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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.580 (Paulin)
S.3559 (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 the enactment of this bill as it is unnecessary considering existing state and federal requirements to cover breast cancer screenings. 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 for a breast ultrasound. While the goal of the bill – expediting the provision of a breast ultrasound to women with dense breast tissue – is laudable, the Affordable Care Act ("ACA") established a process for determining coverage of tests recommended by independent medical experts who regularly review guidelines. Additionally, New York State presently requires coverage for breast cancer screenings in accordance with federally accepted clinical guidelines and prohibits cost-sharing for any covered screening and diagnostic imaging for the detection of breast cancer.

Since 2010, the ACA has required health plans to cover preventive care and screenings, including those with an "A" or "B" rating from the United States Preventive Services Task Force ("USPSTF") and, for women, additional screenings provided for in the comprehensive guidelines supported by the Health and Resources and Services Administration ("HRSA"). The USPSTF is an independent, volunteer panel of national experts in disease prevention and evidence-based medicine, working to improve health of people nationwide by making evidence-based

recommendations about clinical preventive services.[1] HRSA is an agency of the U.S. Department of Health and Human Services, tasked administering programs to provide equitable health care in the nation's highest-need communities.[2] Pursuant to the ACA (which has been incorporated into New York state law), health plans must cover preventive care services recommended by the USPSTF and HRSA.[3] These two organizations both have recommendations regarding screening for breast cancer, which is covered without cost-sharing as preventive care. The USPSTF recommendations concluded that "current evidence is insufficient to assess the balance of benefits and harms of adjunctive screening for breast cancer using breast ultrasonography, magnetic resonance imaging, DBT [dense breast tomosynthesis], or other methods in women identified to have dense breasts on an otherwise negative screening mammogram."[4] To change the law to require coverage of screenings not currently recommended by USPSTF or HRSA disregards these organizations' expertise in reviewing the medical evidence and making clinically-appropriate recommendations.

Further, since 2017, New York has required that covered 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.[5] 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."[6]

Specifically, 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.[7] Similarly, the American College of Obstetricians and Gynecologists stated that, "[w]omen with dense breasts have a modestly increased risk of breast 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."[8] Therefore, current

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[1] United States Preventive Services Task Force, "About the USPSTF," *available at* https://www.uspreventiveservicestaskforce.org/uspstf/.
[2] Health Resources and Services Administration, *About HRSA*, *available at* https://www.hrsa.gov/about.
[3] 42 U.S.C. § 300gg-13; 45 C.F.R. § 147.130; and N.Y. Insurance Law §§ 3216(i)(17)(E), 3221(l)(8)(E), and 4303(j)(3).
[4] U.S. Preventive Services Task Force, "Final Recommendation Statement - Breast Cancer: Screening," Jan. 1, 2016, *available at* https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening.
[5] N.Y. Insurance Law §§ 3216(i)(11)(F), 3221(l)(11)(F), and 4303(p)(5).
[6] 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.
[7] 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/.
[8] The American College of Obstetricians and Gynecologists, "Management of Women With Dense Breasts Diagnosed by Mammography: Committee Opinion Number 265," Reaffirmed in 2024, *available at*

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.[9] Finally, 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 cost-sharing. That said, those determinations are made on a case-by-case basis, considering the patient's symptoms and risks.

As this bill would expand the scope of benefits required by law by adding coverage for additional screenings that are not currently recommended by the USPSTF or HRSA, this legislation would create an unfunded mandate not just for commercial health insurance, but on the entire State. Under the ACA, the State must defray the full cost of any State mandates that are in addition to EHB for all individual and small group health insurance coverage,[10] meaning the cost of this additional benefit for those markets would be entirely funded by New York taxpayer dollars.

For the foregoing reasons, the New York State Conference of Blue Cross and Blue Shield Plans opposes this bill and urges that it not be enacted.

Respectfully submitted,

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https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/03/management-of-women-with-dense-breasts-diagnosed-by-mammography.

[9] N.Y. Public Health Law § 2404-c.

[10] 45 C.F.R. § 155.170(a).