

Craig P. Tanio, M.D.  
CHAIR

STATE OF MARYLAND

Ben Steffen  
EXECUTIVE DIRECTOR



## MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215  
TELEPHONE: 410-764-3460 FAX: 410-358-1236

January 10, 2017

The Honorable Larry Hogan  
Governor  
State of Maryland  
Annapolis MD 21401-1991

The Honorable Thomas V. Mike Miller, Jr.  
President of the Senate  
H-107 State House  
Annapolis MD 21401-1991

The Honorable Michael E. Busch  
Speaker of the House  
H-101 State House  
Annapolis MD 21401-1991

Dear Governor Hogan, President Miller, and Speaker Busch:

Pursuant to Insurance Article § 15-1501, Annotated Code of Maryland, the Maryland Health Care Commission is pleased to submit this year's annual mandated health insurance services evaluation on **Coverage for Digital Tomosynthesis**, (commonly referred to as 3D mammography).

The Commission contracted with NovaRest, Inc. an actuarial consulting firm, to conduct the fiscal impact of this proposed mandate (HB 1006) that failed to pass during the 2016 legislative session. NovaRest indicates in the enclosed report that the mandate would not have a material impact on the total cost of health care in Maryland. However, the Commission strongly urges the Legislature to proceed with caution when considering the adoption of additional mandated health insurance services given their cumulative deleterious impact on affordability over time despite a minimal impact on premiums at the time of adoption.

The Commission also believes it is important to note the following with regard to this proposed mandate on digital tomosynthesis:

- As noted in the report, the U.S. Preventive Services Task Force (USPSTF) found that the evidence is inconclusive to assess the benefits and harms of digital breast tomosynthesis as a primary screening method for breast cancer. That said, the Commission urges the Legislature not to get ahead of the USPSTF recommendations when considering such a mandate in the future.

- The added administrative burden on carriers should be taken into consideration with regard to such a mandate where cost sharing requirements can be applied but deductibles cannot.
- HB 1006 did not address the potential for racial and/or ethnic disparities in coverage for these services and therefore the consultant did not assess that issue in the report. The Commission believes that racial and ethnic data should be collected and analyzed in the context of coverage for digital tomosynthesis before any similar legislation is considered.

Please do not hesitate to contact me at 410-764-3565, if you have any questions.

Sincerely,



Ben Steffen  
Executive Director

cc: The Honorable Mac Middleton, Chair, Senate Finance Committee  
The Honorable Shane Pendergrass, Chair, House Health and Government Operations Committee  
Delegate Sheree Sample-Hughes  
Senator James Mathias  
Linda Stahr  
Sarah Albert (5)

Enclosure



**December 15, 2016**

**Annual Mandate Report:  
Coverage for Digital Tomosynthesis**

Prepared for the Maryland Health Care Commission  
Pursuant to Insurance Article 15-1501  
Annotated Code of Maryland

Donna Novak, FCA, ASA MAAA  
Karen Bender, FCA, ASA, MAAA





NovaRest  
ACTUARIAL CONSULTING



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## ***Evaluation of Proposed Mandated Health Insurance Services***

Insurance Article § 15-1501, Annotated Code of Maryland, requires that the Maryland Health Care Commission (MHCC) annually assess the impact of proposed mandated health insurance services that failed to pass during the preceding legislative session or that were submitted to MHCC by a legislator by July 1 of each year. The assessment reports are due to the General Assembly annually by December 31.

NovaRest, Inc. and its subcontractors, (collectively called “NovaRest” in this report) have been contracted as the MHCC’s consulting actuary, and have prepared the following evaluation: coverage for digital tomosynthesis (sometimes called 3-D mammograms).

This report includes information from several sources to provide more than one perspective on the proposed mandates with the intention of providing a totally unbiased report. As a result, there may be some conflicting information within the contents. Although we only used sources that we considered credible, we do not offer any opinions regarding whether one source is more credible than another, leaving it to the reader to develop his/her own conclusions.

The Affordable Care Act (ACA) describes a broad set of benefits that must be included in any essential health benefits (EHB) package. In its December 2011 bulletin, the Department of Health and Human Services (HHS) provided guidance on the types of health benefits plans each state could consider when determining a benchmark EHB plan for its residents. Each state had the opportunity to update its benchmark plan effective for 2017. Maryland has chosen the small group CareFirst BlueChoice HMO HSA-HRA \$1,500 plan as its 2017 benchmark plan.<sup>1</sup> It is important to note that ACA requires states to fund the cost of any mandates that are not included in the state-specific EHBs for policies purchased through the Health Exchange Market.<sup>2</sup>

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<sup>1</sup> Center for Consumer Information & Insurance Oversight. “List of Proposed Essential Health Benefit Benchmark Plans for 2017 and Beyond.” <https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/Final-List-of-Proposed-BMP.pdf>. Accessed November 6, 2016.

<sup>2</sup> In Maryland this would be the Maryland Health Benefit Exchange.



## *Process*

NovaRest was charged to address the following questions regarding these proposed mandates:

- The extent to which the coverage will increase or decrease the cost of the service;
- The extent to which the coverage will increase the appropriate use of the service;
- The extent to which the mandated service will be a substitute for a more expensive service;
- The extent to which the coverage will increase or decrease the administrative expenses of carriers, including health maintenance organizations, or other organizations authorized to provide health benefit plans in the State, and the premium and administrative expenses of policyholders and contract holders;
- The impact of this coverage on the total cost of health care; and
- The impact of all mandated health insurance services on employers' ability to purchase health benefits policies meeting their employees' needs.

NovaRest reviewed literature (which included reports completed for other states which were either considering or have passed similar legislation), interviewed providers, gathered statistics from public sources regarding the 2015 premium levels for the various markets, and developed an independent estimate of the impact on premiums for each market for each proposed mandate.

To provide as complete a picture as possible regarding the proposed impact of each of these mandates, NovaRest issued a survey to the top six commercial/HMO carriers in the commercial fully insured market in Maryland to ascertain the extent that each of the proposed mandates is currently covered in their policies. The survey responses are included in Appendix I. Data requests quantifying use of the services included in the proposed mandates were part of the surveys. The various claim codes included in these requests are shown in Appendix II. There were very tight time frames for the carriers to respond as well as tight time frames for NovaRest to develop the report. The following chart shows the six major carriers and the degree to which they responded to the surveys.





### Commercial Carriers/HMOs Surveyed and the Degree to Which They Responded

Carrier/HMO	Full Response	Partial Response	Did Not Provide Any Answers
Aetna		X	
CareFirst	X		
CIGNA	X		
Evergreen		X	
Kaiser	X		
United Health Care			X

To determine the extent to which the proposed mandates are currently covered in the Medicaid program, we surveyed the top three Medicaid managed care organizations (MCOs).<sup>3</sup> The surveys sent to these entities are not included to protect the confidentiality of the sole MCO that responded. The claim codes included in the Medicaid managed care survey are the same claim codes included in the commercial carrier surveys. Similar to the surveys for the commercial carriers, the time frames for the Medicaid managed care providers to respond were very tight. The following chart shows the Medicaid managed care providers and the degree to which they responded to the surveys:

Carrier/HMO	Full Response	Partial Response	Did Not Provide Any Answers
AmeriGroup	X		
Priority Partners			X
Maryland Physician Care			X

NovaRest conducted phone interviews with providers to understand when digital breast tomosynthesis (DBT) or 3-D mammogram is important to use for patients and how it related to standard mammograms, which are two-dimensional. Providers stressed the importance of accurate findings to avoid unnecessary requests for further testing or biopsies. See the *Discussions with Providers* section for more detail on the interviews.

