Department of Health and Human Services
Maine People Living Safe, Healthy and Productive Lives
Paul R. LePage, Governor
Mary C. Mayhew, Commissioner

Department of Health and Human Services
Commissioner's Office
221 State Street
11 State House Station
Augusta, Maine 04333-0011
Tel.: (207) 287-3707; Fax (207) 287-3005
TTY Users: Dial 711 (Maine Relay)

January 7, 2013

MEMORANDUM

TO: Senator Margaret M. Craven, Chair; Representative Richard R. Farnsworth, Chair; and Members of the Joint Standing Committee on Health and Human Services

FROM: Mary C. Mayhew, Commissioner

SUBJECT: LD 1886 Resolve Work Group Final Report

Per *LD 1886 Resolve Directing Review of Strategies to Improve Communication between Patients and Physicians,* the designated Work Group convened to address the issue of breast cancer screening in women with dense breast tissue. The Work Group reviewed breast imaging standards, the federal mammography Quality Standards Act, and breast imaging reporting requirements and their impact on reporting of screening mammography results when dense breast tissue is noted by the interpreting physician. The Work Group had a full discussion of issues associated with early detection breast cancer screening options for women with dense breast tissue, with viewpoints from both the patient and health care provider presented. In response to *LD 1886 Resolve*'s directive, the Work Group developed recommended strategies for improving the dialogue between patients and the ordering provider when the screening mammogram demonstrates dense breast tissue.

Enclosed is the Work Group's Final Report that is required to be submitted to the Joint Standing Committee on Health and Human Services.

LD 1886 Resolve Work Group members appreciated the opportunity to discuss the topic of dense breast tissue, and to make recommendations for improved patient-provider communications that will promote the early detection of breast cancer in Maine women.

MCM/klv

Enclosure

Department of Health and Human Services
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RESOLVE

125th Legislature

H.P. 1394 – L. D. 1886

Resolve, Directing Review of Strategies To Improve Communication Between Patients and Physicians

Final Report

Submitted to:

Joint Standing Committee for Health and Human Services

Prepared by:

Department of Health and Human Services

Maine Center for Disease Control and Prevention

Work Group Staff: Maryann Zaremba, Program Manager

Maine CDC Breast and Cervical Health Program

Division of Population Health

STATE OF MAINE

IN THE YEAR OF OUR LORD
TWO THOUSAND AND TWELVE

H.P. 1394 - L.D. 1886

Resolve, Directing Review of Strategies To Improve Communication between Patients and Physicians

Sec. 1. Review and report. Resolved: That the Department of Health and Human Services, Maine Center for Disease Control and Prevention, referred to in this section as "the center," in conjunction with the Maine Medical Association, shall convene a work group to review and report on strategies to improve the dialogue between patients and physicians regarding breast density and breast imaging options. The center shall invite the participation in the work group of representatives of the Maine Osteopathic Association, the Maine Radiological Society, the Density Education National Survivors' Efforts, the Maine Breast Nurse Network, Spectrum Medical Group, a small independent radiographic provider, other radiographic practice groups and hospital-employed radiologists, the Maine Breast Cancer Coalition, the Maine Cancer Consortium, Are You Dense, Inc., the Maine Cancer Foundation, the American Cancer Society and Susan G. Komen for the Cure. The work group shall review breast imaging standards, the federal Mammography Quality Standards Act and breast imaging results protocols and recommend strategies to improve the dialogue between patients and physicians regarding breast density and breast imaging options. The work group shall convene no later than September 1, 2012, and the center shall submit a report with recommendations of the work group by December 7, 2012 to the joint standing committee of the Legislature having jurisdiction over health and human services matters. The center shall perform the work required by this resolve within existing resources.

LD 1886 Resolve Work Group:

Co-Chair
Dr. Sheila Pinette
Director of the Maine CDC DHHS

Co-Chair
Dr. John Benson, FACR, Mt. Desert Island Hospital
Maine Radiologic Society

Work Group Representing Organizations:

American Cancer Society - New England Division
Hilary Schneider, Director of Government Relations and Advocacy
Cheryl Tucker, State Vice President of Health Initiatives

Are You Dense Advocacy, Inc.
JoAnn Pushkin – Founder, DENSE NY, Executive Director – Are You Dense Advocacy, Inc.
(Density Education National Survivors' Effort)

DENSE – Density Education National Survivors' Efforts
Nancy M. Cappello, Ph.D. – President and Founder – Are you Dense Inc.

Maine Breast Cancer Coalition
Pamela Sirois, President

Maine Breast Nurse Network
Elaine Chambers, RN MS, Member, Breast/Osteoporosis Center, Eastern Maine Medical Center

Maine Cancer Consortium
Eileen McDonald, Chair

Maine Cancer Foundation
Tara Hill, Executive Director

Maine DENSE – Density Education National Survivors' Efforts
Barbara Deschenes

Maine Medical Association
Jessa Barnard, Esq. - Associate General Counsel

Maine Osteopathic Association
Angela Westhoff, Executive Director

Maine Radiological Society
Jeffrey A. Young, MD – President

Spectrum Medical Group
Elizabeth Pietras, MD - Division Director, Breast Imaging, Maine Medical Center
Cameron R. Saber, MD, JD, Breast Imaging Specialist, Southern Maine Medical Center
Amy R. Harrow, MD, Section Head, Woman's Center, Eastern Maine Medical Center
Ann Robinson, Preti Flaherty Beliveau & Pachios, LLP

State Representative Meredith Strang Burgess
Maine House District 108

State Representative Terry Hayes (LD 1886 Sponsor)
Assistant Minority Leader
Maine House District 94

Maine Affiliate of Susan G. Komen for the Cure
Regina Rooney, Community Outreach Manager

Western Maine Health/ Stephens Memorial Hospital
Gregory J Hardy, M.D. Medical Staff President

Work Group Meeting Schedule:

1. July 19, 2012 1:00 - 3:30pm See **Appendix A** for Meeting Minutes
2. August 2, 2012 1:00 – 3:30pm See **Appendix B** for Meeting Minutes
3. October 11, 2012 7:00 – 9:00am Consensus on Final Report Language
4.

Goal of Work Group:

To improve exchange of information between patient and provider related to the issue of breast tissue density to allow women to be informed consumers of health care regarding the selection of early detection screening options for breast cancer.

