

Christina C. Clemow, D.O The MetroHealth System HB 371 -Proponent Testimony Senate Health Committee February 9, 2022

Chairman Huffman, Vice Chair Antani, Ranking Member Antonio and members of the Senate Health Committee, thank you for the opportunity to testify in support of House Bill 371 ("HB 371"), a bill that would eliminate disparities in coverage for essential preventive services and ensure patients have access to early screenings and medically necessary detection services for breast cancer. The bill expands an important baseline for how breast cancer screenings will be covered by payers across Ohio.

My name is Dr. Christina Clemow and I am the Division Chief of Breast Imaging and Intervention and a Diagnostic Radiologist at MetroHealth Medical Center in Cleveland, Ohio. MetroHealth is the safety-net health system for Cuyahoga County, caring for the most under resourced members of our community. We employ more than 7,800 people and provide care across four hospitals, four emergency departments, more than 20 health centers, and 40 additional outpatient sites throughout Northeast Ohio. In the past year, MetroHealth has served 300,000 patients with more than 1.4 million visits, with forty percent of the outpatient visits for primary care, while delivering over 2,500 babies. Seventy-five percent of our patients are uninsured or covered by Medicare or Medicaid.

MetroHealth Experience:

Currently, MetroHealth performs over 30,000 breast imaging exams across ten MetroHealth locations in Cuyahoga and adjoining counties annually. We also offer screening services regionally via our mobile mammography van and at regional Discount Drug Mart locations. Screening mammograms are offered through our self-referral program and approximately forty percent of patients seen at the Discount Drug Mart locations are not established with a primary care provider. Forty percent of our patient population is African American compared to the national average of eleven percent. African American women are known to have more aggressive, higher stage breast cancers at diagnosis. Additionally, at MetroHealth twenty five percent of the breast cancers diagnosed are in women under the age of 49 and thirty-one percent of breast cancers are found in women in the 50-59 age group. This points to the importance of annual mammography for women starting in their 40s.

All MetroHealth patients who are found to have dense breasts are given a "Dense Breast Information Card" outlining what it means to have dense breasts, the associated risks, and supplemental screening options for the dense breasted patient. Our MetroHealth patients with dense breasts can receive an automated breast ultrasound (ABUS) supplemental screening exam at the time of their screening mammogram. Alternatively, they may schedule an ABUS exam for a later date. Our breast density notification letters are up to date and notify all women with the Mammography Quality Standards Act (MQSA) required "lay letter" and dense breast verbiage



required by current law is also included, suggesting supplemental screening for patients with dense breasts. We also offer a separate letter insert containing additional information about having dense breasts and scheduling options in an easy-to-read format.

MetroHealth patients are identified as high risk for breast cancer through an inherent Tyrer Cuzick (TC) risk model questionnaire which is completed at the time of the patient's screening mammogram. The goal of the risk assessment is to identify patients who meet criteria for high risk screening breast MRI, patients who may benefit from risk reducing medication, and patients who may carry a pathogenic mutation for breast cancer. The TC model is the most comprehensive and sensitive of all models used to calculate the risk of breast cancer at the population level. Since June 2020, we have identified 2,014 patients that qualify for a high-risk screening breast MRI. We notify all patients of their calculated estimated lifetime breast cancer risk in the mammogram report. If the patients are at high risk for breast cancer, we suggest further evaluation at the high-risk breast clinic and offer supplemental MRI screening to those who qualify.

From our experience at MetroHealth, the key factors that prevent dense breast patients and highrisk patients from receiving additional screening exams include out-of-pocket expenses and lack of education regarding dense breasts and risk of breast cancer, both on the patient and physician referral end. HB 371 addresses patient affordability factors and education.

Support for HB 371:

HB 371 makes important changes to how payers of health care services in Ohio cover screening mammography. The bill would expand current law protections by eliminating required coverage based on age and expanding the definition screening mammography to include digital breast tomosynthesis. The change is appropriate given that the federal Protecting Access to Lifesaving Screenings (PALS) Act passed and is still in effect. The PALS Act postpones recognition of recommendations from the U.S. Preventive Services Task Force (USPSTF) that would limit access to breast cancer screening for women in their forties. At MetroHealth, twenty five percent of breast cancers are identified in women under the age of 49 and one in six breast cancers occur between the ages of 40 - 49 nationally. Arbitrary coverage limits can result in delayed and possible late stage detection for this age group. There is no abrupt change for these women at 50, which is the current task force recommended cut-off.