<sup>3</sup> The decision to issue the survey to the top three Medicaid MCOs was based upon input from Department of Health and Mental Hygiene (DHMH), which oversees the Medicaid program.



We relied upon the analysis completed by the Department of Legislative Services for quantification of the impact of these mandates on the State Employee and Retiree Health and Welfare Benefits Program.

### ***Mandated Coverage for Digital Tomosynthesis (also called 3-D Mammograms)***

House Bill 1006 (<http://mgaleg.maryland.gov/2016RS/bills/hb/hb1006F.pdf>) would require insurers, nonprofit health service plans, or health maintenance organizations (collectively known as carriers), to provide coverage for digital tomosynthesis that, under accepted standards in the practice of medicine, the treating physician determines is medically appropriate and necessary for an enrollee or insured.<sup>4</sup> Carriers may not impose a copayment or coinsurance requirement for digital tomosynthesis that is greater than a copayment or coinsurance requirement for other breast cancer screenings for which coverage is required under this section, nor impose a deductible for this service. “Digital tomosynthesis” means a radiologic procedure that involves the acquisition of projection images over the stationary breast to produce cross-sectional digital three-dimensional images. It is sometimes referred to as 3-D mammogram.

### **Background**

Breast cancer is the third-leading cause of cancer death among women in the United States. In 2016, an estimated 247,000 women will be diagnosed with the disease and 40,000 women will die of it. It is most frequently diagnosed among women aged 55 to 64 years, and the median age of death from breast cancer is 68 years.<sup>5</sup>

Mammograms are a diagnostic tool used in the early detection and diagnosis of breast diseases, most notably cancer, in women.

According to MammographySavesLives.org, mammography has helped reduce breast cancer mortality in the United States by nearly 40 percent since 1990. The ten-year risk for breast cancer in a 40-year-old woman is 1 in 69. One in six breast cancers occurs in women age 40 - 49. Three-quarters of women diagnosed with breast cancer have no family history of the disease and are not

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<sup>4</sup> A carrier is not required to cover breast cancer screenings used to identify breast cancer in asymptomatic women that are provided by a facility that is not accredited by the American College of Radiology, or certified or licensed in Maryland.

<sup>5</sup> SEER Cancer Statistics Factsheets: Female Breast Cancer. National Cancer Institute. Bethesda, MD, <http://seer.cancer.gov/statfacts/html/breast.htm>. Accessed November 6, 2016.



considered high risk. For women 50 years of age and older, skipping a mammogram every other year would miss up to 30 percent of cancers.<sup>6</sup> Early detection has meant that many more women can be treated for cancer and still keep their breasts because localized cancers can be removed without requiring a full breast removal (mastectomy).<sup>7</sup>

Traditional mammograms use an x-ray system that takes images of the breast from two angles. These images are either recorded on film or, more recently, are converted using technology to a digital image and transferred to a computer for review by a radiologist and for long-term storage.<sup>8</sup> Conventional digital screening mammography has essentially replaced film mammography as the primary method for cancer screening in the U.S.<sup>9</sup>

Computer-aided detection (CAD) systems search the digital mammography for abnormal areas of density, mass or calcification that may indicate the presence of cancer. The CAD system highlights these areas on the images so the radiologist can more closely review.

There are limitations to standard two-dimensional mammography. The images themselves are not usually enough to determine the existence of a benign or malignant disease with certainty. Often the discovery of something will require further diagnostic testing up to and including biopsies. An abnormal mammogram when there is no cancer present is called a “false-positive” result. All abnormal mammograms should be followed up with additional testing, which could include diagnostic mammograms, ultrasound, and/or biopsy, to determine if cancer is present. False-positive results can lead to anxiety and other forms of psychological distress as well as additional costs and physical discomfort associated with the additional tests.<sup>10</sup> Five to fifteen percent of screening mammograms require more testing. It is estimated that a woman who has yearly mammograms between ages 40 - 49 has about a 30 percent chance of having a

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<sup>6</sup> MammographySavesLives. “Mammography Facts.” <http://www.mammographysaveslives.org/Facts>. Accessed November 6, 2016.

<sup>7</sup> BreastCancer.org. “Digital Tomosynthesis.” Last modified June 23, 2016, [http://www.breastcancer.org/symptoms/testing/types/dig\\_tomosynth](http://www.breastcancer.org/symptoms/testing/types/dig_tomosynth). Accessed November 6, 2016.

<sup>8</sup> RadiologyInfo.org. “Mammography.” Reviewed September 30, 2015, <http://www.radiologyinfo.org/en/info.cfm?pg=mammo>. Accessed November 6, 2016.

<sup>9</sup> The U.S. Preventive Services Task Force. “Final Recommendation Statement Breast Cancer Screening.” January 12, 2016, <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/breast-cancer-screening1>. Accessed November 6, 2016.

<sup>10</sup> Op. cit. - National Cancer Institute.

false-positive mammogram at some point in that decade and about a 7 - 8 percent chance of having a breast biopsy within the 10-year period.<sup>11</sup>

The US Preventive Services Task Force (USPSTF) indicates that for women at average risk for breast cancer,<sup>12</sup> most of the benefits of mammograms result from biennial screening during ages 50 - 74. While the USPSTF recognizes that screening mammography in women aged 40 - 49 may reduce the risk of breast cancer death, the number of deaths averted is smaller than that in older women and the number of false-positive<sup>13</sup> results and unnecessary biopsies is larger. All women undergoing regular screening mammography are at risk for the diagnosis and treatment of noninvasive and invasive breast cancer that would otherwise not have become a threat to their health, or even become apparent during their lifetime (known as “overdiagnosis”). Beginning mammograms at younger ages and screening more frequently may increase the risk for overdiagnosis and subsequent overtreatment. However, women with a parent, sibling or child with breast cancer are at higher risk and thus may benefit more than average-risk women from beginning screening in their 40s. The USPSTF concluded there is insufficient data to assess the balance of the benefits and harms of screening mammography in women aged 75 and older. The USPSTF also concluded that there is insufficient evidence to assess the benefits and harms of digital breast tomosynthesis as a primary screening method for breast cancer; this includes women with dense breasts on an otherwise negative screening mammogram.<sup>14</sup>

Screening mammograms can find cancers and ductal carcinoma in situ (DCIS is a noninvasive tumor in which abnormal cells that may become cancerous build-up in the lining of breast ducts]). Some of these cancers will never cause symptoms or threaten a woman’s life, while some of these cancers need to be treated. Because doctors often cannot distinguish between the lethal cancers and DCIS from the non-lethal categories, all women are treated as if the cancer will become life-threatening. Treatment of non-lethal cancer and DCIS results in

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<sup>11</sup> Op. cit. - RadiologyInfor.org.

<sup>12</sup> The USPSTF defines average risk as “asymptomatic women aged 40 years or older who do not have preexisting breast cancer or a previously diagnosed high-risk breast lesion and who are not at high risk for breast cancer because of a known underlying genetic mutation (such as BRCA1 or BRCA2 gene mutation or other familial breast cancer syndrome) or history of chest radiation at a young age.”

<sup>13</sup> One provider that was interviewed stated that false positives, unnecessary biopsies, and call-backs were reduced with digital tomosynthesis.