Summary of Associated Factors Reviewed by Work Group:

According to the Maine Center for Disease Control, 1100 Maine women were diagnosed with breast cancer and 184 women died from breast cancer in 2007 (*Maine Annual Cancer Report* 2011 and 2012, Maine Cancer Registry). Maine's numbers are improving: 1091 women were diagnosed in 2008 and 1077 women were diagnosed in 2009. The death rate for breast cancer is also decreasing in Maine, as are death rates for all of the "screenable" cancers (breast, cervical and colorectal cancer). "Screening" refers to tests and exams used to find a disease, such as cancer, in people who do not have any symptoms. Prevention of cervical and colorectal cancer can result from regular screening tests. However, breast cancer is not preventable, and early detection of the disease is critical to our efforts to maximize treatment outcomes and quality of life, while minimizing treatment costs. The decrease in breast cancer mortality is a major medical success and is due in large part to the earlier detection of breast cancer through mammographic screening

The American Cancer Society, American College of Radiology, Society of Breast Imaging and American College of Obstetricians and Gynecologists, among others, recommend that all women have yearly mammograms beginning age 40. Being female, is the main risk factor for developing breast cancer. In addition, a woman's risk for developing breast cancer increases with age. Other risks that contribute to a woman's risk for developing breast cancer include: genetics, family and/or personal history of breast cancer, race, ethnicity, and density of breast tissue.

Breasts are made up of a mixture of fibrous and glandular tissue and fatty tissue. Dense breast tissue is a common finding, found in more than one-half of women younger than 50 years and in nearly one-third of women older than 50 years. Women with denser breast tissue (as seen on a mammogram) have more glandular tissue and less fatty tissue. Breast density is visually determined by the radiologist who reads a mammogram. Breast tissue categorized as "heterogeneously dense" or "extremely dense" contribute to "radiologic masking" or hiding of a tumor, on a mammogram. Due to known limitations of mammography, and an increase in breast cancer awareness, there is an increasing demand for improved breast cancer detection by both the medical community and the general public.

In 1992, the U.S. Congress enacted the Mammography Quality Standards Act (MQSA) to ensure that all women have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages. Congress charged the U.S. Food and Drug Administration (FDA) with developing and implementing MQSA regulations. In 1995, FDA began enforcing MQSA when it initiated an inspection program. FDA has issued several amendments to the comprehensive final regulations over the years.

MQSA requires that all mammography facilities be: accredited by an approved body; certified by the U.S. Department of Health and Human Services (HHS), and; inspected by the HHS, or a state agency acting on behalf of the HHS. The FDA has approved the American College of Radiology as an accrediting body for both screen-film and designated full-field digital mammography systems. In Maine, mammographic facilities are inspected annually by the DHHS/Maine CDC Radiation Control Program for compliance with the Mammography Quality Standards Act. There are currently 58 diagnostic mammographic facilities in the state that have been inspected and certified as complying with the provisions of the Mammography Quality Standards Act.

Related to the reporting of mammography results, MQSA requires:

1. The interpreting physician must prepare a written report containing the results of each examination. This written report, signed by the interpreting physician, must be provided to the patient's health care provider (referring provider) within 30 days of the examination date.
2. The facility must send a written summary of the mammography report to the patient in terms easily understandable by a lay person (i.e., Lay Letter) within 30 days of the examination date. As an approved accrediting body, The American College of Radiology has developed and posted on the ACR website a variety of *Sample Lay Report Letters* that would meet

MQSA reporting standards Attached as **Appendix C** is a copy of the ACR's sample Lay Letter if the mammogram is normal and demonstrates dense breast tissue.
[http://www.acr.org/Quality-Safety/Accreditation/Mammography/Lay-Letters].

Studies continue to demonstrate the positive impact of patient and physician engagement as it relates to improved patient care and lowering of health care costs. However, success is only achieved when both the patient and physician are fully engaged. As required under the FDA's MQSA regulations, all women receive a Lay Letter containing information about the findings of their mammogram. Women can direct questions about the mammogram findings as reported in the Lay Letter to their ordering provider. In general, the "ordering provider" is the woman's primary care provider (i.e. physician, physician-extender, nurse practitioner, etc.) or her obstetrician/gynecologist. At this time, there are no specific recommendations on lowering breast cancer risk for women with dense breasts. There are no special breast cancer screening tests recommended for women with dense breasts. Woman are encouraged to stay actively involved in the management of their breast health by having an annual mammogram starting at age 40, and talking to their health care provider about individual and family risk factors for breast cancer, and which breast cancer screening tests are right for them.

Work Group Definitions:

"Dense breast tissue" is defined as breast composition classified as heterogeneously dense or extremely dense [American College of Radiology BI-RADS breast composition reporting categories].

"Lay Letter" is defined as the MQSA-required mammography report sent to every patient who receives a mammogram that is prepared by the interpreting physician and written in terms easily understood by a lay person.

Work Group Points Of Agreement:

1. Dense breast tissue is very common and is not abnormal.
2. Women who have dense breast tissue do have an elevated risk of developing breast cancer.
3. For women with dense breast tissue, mammograms are still the primary screening tool and secondary screening may be needed in certain situations.
4. Evidence-based best practices for secondary screening options for women with dense breast tissue continue to evolve.
5. Current practice of informing women with dense breast tissue of these facts is inconsistent.
6. Women with dense breast tissue should be informed of these facts.

Work Group Member Concern:

Member American Cancer Society – New England Division participated in the Work Group: has a neutral position on the issue, and does not support or sign onto the recommendations contained in the report.

