American College of Radiology in support of insurance carriers covering Tomosynthesis.

Please feel free to reach out to me if you have any questions.

Thank you,

Laeton J Pang, MD, MPH, FACR, FACRO
Operations Medical Director
Cancer Center of Hawaii
2226 Liliha Street, B2 Level
Honolulu, Hawaii 96817
Phone: (808) 547-6881

Facsimile: (808) 547-6583

HB-481

Submitted on: 1/28/2019 10:18:12 AM

Testimony for HLT on 1/29/2019 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Dr. Lana Wilkinson	Maui Medical Group	Support	No

Comments:

As a radiologist and woman who receives mammograms, on behalf of all women in Hawaii, I support mandated coverage of tomosynthesis by all insurance companies. It is standard of care. Hawaii is far behind the remainder of America and innumerable other countries.

LATE

HB-481

Submitted on: 1/28/2019 4:21:06 PM

Testimony for HLT on 1/29/2019 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Melodie Aduja	Oahu County Committee on Legislative Priorities of the Democratic Party of Hawai'i	Support	No

Comments:

LATE

HB-481

Submitted on: 1/28/2019 4:35:08 PM

Testimony for HLT on 1/29/2019 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Ann S Freed	Individual	Support	No

Comments:

Aloha Chair Mizuno, Vice Chair and members,

The Hawaii Women's Coalition supports this Women's Legislative Caucus Bill,

Mahalo, Ann S. Freed, Co-Chair Hawaii Women's Coalition.

LATE

HB-481

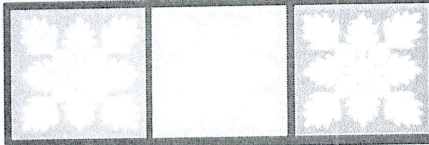
Submitted on: 1/29/2019 9:48:16 AM

Testimony for HLT on 1/29/2019 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Malia Espinda	Individual	Support	No

Comments:

My name is Malia Espinda. I am a breast cancer survivor. HB481 is a positive next-step in the early identification of breast cancer for some women. However, for many women with dense breasts, like myself, a breast ultra sounda may in fact be the life-saving scan that allows physicians to identify cancerous tumors. I encourage the Committee to consider expanding HB481 to ensure the availability of an annual breast ultra sound for those women identified with dense breasts.



January 28, 2019

LATE TESTIMONY

House Committee on Health
The Honorable John M. Mizuno, Chair
The Honorable Bertrand Kobayashi, Vice Chair

LATE

House Bill 481 – Relating to Insurance

Dear Chair Mizuno, Vice Chair Kobayashi, and Members of the Committee:

The Hawaii Association of Health Plans (HAHP) appreciates the opportunity to testify on HB 481 which clarifies that the existing health insurance mandate for coverage of low-dose mammography includes coverage for digital mammography and breast tomosynthesis.

HAHP supports early detection and provides coverage for screenings to our members. We follow evidence based guidelines to ensure our members receive care that is safe and efficacious.

We express concerns on this new mandate as it does not follow widely accepted medical guidelines. Also as this would be a new mandated benefit, it is subject to an impact assessment report by the Auditor pursuant to Sections 23-51 and 23-52 of the Hawaii Revised Statutes.

Thank you for allowing us to express concerns on HB 481.

Sincerely,

HAHP Public Policy Committee