<sup>14</sup> Op. cit. - U.S. Preventive Services Task Force.

“overdiagnosis” and “overtreatment” of breast cancer.<sup>15</sup>

Mammograms may also produce a “normal” result even though breast cancer is present. This situation is called a “false-negative” and usually occurs as a result of high breast density. Breasts contain both dense and fatty tissue. Dense tissue appears as a white area and fatty tissue appears as dark areas on a mammogram. Tumors and dense tissue can have similar density making it more difficult to differentiate between the two.<sup>16</sup>

Mammograms involve x-rays which expose women to a small amount of radiation. The National Institute of Cancer indicates the benefits of mammography outweigh the potential harm from exposure to radiation. Obviously, the more mammograms a woman has, the greater her exposure to radiation.

Breast tomosynthesis, also called three-dimensional (3-D) mammography and digital breast tomosynthesis (DBT), is an advanced form of breast imaging where multiple images of the breast from different angles are captured and reconstructed (“synthesized”) into a three-dimensional image set. In this way, 3-D breast imaging is similar to computed tomography (CT) imaging in which a series of thin “slices” are assembled to create a 3-D reconstruction of the body.<sup>17</sup>

The National Cancer Institute indicates there have not been randomized studies comparing the accuracy of 3-D mammography to standard mammography. Therefore, the National Cancer Institute is unable to determine whether 3-D mammography is more accurate at identifying early cancers and reducing false-positive results.<sup>18</sup>

According to the American Cancer Society, 3-D mammograms have greater radiation exposure than traditional mammograms.<sup>19</sup> The new, low-dose 3-D-only

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<sup>15</sup> Op. cit. - National Cancer Institute.

<sup>16</sup> Ibid.

<sup>17</sup> Op. cit. - RadiologyInfor.org

<sup>18</sup> National Cancer Institute. “Mammograms.” Reviewed March 2014, <https://www.cancer.gov/types/breast/mammograms-fact-sheet#q12>. Accessed November 6, 2016.

<sup>19</sup> American Cancer Society. “Mammograms: What To Know Before You Go.” Revised April 25, 2016, <http://www.cancer.org/healthy/findcancerearly/examandtestdescriptions/mammogramsandotherbr>



mammograms, however, actually use less radiation than a standard two-dimensional digital mammogram.<sup>20</sup>

Although mammograms may reduce the risk of breast cancer death, interpretations of mammograms can be difficult and not all cancers can be seen on a mammogram.

Increased breast density makes it difficult to see cancer on a mammogram and may increase breast cancer risk. Breast implants may also impede an accurate mammogram reading because the implants are not transparent on x-rays and can block a clear view of the tissues behind them.<sup>21</sup>

The ACA requires preventive services recommended by the USPSTF or other scientific bodies be provided in all non-grandfathered health plans with no cost sharing.<sup>22,23</sup> Because neither the USPSTF nor any of the other scientific bodies have recommended digital breast tomosynthesis, 3-D mammograms are not considered a preventive service and do not have to be covered by insurance companies with no cost-sharing for patients.

It should be noted that many in the medical profession disagree with the USPSTF recommendations regarding the frequency of screening mammograms as well as the ages these screenings should start. Dr. Daniel B. Kopans, writing on behalf of the Society of Breast Imaging, cites statistics supporting the benefits of beginning screening at age 40.<sup>24</sup>

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[eastimagingprocedures/mammograms-and-other-breast-imaging-procedures-what-is-mammogram](#). Accessed November 6, 2016.

<sup>20</sup> Dudley, Susan PhD, et al. "Should I "Upgrade" to Digital or 3D? A Mammography Guide." Cancer Prevention & Treatment Fund, Updated 2015, <http://www.stopcancerfund.org/p-breast-cancer/is-digital-mammography-better/>. Accessed November 6, 2016.

<sup>21</sup> Op. cit. - BreastCancer.org, "Digital Tomosynthesis."

<sup>22</sup> Under Section 2713 of the ACA, private health plans must provide coverage for a range of preventive services and may not impose cost-sharing (such as copayments, deductibles, or co-insurance) on patients receiving these services if the services have been recommended by four expert medical and scientific bodies – the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices (ACIP), the Health Resources and Services Administration's (HRSA's) Bright Futures Project, and HRSA and the Institute of Medicine (IOM) committee on women's clinical preventive services.

<sup>23</sup> Siu AL, Bibbins-Domingo K, Grossman DC. Evidence-based clinical prevention in the era of the Patient Protection and Affordable Care Act: the role of the US Preventive Services Task Force. *JAMA*. 2015;314(19):2021-2.

<sup>24</sup> Kopans, Daniel B. M.D. Professor of Radiology Harvard Medical School, "The Facts About Mammography Screening: A Conversation with Your Physician." <https://www.sbi->



3-D mammography has been available since 2011. It was originally approved by the Food and Drug Administration to be used along with standard, two-dimensional digital mammograms, but in 2013 the agency approved a 3-D system that can be used alone.<sup>25</sup> It is not yet considered the standard of care for breast cancer screening. It is being adopted faster throughout the US than the standard two-dimensional digital mammography was in prior years, with 50 percent of the facilities in the Breast Cancer Surveillance Consortium now offering 3-D mammograms.<sup>26,27</sup>

Several studies have found that 3-D mammograms find more cancers than traditional mammograms and also reduce the number of false positives. The rate of false positives has helped fuel the debate about the value of screening mammograms.<sup>28</sup> The reduction in false positives when using 3-D mammograms is a benefit of 3-D mammograms.

A recent study by Elizabeth McDonald, MD and colleagues at the University of Pennsylvania found that 3-D mammogram screening outcomes are sustainable, with significant recall reduction, increased cancer cases per recalled patients and a decline in interval cancers. The rates of women who had to come back for more testing after having 3-D mammograms were:<sup>29</sup>

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[online.org/Portals/0/downloads/documents/pdfs/THE%20FACTS%20ABOUT%20MAMMOGRAPHY%20SCREENING-Kopans.pdf](http://online.org/Portals/0/downloads/documents/pdfs/THE%20FACTS%20ABOUT%20MAMMOGRAPHY%20SCREENING-Kopans.pdf). Accessed November 6, 2016.

<sup>25</sup> Norton, Amy. HealthDay Reporter, "3D Mammograms May Improve Breast Cancer Screening." WebMD, Updated June 24, 2014, <http://www.webmd.com/breast-cancer/news/20140624/3d-mammograms-may-improve-breast-cancer-screening#1>. Accessed November 11, 2016.

<sup>26</sup> The Breast Cancer Surveillance Consortium is a collaborative network of seven mammography registries with linkages to tumor and/or pathology registries. The network is part of the National Cancer Institute.

<sup>27</sup> Breastcancer.org. "Benefits of 3-D Mammograms Last Over Time." Updated February 27, 2016, <http://www.breastcancer.org/research-news/benefits-of-3d-mammograms-last-over-time>. Accessed November 2016.

<sup>28</sup> Ibid.

<sup>29</sup> McDonald, Elizabeth S. M.D. et al. "Effectiveness of Digital Breast Tomosynthesis Compared with Digital Mammography Outcomes Analysis From 3 Years of Breast Cancer Screening." JAMA Oncology, Updated June 2016, <http://jamanetwork.com/journals/jamaoncology/article-abstract/2491465>. Accessed November 6, 2016.



