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March 10, 2023

RE: AN ACT to amend the public health law, in relation to allowing a notice of dense breast tissue to be considered a determination of medical necessity for coverage of a breast ultrasound

A.2516 (Paulin)  
S.2917 (Cleare)

**MEMORANDUM IN OPPOSITION**

Submitted on behalf of the Blue Cross and Blue Shield Plans

The New York State Conference of Blue Cross and Blue Shield Plans opposes enactment of this bill because it is unnecessary in light of existing state and federal requirements. Specifically, this bill would require that, where a provider of mammography services provides notice to a patient that such patient's mammogram demonstrates dense breast tissue, such notice will be considered a determination of medical necessity for the purposes of determining insurance coverage. While the goal of the bill – expediting the provision of a breast ultrasound where a mammogram indicates that a patient has dense breast tissue – is laudable, the Patient Protection and Affordable Care Act (“ACA”) already requires coverage of tests recommended by independent medical experts who regularly review guidelines. Additionally, New York State presently requires coverage in accordance with federally accepted clinical guidelines, and prohibits the imposition of deductibles and copayments for any covered screening and diagnostic imaging for the detection of breast cancer. Finally, as the bill does not restrict its coverage mandate to “essential health benefits” under the ACA, it would result in significant costs to the State.

Since 2010, the ACA has required health plans to cover all screening tests for breast cancer that are designated as “A and B Recommendations” by the United States Preventive Services Task Force (“USPSTF”). The USPSTF is an independent panel of national experts in prevention and evidence-based medicine that promulgates standards in accordance with processes that “align with the National Academy of Medicine’s (formerly the Institute of Medicine) recommendations for

guideline development.”<sup>1</sup> Pursuant to the ACA, insurers must cover such services with A or B Recommendations, which are considered “essential health benefits” and are not subject to copays or deductibles.<sup>2</sup> Current USPSTF recommendations find that “evidence is insufficient to assess the balance of benefits and harms of adjunctive screening for breast cancer using breast ultrasonography, magnetic resonance imaging, DBT, or other methods in women identified to have dense breasts on an otherwise negative screening mammogram.”<sup>3</sup> Notably recommendations regarding breast cancer screenings are presently being updated.<sup>4</sup> This process is indicative of the importance of utilizing USPSTF recommendations for determining coverage of all preventive screenings and tests – namely, to premise such coverage on empirical, clinically based, and peer-reviewed independent guidelines that are revised as our scientific understanding of medical conditions evolves. Since its inception, the USPSTF has proven to be the benchmark for determining appropriate coverage and has directly reduced legislative mandates based on political convenience or activism.

Further, since 2017, New York has required the provision of breast cancer screenings as recommended by the USPSTF and the federal Health Resources and Services Administration (“HRSA”).<sup>5</sup> When covered, such screening and diagnostic imaging for the detection of breast cancer – including diagnostic mammograms, breast ultrasounds, or magnetic resonance imaging – cannot be subject to copayments or deductibles.<sup>6</sup> While ultrasounds are covered when determined to be medically necessary, the State Department of Health has noted that “[g]uidelines vary by organizations and professional societies about the situations in which women, including women with dense breasts, should receive breast ultrasounds or breast MRIs for screening or diagnosis. Research is underway to better define the role of these tests in breast cancer screening and diagnosis.”<sup>7</sup>

For example, in 2021, the American College of Radiology noted that ultrasounds are only “usually appropriate” for average- and intermediate-risk females with dense breasts, and noted disagreement with regard to the former.<sup>8</sup> Similarly, the American College of Obstetricians and Gynecologists stated that, “[w]omen with dense breasts have a modestly increased risk of breast

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1 U.S. Preventative Services Task Force, *Standards for Guideline Development*, available at <https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/standards-guideline-development>.

2 American Cancer Society, *Insurance Coverage for Colorectal Cancer Screening*, available at [https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/screening-coverage-laws.html#:~:text=The%20Affordable%20Care%20Act%20\(ACA,Services%20Task%20Force%20\(USPSTF\)](https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/screening-coverage-laws.html#:~:text=The%20Affordable%20Care%20Act%20(ACA,Services%20Task%20Force%20(USPSTF)).

3 U.S. Preventative Services Task Force, “Final Recommendation Statement - Breast Cancer: Screening,” Jan. 1, 2016, available at <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening>.

4 *Id.*

5 NY Insurance Law §§3216, 3221 and 4303.

6 *Id.*

7 N.Y. Dep’t of Health, “Frequently Asked Questions: Legislation to Improve Coverage for Breast Cancer Screening January 1, 2017,” available at [https://www.health.ny.gov/diseases/cancer/breast/nys\\_breast\\_cancer\\_faqs.htm](https://www.health.ny.gov/diseases/cancer/breast/nys_breast_cancer_faqs.htm).

8 American College of Radiology, “ACR Appropriateness Criteria®: Supplemental Breast Cancer Screening Based on Breast Density,” 2021, available at <https://acsearch.acr.org/docs/3158166/Narrative/>.

cancer and experience reduced sensitivity of mammography to detect breast cancer. However, evidence is lacking to advocate for additional testing until there are clinically validated data that indicate improved screening outcomes.... The American College of Obstetricians and Gynecologists does not recommend routine use of alternative or adjunctive tests to screening mammography in women with dense breasts who are asymptomatic and have no additional risk factors.”<sup>9</sup> Therefore, current law that requires patient notifications regarding dense breast tissue to recommend that such patients “ask [their] doctor if more screening tests might be useful, based on [the individual patient’s] risk” should not be contradicted – as such mandates may result in unnecessary and expensive testing.<sup>10</sup> Further,, it is important to note that USPSTF and HRSA guidelines establish minimum coverage requirements, and ultrasounds following a mammographic determination of dense breast tissue are frequently determined to be medically necessary; and are therefore often covered services that are not subject to coinsurance.

Finally, since this bill does not restrict coverage mandates to screenings as recommended by the USPSTF, this bill could result in significant costs to the State. The Affordable Care Act provides that, while states may require coverage of benefits in addition to essential health benefits, a “State shall make payments (I) to an individual enrolled in a qualified health plan offered in such State; or (II) on behalf of an individual described in subclause (I) directly to the qualified health plan in which such individual is enrolled; to defray the cost of any additional benefits.”<sup>11</sup> Therefore, pursuant to this section, the State would be responsible for the cost of any such screenings to individual and small group commercial insurance products.

For the foregoing reasons, the Blue Cross and Blue Shield Plans urge that this bill not be enacted.

Respectfully submitted,

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Legislative Counsel for the Blue Cross and Blue Shield Plans

4862-2681-2958, v. 2

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9 The American College of Obstetricians and Gynecologists, “Management of Women With Dense Breasts Diagnosed by Mammography: Committee Opinion Number 265,” Reaffirmed in 2020, *available at* <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/03/management-of-women-with-dense-breasts-diagnosed-by-mammography>.

10 N.Y. Public Health Law §2404-c.

11 42 USC §18031(d)(3)(b).