Work Group Recommended Strategies:

1. Understanding that the ordering provider has the responsibility of communication with their patients regarding the findings of the mammogram, the Work Group recommends Maine CDC and the medical community initiate educational opportunities with local ordering providers regarding dense breast tissue and to discuss the current science associated with screening and follow-up methods appropriate for women with dense breast tissue.
2. Recommends Maine radiologists expand their current mammography report issued to the ordering provider by adding the following or similar language if a woman has dense breast tissue (heterogeneously dense or extremely dense):

   According to recent literature, dense breast tissue composition may be an increased or independent risk factor for malignancy. Consider secondary screening modalities if appropriate.
3. Recommends Maine radiologists modify the mammography Lay Letter to notify and inform patients if their mammogram demonstrates dense breast tissue. The American College of Radiology's *Sample Lay Letter for Negative or Benign Finding(s)* can be utilized or adapted to inform patients about dense beast tissue. Attached as **Appendix C** is a copy of the American College of Radiology's sample Lay Letter if the mammogram demonstrates dense breast tissue.
4. Recommends Maine radiologists notify the ordering provider if his/her patient is issued a Lay Letter with notification her breast tissue is dense, by including a statement in the mammography report which indicates a Lay Letter was sent to the patent informing her the mammogram showed her breast tissue was dense. Further recommends that breast imaging facilities send a sample copy of its current Lay Letter(s) to the offices of ordering providers to ensure they are informed of the language contained in the Lay Letter(s).
5. Recommends the ordering provider initiate a conversation with the patient about breast cancer screening options when dense breast tissue is demonstrated on the mammogram.
6. Recommends appropriate medical societies in Maine address the topic of breast cancer screening options for women with dense breast tissue and other breast cancer risk factors at annual meetings, and to offer continuing medical education opportunities for primary care providers around the topic.
7. Recommends DHHS/Maine CDC website include the LD 1886 Resolve Work Group recommendations, as well as links to evidence-based patient and provider resources and medical references on the topic of breast cancer screening options for women with dense breast tissue and other breast cancer risk factors.
8. Recommends the Maine Hospital Association educate all Maine hospitals about LD 1886 Resolve Work Group recommendations, and assess issues of breast cancer screening capacity as appropriate.
9. Recommends LD 1886 Resolve Work Group issue a formal letter of recommendation to the United States Food and Drug Administration supporting the federal Mammography Quality Standards Act be revised to require reporting of dense breast tissue within the patient mammogram Lay Letter.

10. Recommends Maine FDA Certified Mammography Facilities report to a central entity, such as the Maine CDC Radiation Control Program's MQSA Inspectors, whether their mammogram Lay Letter(s) contains information about dense breast tissue when breast composition is reported as dense (heterogeneously dense or extremely dense).
11. Recommends Maine FDA Certified Mammography Facilities provide to the central entity a sample copy of the Lay Letter issued to women with dense breasts.

Work Group Concerns:

1. Proactive education with ordering providers is necessary and needed prior to implementing the Lay Letters.
2. We cannot ensure every woman with dense breast tissue is notified of the density finding if reporting is not mandated.
3. Medical community currently has not reached consensus on recommended follow-up testing for a woman with dense tissue and a normal mammogram result. Notification of dense breast tissue status in the absence of recommended follow-up testing may cause stress and confusion for both the patient and ordering provider.
4. Concern about making reporting requirements for "dense breast tissue" suggests other conditions represent less of a medical concern.
5. Concern for women with breast composition not classified as dense [American College of Radiology BI-RADS breast composition reporting categories "almost entirely fatty", or "scattered areas of fibroglandular density"], and should their Lay Letter provide information about breast composition and impact on screening mammography for breast cancer.
6. Evaluation strategies need to be developed to monitor improvement in patient/provider communications regarding dense breast tissue.

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Appendix A

Minutes LD 1886 Resolve Work Group

Meeting date July 19, 2012

LD 1886: ***Resolve, Directing Review of Strategies To Improve Communications Between Patients and Physicians***

MINUTES July 19, 2012 Work Group Meeting

Co-Chairs

Dr. Sheila Pinette
Director
Maine CDC, DHHS
286 Water Street
Augusta, ME 04330

Dr. John Benson, FACR
Director, Breast Imaging
Mt. Desert Island Hospital
P.O. Box 8
Bar Harbor, ME 04609

Agenda Item	Action/Outcome
1. Welcome by LD 1886 Co-Chairs Dr. Pinette and Dr. Benson	• Welcome to facility/Maine Medical Association and housekeeping • Electronically distributed references were made available to members attending in person
2. Introductions by Work Group Members	

Organization/Affiliation	Representative	7/19/12 Mtg
LD 1886 Resolve Co-Chair	Dr. Sheila Pinette, Maine CDC, DHHS	in person
LD 1886 Resolve Co-Chair	Dr. John Benson, FACR, Mt. Desert Island Hospital	Webex
American Cancer Society - New England Division	Hilary Schneider, Director of Government Relations and Advocacy	in person
Are You Dense Advocacy, Inc.	JoAnn Pushkin - Executive Director, New York	phone
DENSE – Density Education National Survivors' Efforts	Nancy M. Cappello, Ph.D. – President and Founder, CT	phone
Maine Affiliate of Susan G. Komen for the Cure	Regina Rooney, Community Outreach Manager	in person
Maine Breast Cancer Coalition	Pamela Sirois, President	in person
Maine Breast Nurse Network	Elaine Chambers, RN, MS, Dept. Head, Breast & Osteoporosis Cntr, EMMC	in person
Maine Cancer Consortium	Eileen McDonald, Chair	phone
Maine Cancer Foundation	Tara Hill, Executive Director	phone
Maine DENSE	Barbara Deschenes	phone
Maine Medical Association	Jessa Barnard, Esq. - Associate General Counsel	phone
	Gordon H. Smith, Esq. - Executive Vice President	in person
Maine Radiological Society	John Benson, MD, V.P. Maine Radiological Society	phone
State Representative Meredith Strang Burgess	House Chair, Joint Standing Committee on Health and Human Services	phone
State Representative Terry Hayes	Sponsor, LD 1886	phone
Spectrum Medical Group, Inc	Dr. Cameron R. Saber, MD JD, Breast Imaging Specialist, SMMC	phone
	Dr. Amy R. Harrow, MD, Section Head, Women's Center, EMMC	phone
	Ann Robinson, Preti Flaherty Beliveau & Pachios, LLP	in person
Western Maine Health/ Stephens Memorial Hosp.	Gregory J Hardy, M.D. Medical Staff President	phone
DHHS Legislative Assistant	Denise Gilbert	phone