- Year one recall rate: 88 per 1,000 women screened
- Year two recall rate: 90 per 1,000 women screened
- Year three recall rate: 92 per 1,000 women screened

These rates are lower than the recall rate of 104 per 1,000 women screened for 2-D mammograms.

The researchers also found that the rate of recalls went down as more 3-D mammograms were performed; from 130 per 1,000 women screened for women who had one 3D mammogram to 59 per 1,000 women screened for women who had three 3-D mammograms.<sup>30</sup>

The rate of cancer found in women who were called back for more testing increased in women who had 3-D mammograms, meaning that 3-D mammograms found more cancers:<sup>31</sup>

- 4.4% in women who had 2-D mammograms
- 6.2% in year one of 3-D mammograms
- 6.5% in year two of 3-D mammograms
- 6.7% in year three of 3-D mammograms

Rates of interval cancers (cancers that are found within 12 months after a normal mammogram) decreased slightly from 0.7 per 1,000 women screened with 2-D mammograms to 0.5 per 1,000 women screened with 3-D mammograms.

This is the first study to show longitudinal evidence that the benefits of initial 3-D mammogram screening can be sustained and improved over time with consecutive 3-D mammogram screening.<sup>32</sup>

There is concern that 3-D mammograms will result in more diagnosis of ductal carcinoma in-situ, DCIS. A study of 13 hospitals found the rates of DCIS detection did not rise, remaining at 1.4 cases per 1,000 screenings the year after the switch to 3-D screening, the same rate as with 2-D screening. During this time, there was a 15 percent decrease in the number of women being called back for more testing while increasing breast cancer detection rates by more than 40 percent.<sup>33</sup>

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<sup>30</sup> Ibid.

<sup>31</sup> Ibid.

<sup>32</sup> Op. cit. - BreastCancer.Org, "Benefits of 3-D Mammograms Last Over Time"

<sup>33</sup> Op. cit. - Norton, Amy.



There are also differing opinions regarding the effectiveness of various screening mammography for women with dense breast tissue. Dense breasts result in reduced mammographic sensitivity and specificity. They may represent an independent risk factor for breast cancer. Increased tumor size and worsened prognosis are associated with increased breast density.<sup>34</sup> Dense breast tissue makes it more difficult to interpret a mammogram since cancer and dense breast tissue both appear white on the mammogram. Mammograms are still an effective screening tool for dense breasts. There is some evidence that additional tests may make it more likely that breast cancer is detected in dense breast tissue, but these tests carry additional risks and no additional testing method has proven to reduce the risk of dying from breast cancer.<sup>35</sup>

A study completed by the California Health Benefits Review Program concluded that there is “clear and convincing evidence that compared to no screening, digital mammography alone leads to reduced breast cancer-related mortality, and may detect breast cancer at an earlier stage among some subgroups of women. There is insufficient evidence to indicate whether adding digital breast tomosynthesis to digital mammography for breast cancer screening would alter these key clinical outcomes.”<sup>36</sup>

MD Anderson, one of the premier cancer treatment providers in the country, recommends 3-D mammograms for any woman needing breast screening and especially for women with dense breast tissue.<sup>37</sup>

The American College of Radiology no longer considers digital breast tomosynthesis experimental, citing higher cancer detection rates and fewer

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<sup>34</sup> Refferty, Elizabeth A. M.D. et al. “Breast Cancer Screening Using Tomosynthesis and Digital Mammography in Dense and Nondense Breasts.” JAMA, 2016, <http://jamanetwork.com/journals/jama/fullarticle/2516698>. Accessed November 6, 2016.

<sup>35</sup> Mayo Clinic. “Dense Breast Tissue: What It Means to Have Dense Breasts.” Updated February 2015, <http://www.mayoclinic.org/tests-procedures/mammogram/in-depth/dense-breast-tissue/art-20123968?pg=2>. Accessed November 6, 2016.

<sup>36</sup> California Health Benefits Review Program. “Analysis of California Assembly Bill (AB) 2764 Health Care Coverage: Mammography.” May 6, 2016, [http://chbrp.ucop.edu/index.php?action=read&bill\\_id=225&doc\\_type=3](http://chbrp.ucop.edu/index.php?action=read&bill_id=225&doc_type=3). Accessed November 6, 2016.

<sup>37</sup> Bramlet, Kellis. “What You Should Know about 3-D Mammography.” MD Anderson Center, October 2015, <https://www.mdanderson.org/publications/focused-on-health/october-2015/FOH-3D-mammography.html>. Accessed November 6, 2016.



patient recalls for additional testing, and believes it has been shown to improve key screening parameters compared to standard two-dimensional digital mammography.<sup>38</sup>

## **Prevalence of Coverage**

### **Medicare**

Medicare started covering 3-D mammograms in January 2015. The national average reimbursement rates are about \$56 higher than the 2-D reimbursement rates.<sup>39</sup>

### **Maryland Medicaid Managed Care**

One Medicaid managed care organization indicated that digital tomosynthesis is not covered under Medicaid. This managed care company considers 3-D mammograms to be experimental and investigational and not medically necessary for all indications. They cite the USPSTF conclusion that there is insufficient evidence to evaluate the benefits and harms of DBT when used as a primary screening method for breast cancer. They also cite USPSTF's conclusion that there is insufficient evidence "to assess the balance of benefits and harms of adjunctive screening for breast cancer using breast ultrasonography, magnetic resonance imaging (MRI), DBT, or other methods in women identified to have dense breasts on an otherwise negative screening mammogram."

This Medicaid MCO provided the following summary of the reason for excluding this procedure:

*The optimal role for DBT in the diagnosis and assessment of breast cancer remains undefined. There is evidence to suggest that use of mammography in addition to DBT may increase the number of cancers detected, which would then translate into a decrease in the number of females who undergo unnecessary recalls or breast biopsies. However, the published feasibility and experimental studies are unclear if DBT should be utilized for diagnostic, screening or surveillance purposes, or if it*

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<sup>38</sup> American College of Radiology. "Digital Breast Tomosynthesis." <http://www.acr.org/Advocacy/Economics-Health-Policy/Managed-Care-and-Private-Payer/Common-Coverage-Issues-with-Private-Payers/Digital-Breast-Tomosynthesis>. Accessed November 6, 2016.

<sup>39</sup> Hologic. "2016 Coding & Reimbursement Guide: Breast Imaging." Updated January 2016, <http://www.hologic.com/sites/default/files/white-papers/2016%20Breast%20Imaging%20Coding%20and%20Reimbursement%20Guide.pdf>. Accessed November 6, 2016.



*should be used in lieu of or in conjunction with other imaging technologies. In addition to these issues, there are persistent concerns regarding radiation exposure, and the steep learning curve for radiologist to accurately interpret the DBT results.*

The average cost of mammograms for this MCO for the 12-month period ending 9/30/2016 was about \$138. The average cost for treating a woman with breast cancer for the same period was \$6,509.

**Maryland Commercial Carriers and HMOs**

The ACA requires that coverage of preventive services, including mammograms for breast cancer screening, be provided without a copay or deductible in plans that started after August 1, 2012. The law does not apply to health plans that were in place before the law was passed (called grandfathered plans). However, the ACA generally defers to the USPSTF for determination of the types and frequency of services deemed to be “preventive”. HHS has indicated that breast cancer mammography screenings every 1 - 2 years for women over age 40 are considered preventive.<sup>40</sup>

<b>Market</b>	<b>% of Market Currently without 3-D Mammogram Coverage</b>
Individual	9%
Small Group	29%
Large Group	26%
<b>Total</b>	<b>24%</b>

One carrier considers digital breast tomosynthesis experimental and investigational because of insufficient evidence of its effectiveness. On its website, it cites many studies to support this policy.