Additionally, HB 371 would also require coverage of supplemental breast cancer screening exams if the screening mammogram demonstrates that the patient has dense breast tissue, or if the patient is at increased risk of breast cancer. Requiring payer coverage for supplemental screening exams for these qualifying patients would be a huge win. An increase in breast tissue density is associated with an increased risk of breast cancer.¹ Patients with dense breasts have a four-to-six-fold increased risk of developing breast cancer and 40% of all women have dense

¹ Boyd NF, Byng JW, Jong RA et al. Quantitative classification of mammographic densities and breast cancer risk: results from the Canadian National Breast Screening Study. **J Natl Cancer Inst** 1995;87(9):670–675.



breasts.² Although mammography remains the gold standard for screening for breast disease, the sensitivity of mammography is diminished in dense breasts.³ Sensitivity of cancer detection using mammography combined with ultrasound is ninety seven percent.⁴ Furthermore, a recent study found that the addition of ABUS to screening mammography yielded an additional 1.9 detected cancers per 1,000 women screened.⁵ At MetroHealth, the use of ABUS has enabled us to find early invasive and small cancers (< 1 centimeters). The early detection has allowed some patients to avoid systemic chemotherapy. We find that some patients refuse the ABUS out of fear of out of pocket expenses. ABUS is a covered exam that is applicable to the patient's co-pay and deductible. Medicaid does not include cost sharing and Medicare has a \$27 co-pay.

This bill would also support high risk screening breast MRIs for our high-risk population. Currently, twelve percent of our patients have been identified as intermediate or high risk per our new MagView reporting system using the Tyrer-Cuzick (TC) risk assessment model. Since June 2020 we have identified 2,014 patients that qualify for supplemental high risk screening breast MRI. Breast MRI detects two and a half times more breast cancers than a 3D mammogram in women with dense breasts.⁶ The Journal of Clinical Oncology abbreviated MRI for breast cancer screenings study resulted in an additional cancer yield of 18.2 per 1,000 patients.⁷ Furthermore, Kuhl et, al. found that in women with average risk for breast cancer, MRI screening improved early diagnosis of prognostically relevant breast cancers.⁸ Most high risk breast MRI screenings are covered by insurance, but recently at MetroHealth, we've found some women are aging out of this coverage. The bill would ensure coverage of this important life saving exam.

Mr. Chairman, thank you for allowing me to testify today. I urge full support of HB 371.

² Boyd NF, Guo H, Martin LJ et al. Mammographic density and the risk and detection of breast cancer. **N Engl J Med** 2007;356(3):227–236.

³ Mandelson M, Oestreicher N, Porter PL, et al. Breast density as a predictor of mammographic detection: comparison of intervaland screen-detected cancers. J Natl Cancer Inst 2000; 92:1081-1087

⁴ Kolb TM, Lichy J, Newhouse JH. Comparison of the performance of screening mammography, physical examination, and breast US and evaluation of factors that influence them: an analysis of 27,825 patient evaluations. **Radiology** 2002;225(1):165–175.

⁵ Brem RF, Tabár L, Duffy SW, et al. Assessing improvement in detection of breast cancer with three -dimensional automated breast US in women with dense breast tissue: the SomoInsightStudy. *Radiology* 2015; 274:663–673

⁶ Comstock CE, Gatsonis C, Newstead GM, et al. Comparison of Abbreviated Breast MRI vs Digital Breast Tomosynthesis for Breast Cancer Detection Among Women With Dense Breasts Undergoing Screening. JAMA. 2020;323(8):746–756. doi:10.1001/jama.2020.0572

⁷ Kuhl CK, Schrading S, Strobel K, Schild HH, Hilgers RD, Bieling HB. Abbreviated breast magnetic resonance imaging (MRI): first postcontrast subtracted images and maximum-intensity projection-a novel approach to breast cancer screening with MRI. J Clin Oncol 2014;32(22):2304–2310.

⁸ Kuhl CK, Strobel K, Bieling H, Leutner C, Schild HH, Schrading S. Supplemental Breast MR imaging screening of women with average risk of breast cancer. **radiology** 2017;283(2):361–370.