3. Overview: • Dr. Pinette: - LD 1886 Resolve • Dr. Benson: - Breast imaging standards - Federal Mammography Quality Standards Act (MQSA) - Breast imaging results protocols	• Dr. Pinette read LD 1886 Resolve to ground the Work Group Members to the legislative task of "...review and report on strategies to improve the dialogue between patients and physicians regarding breast density and breast imaging options..." • Dr. Benson reviewed current requirements placed on Maine radiologists, and Maine Radiological Society position on the issue of breast density: - All mammography must be approved by the Food and Drug Administration's MQSA; in Maine, it is commonly achieved by receiving accreditation through the American College of Radiology (ACR). Part of ACR accreditation requirements include a reporting requirement (Breast Imaging and Reporting Data System) for mammogram results, and this system does include reporting categories for "overall breast composition". Per BIRAD reference materials: *For consistency, breast composition should be described for all patients using the following patterns:* 1.*The breast is almost entirely fat (< 25% glandular)* 2.*There are scattered fibroglandular densities (approximately 25-50% glandular)* 3.*The breast tissue is heterogeneously dense, which could obscure detection of small masses (approximately 51-75% glandular)* 4.*The breast tissue is extremely dense. This may lower the sensitivity of mammography (>75% glandular)* - MQSA requires Patient Results Lay Letter with explanation of results and recommended action based on results. Currently, MQSA is silent on requirement that Patient Lay Letter have statement on breast composition. Some Maine radiologists have modified their facility's Lay Letter to include reporting of breast composition. MDI Sample Letter included with Work Group reference materials. - Breast Imagers know breast density is an independent risk factor for developing breast cancer. - Referenced work of Connecticut (CT) radiologist (JW): In study of 8,000 ultrasounds, 28 cancers were detected (3.2/1000), of which cancer was not visible on mammogram. Reported in CT, there is an insurance mandate to cover an ultrasound if the mammogram demonstrates dense breast tissue. - If you tell your patients that they have dense breasts, then next step is to recommend additional imaging options, generally an ultrasound. • Dr. Benson responses to Member questions/comments: - Clarified MDI defines dense breast as composition/density ratings 3 or 4: no idea what percent of Maine facilities include density composition rating on Patient Lay Letter. Action: will send email out to Maine Radiological Society Members to assess what percent of radiologists currently include density in Lay Letter. - Currently no statewide guidelines that allow for automatic referral for screening ultrasound when density 3 or 4. Individual facilities are developing their own standing protocols around this issue: on *Mammogram Requisition Form*, inclusion of box "Reflex Ultrasound if Density 3/ 4". Requires medical staff buy-in; acknowledged staff currently have not reached consensus on guidelines for mammography. Currently, if mammogram imaging is abnormal, radiologists are empowered to conduct a diagnostic ultrasound. - Dr. Hardy commented that radiologists at his facility do not include density rating in Lay Letter due to

	their concern about putting primary care doctors in an awkward situation about recommending further testing given unsure insurance coverage for additional imaging. Dr. Benson acknowledged a conversation between radiologists and medical staff needs to take place to discuss patient, provider and coverage issues.
4. Discussion: • Work Group members: - Suggestions for strategies to improve dialogue between patients and physicians regarding breast density and breast imaging options	Deschenes: Shared personal experience: breast cancer detected late; mammogram reported as normal, with dense tissue; Pen Bay Medical Center also reporting on breast density in Lay Letter; Inconsistencies among Maine hospitals: advocating for all women statewide to receive information about their breast density on mammogram Lay Letter; Referenced sample Lay Letter issued by ACR, and distributed to Work Group members on July 18th: *SAMPLE_BIRADS-12_2_LayLetters_7-18-2012.pdf* Benson: Regarding rural communities: hard to get women to come out for mammogram: education on both mammography and issue of breast density is needed. Informally, noted there is "talk" that MQSA is considering making breast density language a reporting requirement in the Lay Letter Strang Burgess: Original LD language stated "required" regarding inclusion of breast density language in the Lay Letter, but committee members agreed there first was a need to have discussion and education about these breast cancer detection issues. Intent of Resolve was to ensure this statewide discussion was promoted and "moved along." Shared personal experience: breast cancer detected late; mammogram reported as normal, with dense tissue. Chambers: Inquired into CT experience: following passage of mandated benefit, was there any issues related to access for the screening ultrasound? Are there lessons learned in planning to ensure women have access to the recommended screening ultrasound? Cappello: Shared personal experience: also diagnosed with late stage breast cancer and had dense breast tissue; Supports mammography: first line of defense against breast cancer. CT, 2005 - passed insurance bill mandating coverage of whole breast ultrasound when mammogram normal, but composition dense. Problem: many facilities were refusing to conduct whole breast ultrasounds; turning patients away; lack of knowledge about legislation, all of which resulted in the need for extensive education around the mandate and breast density to be conducted for the next four years. Lessons learned: much planning and communication between imaging facility and referring doctor is needed to fully address all the associated issues that come with the legislation. Benson: Does not anticipate huge access problem: change will come gradually, both on part of imaging facility, referring provider and patient, resulting in "baby steps" toward change. Acknowledged variance in technologists, readers and technology among Maine facilities to handle demand for screening ultrasounds.

	Robinson:	Concurred on concern about access, per her understanding of CT experience. Questioned the validity of the cancer predictive value [per Dr. Benson "...low...30% range..."] that resulted from the additional imaging and biopsies as reported in CT, and asked clinicians to comment. Per the LD 1886 hearings, recalls concern about those women receiving a Lay Letter that does not report dense breast tissue because their composition rating represented fatty tissue (i.e. rating of 1/ 2): did this represent a false sense of security to these women?
	Saber:	Confirmed there is controversy over an acceptable screening threshold: trend is toward more ultrasound and MRI, depending on the woman's risk and history. Confirmed concern about liability and false sense of security when reporting 1 / 2 density ratings. Suggested we deal with lack of specificity around screening ultrasounds and evaluate this issue as we proceed. For now, suggested we proceed with inclusion of density rating in Lay Letter and have it play out.
	Benson:	Commented that "benign biopsies" are not "unnecessary biopsies": there is no perfect imaging test and there will be false positives.
	Saber:	Recommends we are all on the "same page" when density information included in the Lay Letter, especially as it pertains to primary care providers and hospitals. Concerned the onus will fall on the PCP to communicate with the patient about risk factors and need for additional testing. Should breast imagers perform screening US on women with density 1 and 2? Or limit to those with only density 3 and 4? Need to develop recommendations so primary care providers can make consistent referrals and maintain trust level with radiologist.
	Pinette:	Ask the Group if the recommendation should be: If your radiologist includes information in your Lay Letter that your breast tissue is dense, then the mammography facility will provide a formatted letter with recommendations for the patient to advocate for available breast cancer screening options? Suggested another recommendation could be for radiologist to consider development of a "call-back" system depending on the mammogram/density reporting so the onus is not on the referral provider or woman: this is similar to the gastrointestinal call-back system used when polyps are found during a colonoscopy. Also suggested the Maine CDC could prepare materials about dense breast tissue and its impact on breast cancer detection.
	Robinson:	Noted during the original legislative hearing, there was recognized concern about the differences between including "informational " language in the Lay Letter, versus including a specific "recommendation" for additional testing.
	Harrow:	Question: is the Group suggesting if density categorized as 3 or 4, is the mammogram result categorized as BIRAD 0: Need additional imaging evaluation and/or Prior mammogram for comparison?
	Benson:	No, because the mammogram is not considered abnormal. Referral for a screening ultrasound