<sup>40</sup> HHS. “Preventive Services Covered Under the Affordable Care Act.” <http://www.hhs.gov/healthcare/facts-and-features/fact-sheets/preventive-services-covered-under-aca/#CoveredPreventiveServicesforWomenIncludingPregnantWomen>. Accessed November 6, 2016.

Another carrier indicated that, although it does not have a specific exclusion, it does not routinely cover digital breast tomosynthesis. They too, cited the USPSTF conclusions.

A third carrier covers 3-D mammograms 100 percent when medically necessary. A medical necessity review is required to determine why a routine screening mammogram would not be sufficient.

Two carriers in the market cover 3-D mammograms the same as any other mammogram. Based upon the survey responses, a minimum of 76 percent of members covered in the fully insured market in Maryland have full coverage for 3-D mammograms.<sup>41</sup>

### ***State Employee and Retiree Health and Welfare Benefits Program***

According to an analysis completed by the Maryland Department of Legislative Services, the State Employee and Retiree Health and Welfare Benefits Program currently provides coverage for digital tomosynthesis as required under the bill.<sup>42</sup>

### ***Self-Funded Plans***

The prevalence of this coverage among self-funded plans, which would not otherwise be required to provide state mandated benefits, demonstrates the degree to which the proposed benefits are deemed necessary. To ascertain this, we included questions regarding self-funded plans as part of our surveys to the carriers. The results by carrier are:

- One carrier indicated that 100 percent of fully-insured and self-funded plans – with just a small number of self-funded opt-out exceptions<sup>43</sup> - have covered DBT in 2016.
- Another carrier indicated that coverage would be the same as under fully insured plans.
- A third carrier indicated that some, but less than half of plans, cover the benefit to the same extent as fully-insured plans. Typically, self-funded and fully insured plans have similar coverage.
- A fourth carrier indicated that coverage for self-funded plans is typically the same as for fully-insured plans.

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<sup>41</sup> The 76% may be understated because we did not get a response from one major carrier.

<sup>42</sup> Department of Legislative Services. “Fiscal and Policy Note HB 1006 Health Insurance-Coverage for Digital Tomosynthesis.”  
[http://mgaleg.maryland.gov/2016RS/fnotes/bil\\_0006/hb1006.pdf](http://mgaleg.maryland.gov/2016RS/fnotes/bil_0006/hb1006.pdf). Accessed November 6, 2016.

<sup>43</sup> “Opt-out” means a self-funded plan elects not to follow the carrier’s standard protocol for this procedure.



### **Other States**

In July 2016, the State of Connecticut Insurance Department issued guidance that digital tomosynthesis must be covered but could be subject to fees or deductibles.<sup>44</sup>

On October 5, 2015, Pennsylvania Governor Tom Wolf clarified that the existing state mammogram law included 3-D mammograms and must be covered at no cost to women in the same manner as traditional two-dimensional mammograms.<sup>45</sup>

Illinois passed a mandate effective July 1, 2016 requiring all insurance companies to cover 3-D mammograms.<sup>46</sup>

Many states have passed state laws requiring providers to notify women if their screening mammograms find dense breast tissues. According to Are You Dense (an advocacy group), Delaware, Louisiana, Michigan and North Dakota passed laws in 2015. The other states are Alabama, Arizona, California, Hawaii, Maryland, Massachusetts, Missouri, Minnesota, Nevada, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, Rhode Island, Tennessee, Texas and Virginia.<sup>47</sup> Most of these laws do not require 3-D mammograms be covered.

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<sup>44</sup> Stuart, Christine. "Insurers Making Plans for Newly Mandated Coverage of 3D Mammograms." CT News Junkie, August 25, 2016, [http://www.ctnewsjunkie.com/archives/entry/insurers\\_making\\_plans\\_for\\_newly\\_mandated\\_coverage\\_of\\_3d\\_mammograms/](http://www.ctnewsjunkie.com/archives/entry/insurers_making_plans_for_newly_mandated_coverage_of_3d_mammograms/). Accessed November 6, 2016.

<sup>45</sup> PA.Gov. "3D Mammography FAQs." <http://www.insurance.pa.gov/Coverage/Pages/3D-Mammography-FAQs.aspx>. Accessed November 6, 2016.

<sup>46</sup> Vojcic, Sonja. "3D Mammograms to be Covered by Insurance in Illinois." Health News, September 2, 2015, <http://www.ahchealthnews.com/2015/09/02/3d-mammograms-to-be-covered-by-insurance-in-illinois/>. Accessed November 6, 2016.

<sup>47</sup> Peres, Judy. "Laws Get Ahead of Doctors on Mammography, Breast Density." Chicago Tribune, October 6, 2015, <http://www.chicagotribune.com/lifestyles/health/breastcancer/sc-breast-cancer-density-health-20150924-story.html>. Accessed November 6, 2016.



### Utilization of Services

Below is a chart showing the number of traditional mammogram services and the number of digital tomosynthesis services included in the MHCC MCDB for 2014 prior to the several carriers changing their coverage of 3-D mammograms in 2015.

	Member Months	Traditional Mammogram (2014 MCDB)	Digital Tomosynthesis (2014 MCDB)
		# Services	# Services
<b>Facility Outpatient</b>			
Individual	2,662,865	1,013	16
Small Group	3,461,580	841	192
Large Group	6,539,751	1,473	1,003
<b>Total</b>	12,664,196	3,327	1,211
<b>Professional Svcs</b>			
Individual	2,662,865	37,925	10
Small Group	3,461,580	49,425	46
Large Group	6,539,751	94,411	120
<b>Total</b>	12,664,196	181,761	176
<b>Facility Outpatient and Professional Services</b>			
Individual	2,662,865	38,938	26
Small Group	3,461,580	50,266	238
Large Group	6,539,751	95,844	1,123
<b>Total</b>	12,664,196	185,088	1,387
Note: One large carrier informed MHCC that coverage of digital tomosynthesis for breast cancer screening was added as a benefit in 2015, thus the low numbers in 2014.			

The following chart shows information provided by the carriers on the total number of members having a standard two-dimensional mammogram and the total number of members having digital tomosynthesis (3-D mammogram).



Total Market	Total Members having a Standard 2-D Mammogram in Calendar Year 2015	Total Members Having a 3-D Mammogram in Calendar Year 2015
Carrier #1	6,608	532
Carrier #2	59,331	21

### Cost of Treatment

3-D mammograms are more expensive, typically from \$50 to \$100 more per screening, than the traditional 2-D mammogram.<sup>48</sup> Below is a chart showing the number of standard 2-D mammogram services and the number of digital tomosynthesis (3-D mammogram) services included in the MHCC MCDB for 2014<sup>49</sup>.

	Member Months	Standard 2-D Mammograms (2014 MCDB)			3-D Mammograms (2014 MCDB)		
		PMPM		Paid to Allowed Ratio	PMPM		Paid to Allowed Ratio
		Allowed	Paid		Allowed	Paid	
<b>Facility Outpatient</b>							
Individual	2,662,865	\$0.122	\$0.121	99.3%	\$0.001	\$0.001	100.0%
Small Group	3,461,580	\$0.077	\$0.075	98.3%	\$0.017	\$0.017	98.8%
Large Group	6,539,751	\$0.068	\$0.067	98.1%	\$0.042	\$0.041	96.5%
<b>Total</b>	12,664,196	\$0.082	\$0.081	98.5%	\$0.027	\$0.026	97.0%
<b>Professional Svcs</b>							
Individual	2,662,865	\$1.106	\$1.105	99.9%	\$0.000	\$0.000	100.0%
Small Group	3,461,580	\$1.106	\$1.104	99.8%	\$0.001	\$0.000	52.5%
Large Group	6,539,751	\$1.101	\$1.095	99.5%	\$0.000	\$0.000	67.1%
<b>Total</b>	12,664,196	\$1.104	\$1.100	99.6%	\$0.000	\$0.000	63.3%
<b>Facility Outpatient and Professional Services</b>							
Individual	2,662,865	\$1.228	\$1.226	99.8%	\$0.001	\$0.001	100.0%
Small Group	3,461,580	\$1.183	\$1.179	99.7%	\$0.018	\$0.018	97.4%
Large Group	6,539,751	\$1.170	\$1.162	99.4%	\$0.043	\$0.041	96.2%
<b>Total</b>	12,664,196	\$1.186	\$1.180	99.6%	\$0.027	\$0.026	96.5%

<sup>48</sup> Ibid.

<sup>49</sup> While preventive mammograms are covered with no cost sharing under the ACA, non-preventive mammograms, such as follow-ups to abnormal results, cancer, etc. may require cost sharing. Also, grandfathered plans may require cost sharing. This explains the difference between the allowed and paid amounts.



## **Discussions with Providers**

We interviewed three physicians who either specialized in treating breast cancer patients or specialized in providing mammograms. All consistently concurred that digital tomosynthesis was medically necessary for screening women with dense breasts. There was less consistency regarding the need for all women to have digital tomosynthesis. Some physicians thought 3-D mammograms were only required for women who have dense breasts and/or some other condition (such as scarring from prior breast surgeries, radiation, etc.), while some thought all women would benefit from 3-D mammograms. Physicians who interpret mammograms indicated that they are better able to detect early cancers, have fewer call-backs due to unclear imaging associated with 2-D mammograms, and fewer biopsies resulting in normal results. They believe that these savings more than offset the additional cost of the 3-D mammograms and that all women would benefit from 3-D mammograms, not just those with dense breasts. One provider stated that the additional cost is about \$60 per mammogram, which was on the low end of the NovaRest estimated range. Some believe that 3-D mammography will become the standard of care, just as digital mammograms have almost universally replaced film mammograms.

## **Questions Concerning Mandated Coverage for Digital Tomosynthesis**

### **The extent to which the coverage will increase or decrease the cost of the service.**

Mandating a service or product increases the demand for that service and product, which typically increases the cost of the service, where allowed. Carriers can offset this upward pressure on price by contracting with providers. States with mandates did not report an increase in the cost of the service. Potential increases in cost are not expected to have a significant impact on PMPM or percentage of premium estimates.

### **The extent to which the coverage will increase the appropriate use of the service.**

There is anecdotal evidence that some women, especially those with dense breasts, are not receiving digital tomosynthesis due to the lack of coverage. This mandate would increase the appropriate use of digital tomosynthesis to the extent that it is currently not covered and women are not willing or able to pay the additional cost.





**The extent to which the mandated service will be a substitute for a more expensive service.**

Digital tomosynthesis would replace the less expensive mammograms. If digital tomosynthesis is more effective in identifying potential breast cancers, it may eliminate unnecessary call-backs and biopsies resulting in normal results, which would be a cost savings from these more expensive services, as well as save lives by detecting cancers at an earlier stage when they are more easily treated and the prognosis is better.

**The extent to which the coverage will increase or decrease the administrative expenses of carriers, including health maintenance organizations, or other organizations authorized to provide health benefit plans in the State, and the premium and administrative expenses of policyholders and contract holders.**

One carrier stated:

*The (proposed) language is “Carriers may not impose a copayment or coinsurance requirement for digital tomosynthesis that is greater than a copayment or coinsurance requirement for other breast cancer screenings for which coverage is required under this section; nor impose a deductible for this service.” That adds unnecessary complexity and opportunity for member confusion at adjudication. Member benefits are not set at this level of detail. Diagnostic mammograms are covered under a much broader category of diagnostic services (generally x-rays) which in some plans are deductible & coinsurance. Having to exclude one specific test from the broader benefit category adds administrative cost to make a unique benefit category or creates member confusion on financial implications of their benefit plan. The vast majority of all mammographies get covered as preventative.*

Another carrier indicated that there may be additional costs if out-of-network providers are used.



## ***Financial Impact on Premiums: Analyses in Other States***

### **California**

The California study assumed there would be a 91 percent increase in the use of DBT under the proposed mandate. The overall number of mammograms would not increase. The increase in premium ranged from 0.05% for those enrolled in Covered California (the ACA Exchange Market for individuals in California) to 0.06% for those enrolled outside Covered California. Employer premiums were estimated to increase by 0.03%. These estimates translate into premium increases of \$0.13 PMPM to \$0.20 PMPM.

### **Connecticut**

ConnectiCare told Insurance Department regulators that the 3D mammogram mandate would increase premiums by \$1.38 PMPM. However, Anthem officials indicated there would be no increase in premiums resulting from the mandate.<sup>50</sup>

### ***Carriers' Estimates***

Maryland carriers responding to our surveys provided estimates which ranged from \$0.20 PMPM to \$1.20 PMPM, which translates to an impact on premiums of less than 0.1% to 0.3%.

### ***Provider Estimate***

As indicated above, one provider stated that the additional cost is about \$60 per mammogram, which was on the low end of the NovaRest estimated range.

### ***NovaRest Estimate***

NovaRest independently developed a range of estimates based upon the following assumptions:

- Utilization rates were based upon the 2014 MCDB data for all commercial payers; overall utilization would not increase. We generated a range of estimates based upon the assumptions that the percent of 3-D mammograms would increase to reflect 40%, 50% and 100% of all mammograms.
- Allowed costs for 2-D mammograms was based upon the 2014 MCDB for commercial carriers.
- Costs for 3-D mammograms was estimated to be \$60 - \$100 greater than the cost for a 2-D mammogram.

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<sup>50</sup> Op. cit. – Stuart, Christine.



- Paid to allowed ratios for all mammograms is 0.995, based on 2014 MCDB data.
- The marginal impact assumes 76 percent of members are already insured by carriers that currently provide this coverage. This percentage varies by market.<sup>51</sup> Marginal cost is defined as the additional cost carriers will incur if required to provide coverage for a proposed mandate that they would not have provided otherwise.

The following charts show the gross and marginal percentage impact on premiums. Depending on the assumptions, the percentage impact on premiums ranges from 0.10% to 0.18% on a gross basis and from 0.02% to 0.10% on a marginal basis. Please note that these are the maximum costs since we have not assumed any savings that may result from fewer total mammograms in aggregate due to fewer call-backs required for digital tomosynthesis as well as any long-term savings associated with earlier detection of cancers when they are easier and less expensive to treat.