		would simply be a suggestion. Referenced earlier discussion about a "Reflex order" on Mammogram Requisition. Once a PCP bought into the recommendation, then checking the "Reflex order" automated the referral.
	Hardy:	Suggested the possibility of empowering the radiologist to perform additional imaging as deemed necessary, although logics of such a suggestion are not known.
	McDonald:	Requested members from CT to discuss their extensive education efforts that went into this campaign, and what lessons could be learned from the experience regardless of the legislative end of the campaign.
	Cappello:	Recommended the Work Group or Maine Radiological Society invite CT radiologists to address Maine on issues associated with lessons learned and implementation of these dense tissue recommendations. The primary goal was always to ensure application of the recommendations was consistent across the state, regardless of geographical location, radiologist or referring provider.
	Chambers:	What materials did CT use to educate the referring provider?
	Cappello:	Described education efforts conducted by the CT Radiology Groups with primary care and referring providers around the topic of dense breasts. The CT Radiological Society played an early lead in the discussions as well. Regarding the USPSTF recommendations for mammography, breast health leadership in CT called a meeting and reached unanimous consensus that screening mammograms should continue to be recommended for women age 40 and older on an annual basis. Since implementing the dense breast campaign in CT, the state has reported an increase detection rate for early, small, node-negative cancers.
	Pushkin:	NY bill on Governor Cuomo desk waiting to be signed: if passed, NY has drafted education materials for women that they would be willing to share. Questions were asked about references used in preparing the education materials, as well as costs. <u>Action</u>: Ms. Pushkin will research.
	Benson:	Suggested if Work Group is in agreement, then details about public relations, education materials and service announcement could be included in the list of recommendations coming out of the Work Group.
	Sirois:	Explained the Maine Breast Cancer Coalition's Support Service Fund and availability to individuals with access and coverage limitations. How will these costs be covered if we go forward with this new recommendation?
	McDonald:	Do not underestimate the magnitude of the efforts needed to address the issue of coverage for these additional services. The Cancer Consortium heard concern from members about this topic, largely around the issue of coverage, especially in rural areas of the state.
	Zaremba:	Clarified that the Breast and Cervical Health Program (MBCHP) is allowed under federal guidelines to cover additional imaging when the mammogram is abnormal: if the mammogram is reported to be normal, regardless of dense composition, an ultrasound would not be covered.
	Schneider:	Requested we clarify the comment that Medicaid and Medicare currently cover ultrasounds: is

		it because they are allowed services, or is the screening mammogram being coded as abnormal?
	Hardy:	Confirming frequent denials for ultrasounds when not based on abnormal mammogram at his facility.
	Saber:	To secure buy-in with our primary care providers on this recommendation, the issue of guaranteed coverage will be a concern. Coverage mandate may be a goal of the group, but not under current Resolve language.
	Schneider:	Per Resolve language to "...improve the dialogue between patient and physicians regarding breast density and breast imaging options..." the issue of patient cost does need to be discussed if improvement is going to be achieved. Maine's experience with the mandated benefit for screening colonoscopies was referenced: patient's reported when they had a colonoscopy, and a polyp was removed, the procedure was coded as diagnostic, and coverage was denied. Accordingly, under Maine law, polyp removal during a colonoscopy must be billed as a screening procedure, and fully covered by a health plan. Coverage is a critical piece to a patient's informed decision making process.
	Benson:	If there is any place for legislation in this discussion, it does seem we could advocate for coverage of screening ultrasounds.
	Schneider:	Noted the Maine Legislature did not pass any insurance mandates last year, and refused to do so until Maine identifies an essential Health Benefits package under the Affordable Care Act. Once established. Of an insurance mandate goes beyond the package, the State would be responsible for the service.
	Burgess:	Reminded the members: there is no pending legislation, but a Resolve with recommendations. What can we do without legislation, but with education, to get providers on the same page, and to inform patients about the issue of dense breast tissue through the Lay Letter? Suggested someone from the Bureau of Insurance could speak with the Group, and/or lobbyists from Maine's health insurance plans could also be invited to hear our recommendations and concerns.
	Robinson:	Bill evolved into a Resolve because there was recognition that a mandatory letter, as well as a mandated benefit, was premature and more discussion and analysis of the literature was needed before the legislature was requested to go that next step; Urged the Group not to formulate recommendations today, but to proceed with additional discussion and additional organizations invited to the table; As an additional conversation, radiologists need to weigh in on the question: is the science behind screening ultrasound being a predictive tool for breast cancer diagnosis worthy of mandating coverage for the service?
	Saber:	Screening ultrasound is useful and helpful to the radiologist in screening for breast cancer in women with dense breasts. But, if the question is has screening ultrasound been vetted and proven to be a sensitive test worthy of mandated coverage, we are not there now, but it is certainly a direction we can work toward.