Assumed utilization provided by MHCC and cost is \$60 more than traditional mammogram							
Market	Average Premium PMPM	40% of Mammograms will be 3D		50% of Mammograms will be 3D		100% of Mammograms will be 3D	
		Gross	Marginal	Gross	Marginal	Gross	Marginal
Individual	\$235.44	0.06%	0.01%	0.06%	0.02%	0.08%	0.03%
Small Group	\$360.28	0.13%	0.03%	0.14%	0.04%	0.17%	0.07%
Large Group	\$428.29	0.10%	0.02%	0.10%	0.03%	0.13%	0.05%
<b>Total</b>	<b>\$373.97</b>	<b>0.10%</b>	<b>0.02%</b>	<b>0.11%</b>	<b>0.03%</b>	<b>0.14%</b>	<b>0.06%</b>

<sup>51</sup> The source of the members was an accumulation of the 2015 Supplemental Health Care Exhibits for carriers/HMOs in Maryland. Carefirst and CIGNA members already have coverage for this benefit.



<b>Assumed utilization provided by MHCC and cost is \$100 more than traditional mammogram</b>							
<b>Market</b>	<b>Average Premium PMPM</b>	<b>40% of Mammograms will be 3D</b>		<b>50% of Mammograms will be 3D</b>		<b>100% of Mammograms will be 3D</b>	
		<b>Gross</b>	<b>Marginal</b>	<b>Gross</b>	<b>Marginal</b>	<b>Gross</b>	<b>Marginal</b>
Individual	\$235.44	0.07%	0.02%	0.08%	0.03%	0.11%	0.06%
Small Group	\$360.28	0.15%	0.05%	0.16%	0.06%	0.22%	0.12%
Large Group	\$428.29	0.11%	0.04%	0.12%	0.05%	0.17%	0.09%
<b>Total</b>	<b>\$373.97</b>	<b>0.12%</b>	<b>0.04%</b>	<b>0.13%</b>	<b>0.05%</b>	<b>0.18%</b>	<b>0.10%</b>

**The impact of this coverage on the total cost of health care.**

The total cost of health care would only change to the extent that the cost of the service would change or the utilization of the service would change. We do not anticipate any significant change in the cost, but the utilization of the service would increase. In other words, 3-D mammograms could represent a higher percentage of all mammograms and since they are more expensive, could put upward pressure on the total cost of health care. However, there are other factors that exert downward pressure, such as the lower recall rate associated with 3-D mammograms and the savings of the costs associated with the additional testing necessitated because of these call backs as well as the lower costs of treating cancer at earlier stages.

**The impact of all mandated health insurance services on employers' ability to purchase health benefits policies meeting their employees' needs.**

Any mandate or regulation that results in the increase of costs and administrative complexity to the fully-insured premiums will serve as another incentive for employers to consider self-insuring. The Employee Benefit Research Institute (EBRI) released the results of a study it completed examining the trends from 1996 - 2015 in self-insured health plans among private-sector employers. The key findings were:<sup>52</sup>

<sup>52</sup> Op. cit. - Fronstin, Paul.



- The percentage of private-sector employers offering health plans of which at least one was self-insured increased from 28.5% in 1996 to 49% in 2015, representing a 36.8% increase.
- Between 2013 and 2015, the percentage of employers offering health plans with at least one self-insured plan increased for employers with 100 - 999 employees (mid-size employers) from 25.3% to 30.1%; for small employers (25 - 99 employees) the percent increased from 13.3% to 14.2%, and decreased for large employers (>1,000 employees) from 83.9% to 80.4%.
- The percentage of health-covered employees enrolled in self-insured plans increased from 58.2% to 60.0% from 2013 - 2015, with the largest increases occurring with small and mid-size employers.

It is not the cost of any single mandate that drives employers to self-insure, but rather an accumulation of multiple mandates. The ACA has several components that appear to incent employers away from fully insured plans including EHBs, health insurance tax and, in the case of employers with fifty or fewer employees, benchmark plans, and metal-level plans.

NovaRest estimates the percentage impact on premiums ranges from 0.10% to 0.18% on a gross basis and from 0.02% to 0.10% on a marginal basis. Given the low-cost impact of the proposed mandate, it is unlikely that its passage alone would cause a major shift to self-insurance.



The cost of mandated health insurance services could be defined either as the full cost of the service or as the marginal/additional cost of the mandate. The marginal cost equals the full cost of the service minus the value of the services that would be covered without the mandate.

Based on the most recent mandate report published by the MHCC in January 2012, the full cost and marginal cost as a percentage of premium of the 44 mandates at that time is shown in the following table:

	Large Group Market	Small Group Market	Individual Market	State Employee Plan
2012 Full Cost of Mandates as a % of Premium	18.8%	22.0%	19.6%	17.9%
2012 Marginal Cost of Mandates as a % of Premium	3.5%	2.7%	3.6%	3.3%



## Appendix I: Carrier Survey Responses

1. For calendar year 2015, what percent of your fully-insured policies provided coverage for digital tomosynthesis, by market?

	Market	Percent of Members with Coverage for Digital Tomosynthesis
Carrier #1	Individual	0%
	Small Group	0%
	Large Group	0%
Carrier #2	100% of our members have coverage when medically necessary	
Carrier #3	Individual	0%
	Small Group	0%
	Large Group	0%
Carrier #4	Individual	100% as of 5-15-15
	Small Group	100% as of 5-15-15
	Large Group	100% as of 5-15-15

2. For carriers that covered digital tomosynthesis, please provide the following information for calendar year 2015:

	Market	Member months with digital tomo coverage	# of non-digital tomo mammo	Allowed Charges for non-digital tomo mammo	Allowed Charge/Service	PMPM for non-digital tomo mammo	# digital tomo mammo	Allowed Charges for digital tomo	Allowed Charge/Service	PMPM for digital tomo
Carrier #1	Individual	2,134,189	19,419	\$2,820,267	\$145.23	\$1.32	8,000	\$1,804,078	\$225.51	\$0.85
	Small Group	2,130,507	13,772	\$2,087,906	\$151.61	\$0.98	6,595	\$1,528,910	\$231.83	\$0.72
	Large Group	2,309,667	11,333	\$1,675,669	\$147.86	\$0.73	4,474	\$1,031,633	\$230.58	\$0.45
	Total	6,574,363	44,524	\$6,583,842	\$147.87	\$1.00	19,069	\$4,364,621	\$228.89	\$0.66
Carrier #2	Total		59,331				21			
Carrier #3	Individual	4,316	53	\$12,319.58	\$232.44	\$2.85	4	\$374.65	\$93.66	\$0.09
	Small Group	0	0	0	0	0	0	0	0	\$0.00
	Large Group	732,586	8,312	\$1,773,596.68	\$213.38	\$2.42	746	\$67,586.07	\$90.59	\$0.09
	Total	736,902	8,365	\$1,785,916.26	\$445.79	\$5.27	750	\$67,906.72	\$184.25	\$0.09



	<b>Market</b>	<b>Total Members having a Mammogram in Calendar Year 2015</b>	<b>Total Members having Digital Tomosynthesis Mammogram in Calendar Year 2015</b>
Carrier #1	Individual	42	4
	Small Group	0	0
	Large Group	6,566	528
	Total	6,608	532
Carrier #2	Total	59,331	21
Carrier #3	Individual	26,933	7,985
	Small Group	20,367	6,595
	Large Group	15,579	4,442
	Total	62,879	19,022

3. If digital tomosynthesis is not covered by all plans, please provide the following information for calendar year 2015. If possible, please provide the information by market as well as the total. If information is not readily available by market, please show for all markets combined.

	<b>Market</b>	<b>Number of Tomosynthesis Mammograms Denied in Calendar Year 2015*</b>	<b>Charges for Denied Tomosynthesis Mammograms in Calendar Year 2015*</b>	<b>Cost per Denied Claim in Calendar Year 2015*</b>
Carrier #1	MD/DC/VA	544	\$65,280	\$120
	Total-National	12,872	\$1,544,640	\$120
Carrier #2	Individual	0	\$0	\$0
	Small Group	0	\$0	\$0
	Large Group	58	\$5,822	\$100
	Total	58	\$5,822	\$100



4. Are there any copays/cost sharing applied to mammograms? Please describe the circumstances when a copay/cost sharing would apply for a mammogram. What is the average copay/cost sharing amount applied in calendar year 2015?

	<b>Response</b>
Carrier #1	We had no copay/cost sharing amount applied in calendar year 2015 because digital mammography was neither covered nor excluded. Our EOCs were silent and service was not readily available. Approval would have been provided on a case-by-case basis based on medical necessity. If a test was performed the applicable cost share would have applied for the service which in most cases would have been the preventive \$0.  Copays/cost sharing would only be applicable when the service is not a preventive or part of a follow up screening test.
Carrier #2	No. HB 1006 is limited to breast cancer screenings, therefore, the carrier does not impose cost sharing provisions as this service is considered a preventive service mandated by the Affordable Care Act.
Carrier #3	Average Copay/Cost Sharing = \$10.41
Carrier #4	For non-preventive mammograms, plans may have cost sharing.
Carrier #5	Copays and coinsurance amounts vary by service and are determined by the particular plan in which the member is enrolled.

5. If digital tomosynthesis mammograms are currently covered, are there any limitations such as pre-authorization, medical protocols, etc. applied? If so, please describe.

	<b>Response</b>
Carrier #1	Digital breast tomosynthesis is considered a medically appropriate imaging option in the screening of breast cancer. Pre-authorization and medical protocols are not applied.
Carrier #2	Medical necessity review is required to determine why a routine screening mammogram would not be sufficient.
Carrier #3	Preventive Services Benefits for preventive care include the following:  A. Cancer Screening Services. Benefits include: 4. Breast Cancer Screening. At a minimum, benefits will be provided for breast cancer screening in accordance with the latest screening guidelines issued by the American Cancer Society. The current recommendations of the United States Preventive Service Task Force regarding breast cancer screening, mammography, and prevention shall be considered the most current other than those issued in or around November 2009.  Note: According to the Medical Policy: Digital tomosynthesis mammograms are considered medically necessary as an imaging option in the screening or diagnosis of breast cancer. There are no prior authorization requirements for digital tomosynthesis mammograms.
Carrier #4	Since the service was under review by the US Preventive Services Task Force (USPSTF) who did not define the efficacy of this treatment modality in for preventive care in 2015, we had no specific exclusions for coverage of service.



6. If digital tomosynthesis mammograms are not currently covered, what is the rationale for excluding this service?

	<b>Response</b>
Carrier #1	The service was under review by USPSTF so we did not list it as an exclusion. We would have covered it as medically necessary.
Carrier #2	See Breast Tomosynthesis (3D Mammography) section of CPB
Carrier #3	N/A
Carrier #4	The carrier's policy for tomosynthesis prior to August 2016 was that tomosynthesis was experimental, investigational or unproven. However, claims for tomosynthesis were not subject to prior authorization or medical necessity review. Since that time, the revised coverage policy indicates the carrier's position, stated in Item No. 5.
Carrier #5	N/A

7. What would be the impact on premium if this proposed mandate were to pass? Please express as a PMPM and as a percentage of premium, by market, in the following table:

	<b>Market</b>	<b>Impact on Premium (PMPM)</b>	<b>Impact on Premium (% of premium)</b>
Carrier #1	Individual	\$0.49	0.23%
	Small Group	\$0.30	0.09%
	Large Group	\$0.23	0.07%
	Total	\$0.33	0.11%
Carrier #2	Individual	\$1.20	0.30%
	Small Group	\$1.20	0.30%
	Large Group	\$1.20	0.30%
	Total	\$1.20	0.30%
Carrier #3	Total	\$0.27	0.06%
Carrier #4	Individual	\$0.20	<0.1%
	Small Group	NA	NA
	Large Group	\$0.20	<0.1%
	Total		

8. Please identify any administrative concerns/costs associated with this proposed mandate.

	<b>Response</b>
Carrier #1	It could be assumed that utilization would increase and therefore expense as well, if medical necessity review requirements were removed.
Carrier #2	Any potential costs incurred with out-of-network providers.



9. Please provide any other comments or suggestions regarding this proposed mandate.

	<b>Response</b>
Carrier #1	The medical efficacy of these services should be determined and successful education of consumers on the medically appropriate use of this technology should be considered.
Carrier #2	The language above is "Carriers may not impose a copayment or coinsurance requirement for digital tomosynthesis that is greater than a copayment or coinsurance requirement for other breast cancer screenings for which coverage is required under this section; nor impose a deductible for this service. " That adds unnecessary complexity and opportunity for member confusion at adjudication. Member benefits are not set at this level of detail. Diagnostic mammograms are covered under a much broader category of diagnostic services (generally xrays) which in some plans are deductible & coins. Having to exclude 1 specific test from the broader benefit category adds administrative cost to make a unique benefit category or creates member confusion on financial implications of their benefit plan. The vast majority of all mammographies get covered as preventative.

10. How does your coverage typically differ for self-funded plans or, is it typically the same coverage as fully insured plans? If coverage for self-funded plans differs, what is the estimate of the proportion of self-funded plans that cover this benefit to the same extent as fully-insured plans?

	<b>Response</b>
Carrier #1	<ul style="list-style-type: none"> <li>o 100% of our insured and self-insured group medical plans - with just a small handful of self-insured opt-out exceptions – have covered DBT in 2016</li> <li>o Diagnostic DBT covered under medical with cost share</li> <li>o Screening DBT covered under medical with cost share first half of year, then at the preventive level (e.g., 100%) for the second half of the year and going forward.</li> <li>o Only a handful (very small percentage) of self-insured clients have asked not to cover screening DBT</li> </ul>
Carrier #2	Some, but less than half - Typically self-funded and FI plans have similar coverage.
Carrier #3	Typically the same
Carrier #4	Coverage would be the same as fully insured plans



## **Appendix II: Claim Codes**

### **Tomosynthesis CPT/HCPCS Code Table**

77061	tomosynthesis	Digital breast tomosynthesis; unilateral
77062	tomosynthesis	Digital breast tomosynthesis; bilateral
77063	tomosynthesis	Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)
76499	tomosynthesis	Unlisted diagnostic radiographic procedure
76090	mammograms	Mammography; diagnostic, unilateral.
76091	mammograms	Mammography; diagnostic, bilateral.
76092	mammograms	Mammography, screening, bilateral (two view film.
77052	mammograms	Mammogram, Screen/Yearly CAD screening
77051	mammograms	mammogram unilateral CAD Diagnostic
G0202	mammograms	Screening mammography, producing direct digital image, bilateral, all views
G0204	mammograms	Diagnostic mammography, producing direct 2D digital image, bilateral, all views
G0206	mammograms	Diagnostic mammography, producing direct 2D digital image, unilateral, all views
G0279	tomosynthesis	Diagnostic digital breast tomosynthesis, unilateral or bilateral

### **ICD-9-CM CODES Used**

V76.11 Special screening for malignant neoplasm, screening mammogram for high-risk patients
V76.12 Special screening for malignant neoplasm, other screening mammography

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