	Deschenes:	Recalled process used following public hearing and discussion and negotiated the Resolve, and wording was chosen because the first step was education. Personal goal is clearly legislation. We need to find a way to inform women of risk: second priority is coverage.
	Benson:	Suggested an announcement from this Group would carry a lot of weight, and perhaps be better than legislation that dictates physician behavior
	Pushkin:	DENSE is looking for "standardized" education given to all women in the state.
	Benson:	Preference would be to have all imaging facilities adopt a Lay Letter which includes language about breast density without legislation. If MSQA adopts the SAMPLE letter currently drafted by ACR, future discussion will be unnecessary.
	Harrow:	Breast density is subjective as classified by a radiologist; Completely supported patient education and recommendation to provide women with best options, but needed to acknowledge not all breast ultrasound is created equal and very operator dependent; Supported need for patient education, but have concerns about mandating by law. Currently has encountered problems in ordering both screening mammograms (when conflicting with USPSTF guidelines), as well as a screening ultrasound.
	Benson:	Reinforced comment about "operator" variability, and suggested there could be additional education for radiologists and technicians on proper methods and standards on ultrasound practice.
	Hardy:	Physicians have an obligation to inform patients about their risks, including breast density. We are all part of bigger health systems, perhaps we can make a System's policy change to improve patient care?
	Pushkin:	DENSE is tackling this issue on two fronts: (1) on the federal level, requesting the topic be included at the latest MQSA review committee; head of Committee suggested this could take years on the federal level and encouraged state level efforts in the meantime. It was noted that the ACR Sample Letter was only a suggestion, and could not be federally mandated. (2) Federal bill (HR 3102) has also been entered, and currently meeting with senate sponsors to move forward.
	Pinette:	Action: Encouraged members to submit strategies for consideration at the 8/2 meeting to Maryann Zaremba (maryann.m.zaremba@maine.gov) Action: Invite Bureau of Insurance to next meeting, as well as insurance industry lobbyists H. Schneider will provide contact information for lobbyists.
	Benson:	Action: will be discussing the issue within his breast imaging team at MDI about getting word out in and will send some blast emails to Maine Radiological Society membership around the issue
	Chambers:	Action: Recommended Maine Primary Care Association and Mid-Level Practitioners are invited to next meeting. J. Barnard will provide contact information for Pam Cahill.
	Schneider:	Action: Recommended Maine Hospital Association also receive an invitation to the next meeting. Dr. Benson noted Art Blank, MDI CEO is the new MHA Board of Directors Chair.

	Hayes: Thanked all members for their contributions to conversation, and hopes to be at the 8/2 meeting. Pinette: Action: Adjourning meeting
5. Next Meeting of LD 1886 Work Group:	• Thursday August 2, 2012 1:00 – 3:30pm – Maine Medical Association (Webex will again be offered for members who cannot attend in person.) - Meeting agenda will be to review strategies and make recommendations for Work Group report

Appendix B

Minutes LD 1886 Resolve Work Group Meeting

Meeting date August 2, 2012

LD 1886: ***Resolve, Directing Review of Strategies To Improve Communications Between Patients and Physicians***

MINUTES August 2, 2012 Work Group Meeting

Co-Chairs

Dr. Sheila Pinette
Director
Maine CDC, DHHS
286 Water Street
Augusta, ME 04330

Dr. John Benson, FACR
Director, Breast Imaging
Mt. Desert Island Hospital
P.O. Box 8
Bar Harbor, ME 04609

Agenda Item	Action/Outcome		
▪ **Introductions by Work Group Members and Invited Guests**	Organization/Affiliation	Representative	8/2/12 Mtg
	LD 1886 Resolve Co-Chair	Dr. Sheila Pinette, Maine CDC, DHHS	In person
	LD 1886 Resolve Co-Chair	Dr. John Benson, FACR, Mt. Desert Island Hospital	Webex
	American Cancer Society - New England Division	Cheryl Tucker, State Vice President of Health Initiatives	In person
		Terry Baker, Community Executive, Health Initiatives	In person
	Anthem Insurance Companies, Inc.	Kristine Ossenfort, Lobbyist	In person
	Are You Dense Advocacy, Inc.	JoAnn Pushkin - Executive Director, New York	Webex
	Bureau of Insurance/ Department of Professional and Financial Regulation	Joanne Rawlings-Sekunda, Health Policy Analyst	In person
	DENSE – Density Education National Survivors' Efforts	Nancy M. Cappello, Ph.D. – President and Founder, CT	Webex
	Maine Affiliate of Susan G. Komen for the Cure	Regina Rooney, Community Outreach Manager	In person
	Maine Breast Cancer Coalition	Pamela Sirois, President	In person
	Maine Breast Nurse Network	Elaine Chambers, RN, MS, Dept. Head, Breast & Osteoporosis Cntr, EMMC	Webex
	Maine Cancer Consortium	Eileen McDonald, Chair	Webex
	Maine Cancer Foundation	Tara Hill, Executive Director	Webex
	Maine DENSE	Barbara Deschenes	In person
	Maine Hospital Association	Sandra Parker, VP and General Counsel	In person
	Maine Medical Association	Jessa Barnard, Esq. - Associate General Counsel	In person
	Maine Osteopathic Association	Angela Westhoff, Executive Director	In person
	Maine Primary Care Association	Caroline Zimmerman, Director of Health Initiatives	Webex
	Maine Radiological Society	John Benson, MD, V.P. Maine Radiological Society	Webex
	State Representative Meredith Strang Burgess	House Chair, Joint Standing Committee on Health and Human Services	Webex

	State Representative Terry Hayes	Sponsor, LD 1886	In person
	Spectrum Medical Group, Inc	Dr. Elizabeth Pietras, MD, Div. Director, Breast Imaging, MMC	In person
		Dr. Cameron R. Saber, MD JD, Breast Imaging Specialist, SMMC	In person
		Dr. Amy R. Harrow, MD, Section Head, Women's Center, EMMC	Webex
		Ann Robinson, Preti Flaherty Beliveau & Pachios, LLP	In person
	Western Maine Health/ Stephens Memorial Hosp.	Gregory J Hardy, M.D. Medical Staff President	Webex
	DHHS Legislative Assistant	Denise Gilbert	Webex

• **Dr. Pinette:** - **Review of LD 1886 Resolve** - **Review of highlights from 7/19/2012 Workgroup Meeting** - **Review of goals for 8/2/2012 Workgroup Meeting**	• Pinette reviewed Resolve with Work Group members. • Pinette: referenced 8/1/2012 email to Workgroup members with Summary of Minute Highlights from July 19th workgroup meeting: 1. Current ACR reporting guidelines for breast imaging providers relating to breast tissue composition; 2. ACR Sample Lay Letter with optional language to include if mammogram results are Negative/Benign, but breast tissue density categorized as "heterogeneously dense" or "extremely dense"; 3. Dense breast tissue is very common and not abnormal, but can make it harder to find cancer on a mammogram. High breast tissue density is considered a risk factor for the development of breast cancer; 4. Personal stories from women who reported having normal mammogram readings, and subsequently were diagnosed with late-stage breast cancer; 5. Unknown how many breast imaging facilities in Maine have initiated dialogue with their medical staff to discuss adoption of modified Lay Letter when breast tissue is dense; 6. Primary care providers will primarily be responsible for counseling women on follow-up testing recommendations associated with dense breasts; 7. To ensure consistent and appropriate referrals across the state, recommendations are needed for follow-up testing when mammogram reported as normal with dense tissue; 8. Coverage for follow-up testing must be addressed if women receive notification that they have dense breast tissue. • Goal for 8/2nd workgroup meeting will be the development of a set of recommendations and strategies to improve communications between patients and physicians that will be included in report submitted to the Legislature's Health and Human Services Joint Standing Committee by 12/7/2012: a draft report must be submitted to the DHHS Commissioner one month prior for final review (11/7/2012). At end of meeting, decision will be made if an additional meeting is needed, or if review of 8/2nd minutes, and draft recommendations can be conducted electronically. It was noted that only one workgroup member submitted written recommendations as requested for discussion at the 8/2nd meeting. • Requested approval of the 7/19th Minutes and Summary of Minute Highlights: Work Group member responses: Hayes: In response to Summary Highlight #8 [*Coverage for follow-up testing must be addressed if women receive notification that they have dense breast tissue*], noted that coverage for follow-up testing is beyond the scope of LD 1886.

	Benson: Acknowledged coverage is not part of Resolve, but coverage is part of discussion that needs to take place between patient and radiologist if additional testing is recommended for women with dense breast tissue. Chambers: Coverage is a real issue for Maine women. Benson: Checked with Business office: all screening breast ultrasounds have been covered, although number is small: Clinical Indication was dense breasts/family history. Robinson: Supported distinction between coverage as issue between patient/providers, but possible recommendation from Work Group addressing coverage was totally outside the scope of the Resolve. Hayes: Focus should be on "information flow": regardless of insurance coverage, same information should be shared between provider and patient, allowing the woman to be an informed consumer of health care. Physicians should not be withholding information from patients based on insurance coverage: issue of coverage at this point is "too far down-stream". Pinette: As an internist and primary care provider: noted no physician would withhold information from a patient, but did acknowledge the dilemma that is created for patients once the information is given and additional testing is recommended to patients without insurance coverage. Benson: Noted radiologists are unaware of a patient's insurance status when the mammography report and lay letters are produced. Deschenes: Refocused on Resolve language: noting the emphasis on the "informed piece" of the issue, and noting it does not address any aspect of the insurance. Every woman has the right to know the density of her breasts: goal of legislation is to have every woman informed on this topic. Education of both providers and patients on this issue is a good start. Pinette: In light of continued discussion, recommended Summary Highlight #8 not be changed. Motion to accept Minutes as prepared was made and seconded: no opposition was reported. Minutes from 7-19-2012 were accepted.
▪ **Opportunity for Comment/Feedback from invited guests to the Work Group**	• Based on discussion at the 7/19th Work Group meeting, representatives from Maine Hospital Association (MHA), Maine Nurse Practitioner Association (MNPA) and Maine Primary Care Association (MPCA) were invited to address the Work Group. These representatives were allowed to provide introductory comments and accept questions from the Work Group: <u>Maine Hospital Association:</u> Parker: Thanked the Work Group for the invitation to be included in the discussion. In reference to the 7/19th Minute Summary Highlight #7 [To ensure consistent and appropriate referrals across the state, recommendations are needed for follow-up testing when mammogram reported as normal with dense tissue], questioned if this recommendation was also within the scope of the Resolve: it was clarified that Minute Summary Highlights were not Work Group recommendations. Benson: At the 7/19th meeting, the issue of access to ultrasound screening services came up as an issue. As most ultrasounds are conducted in hospitals, the Work Group wanted to ask the MHA if hospitals had enough machines, trained sonographers, and trained radiologists to handle the increase in demand for screening ultrasounds. Parker: Unable to respond to hospital capacity questions, but will share the concern with MHA members. Hayes: How would the Work Group get a handle on hospital "capacity" to address a possible increase in demand for screening ultrasounds?

	Pietras: Using Maine Medical Center as an example: approximately 20,000 mammograms conducted over past year; of which, estimated 40-50% reported dense breast tissue. Time involved for a screening mammogram takes on average 15 minutes; for a screening ultrasound, depending on sonographer with radiologist review, takes 30-60 minutes. Assuming this volume of demand over the next six months, capacity would be an issue. Hayes: Then for the Work Group, "phased-in" follow-up recommendations should be considered? Pietras: From a radiologist's perspective, reported there are a variety of current and future imaging options that could be considered as follow-up options depending on the individual needs of the woman with dense breasts: ultrasound is only one of these options. Concerned about making specific recommendations for all women with dense breast tissue that may be limiting in follow-up options and even short-sighted given the current advances being made in nuclear medicine. Also important not to overlook the role of a clinical breast exam (CBE) and breast self exams (BSE) as follow-up options for women with dense breasts. Hayes: Clarified legislation was not intended to define the "next steps" to follow once a woman knew she had dense breasts: the goals were to have the woman be a partner/participant with her providers in the selection of the follow-up option. Pinette: Concurred clinical follow-up guidelines should not be included in Work Group recommendations, but believes the "next steps" should involve conversation between the woman and her primary care provider (PCP) and/or radiologist. Rooney: Asked if any work group participants have had a such a conversation with their PCP/radiologist, so we can learn what that conversation would "look like" and possible recommendations for improvement. Hardy: Issues of insurance and capacity are "ahead of ourselves." In personal practice, sees increasingly more mammography reports indicating the breast tissue is dense, but currently not addressing issue of density with patient. Suggests the question is who does the talking with the patient, and how does she get informed? Hayes: Shared personal story: reported she has annual mammograms and did not know if her tissue was dense: initiated conversation with her PCP, who reviewed the full mammogram report with her and discussed in detail. PCP indicated a patient has never asked the question previously. Hardy: This needs to change: providers reading the mammography report need to initiate the conversation. Deschenes: Shared she had been told she had dense breasts, but had not been told about the impact dense tissue has on a mammogram reading. Noted there is much information distributed about early detection, screening mammography, but not density and the potential that dense tissue can hide a breast tumor. Pinette: Aggressive tumors will be missed in younger women with dense breast tissue. With the 2009 United States Preventive Services Task Force (USPSTF) recommendations stating women age 50 and older should receive screening mammography biennially, tumors may go undetected in younger women in their 40's. <u>Maine Nurse Practitioner Association</u>: Not present nor on phone. <u>Maine Primary Care Association</u>: Zimmerman: Thanked the members for the invitation to address the Work Group. Acknowledged the role of primary care physicians in the role of patient education is huge, with the primary goal to provide the highest quality patient care. After reviewing the 7/19th Minutes, supports the suggestion to:

standardize educational information; share patient letters from imaging providers with PCPs to ensure the provider knows what the woman has received regarding dense tissue; keeping PCPs current with imaging recommendations for breast cancer screening and follow-up testing. Regarding patient engagement, many primary care practices around the state are involved in the Patient Centered Medical Home movement, which will also enhance improved provider/patient communications. Acknowledging health insurance coverage is beyond the scope of the Resolve Work Group, but assured the members that both access and coverage for follow-up tests will be an issue with both providers and patients.
Work Group members did not have specific questions for MPCA.

Bureau of Insurance / Maine Department of Professional and Financial Regulation

Rawlings-Sekunda: Formerly ignorant to the issue, and here to listen. Was concerned that the Work Group was proposing to recommend coverage for follow-up testing, but will now share with the Bureau that this recommendation is not under consideration by the Work Group.

Barnard: Are you aware of any plans/policies in Maine that do cover follow-up services such as ultrasounds, and other imaging options?

Rawlings-Sekunda: No, that level of detail by plan is not available. Reminded members about issues associated with the State's Essential Health Benefits (EHB) which were established in March 2012 under the Affordable Care Act, and noted any new state mandates would end in 2014, or need to be covered by the State.

Anthem Insurance Companies, Inc.

Ossenfort: Concurred, that potential of insurance mandate was outside the scope of the Resolve.
Noted that the Resolve did identify members to the Work Group, and recommended the newly invited participants be referred to as "interested parties"; "stakeholders" or "invited guests".
Also noted there are differences between an individual company's coverage policies and those policies established by self-insured plans: self-insured plans are not required to comply with insurance mandates.

Pinette: Asked a question from 7/19th meeting: are there additional reimbursement codes for ultrasound procedures?

Benson: Reported there is only one procedure code for ultrasound.

Chambers: Clarified the question was related to coverage for the single procedure code if the "Clinical Indication" was listed as "screening."

Deschenes: In regard to expenses, asked the members to consider the cost of a late-diagnosis of breast cancer: noting early detection would save lives and money.

Aetna Health Inc.: Not present nor on phone.

Cigna: Not present nor on phone.

Harvard Pilgrim Health Care, Inc.: Not present nor on phone.

	Maine Osteopathic Association	
	Westhoff:	Reported she was out-of-town for 7/19th meeting: no specific comments to add at this time. Regarding the general topic of doctor/patient communication, MOA is involved in continuing medical education (CME) opportunities for osteopathic providers, and supports the role of standardized CME to improve communications on the issue of breast density.
▪ **Recommendations and Strategies to Improve Communications between Patents and Physicians**	Pinette:	Reminded Work Group members that at the 7/19th meeting, it was recommended that the Sample Lay Letter prepared by American College of Radiologists could be recommended for adoption by imaging providers for women with dense breasts.
	Benson:	Suggested Work Group distribute Sample Lay Letter to all appropriate physicians statewide with recommendation to adopt same or similar model for informing women about dense breasts.
	Hayes:	Expressed concern that Work Group "encouragement" would not ensure standard notification to all women with dense breasts. This would mean notification would be discretionary by physician. How would we ensure all women receive the notification?
	Robinson:	Questioned if Resolve Work Group could require standard language; suggested that would require legislative approval.
	Hayes:	Unsure if we are prohibited from making the recommendation to have legislation around Lay Letter notification of dense breast. If we are, what else could we recommend that will achieve our goal of ensuring all women be informed of her breast density status? Uncomfortable with the use of the term "encourage".
	Robinson:	Could use "strongly encourage." As this is the first step in educating providers and patients on the topic, could assess imaging providers: how many are sending out Lay Letters with reference to breast density now, and assess same again in one year.
	Chambers:	Issuance of Lay Letter to the woman would be the only way we could ensure density information was provided. Asked Dr. Benson for feedback from Maine Radiological Society (MRS) members regarding this issue.
	Benson:	Reported he received full range of responses: some practices have already adopted a letter and inform patient; some practices not supporting the immediate follow-up with ultrasound based on the density assessment, and: some practices currently assessing and reviewing the issue at their facility.
	Chambers:	Inclusion of dense information in Lay Letter would partially meet the Resolve goal: still have the issues of assisting referring providers with appropriate information to communicate follow-up options with patient. Did MRS members comment on that issue?
	Benson:	That could also be a recommendation from the Work Group: perhaps "…facilitate the education of referring providers of these patients..." Noted members of his facility did not know breast density was a risk factor for breast cancer.
	Deschenes:	Citing the Connecticut experience, if the "positive" of mandated reporting would be an increase in early-stage cancers, what is the "negative."
	Benson:	Organized medicine in general is against "mandated behavior" and detracts from the art of practicing medicine.
	McDonald:	Concerned about the practical side of mandating "communications." As the scientific evidence changes and the message needs to be revised, who is responsible for updating the legislation in a timely manner?
	Cappello:	Reviewed the legislative activities in both Connecticut, and recently New York, to mandate reporting of dense tissue to ensure all women receive this information. Also reviewed the 1992 enactment of the

		MQSA reporting standard for all women to receive a Lay Letter with the results of the mammogram because the voluntary reporting approach did not work.
	Pushkin:	Commented that per the New York legislation, multiple drafts of the mandated reporting language were reviewing to address concerns about scientific evidence and settled on "conditional and informative" language.
	Rooney:	Noted "mandated" language can include any degree of specificity about "density" as a risk factor for breast cancer.
	Barnard:	What other conditions have mandated reporting and mandated follow-up? Cited many ongoing efforts to improve both patient and provider education around specific clinical conditions and treatment options, of which no reporting mandates have been involved.
	Hayes:	In an effort to consolidate ideas that have been raised, suggested the following: ▪ Common goal: achieve early detection and treatment of breast cancer ▪ Suggested activities: informing patients; providing info to patients, and educating providers ▪ Suggested tools: legislation; Lay Letter; minimum standards of practice; Continuing Medical Education (CME) modules. ▪ Dictation of "follow-up" steps is not necessary.
	Benson:	Given that the Lay Letter is already mandated by MQSA, not in support of an additional reporting mandate for the Lay Letter.
	Pietras:	As stated, radiologists are currently mandated to provide detailed mammography reports which include reporting of dense breast composition (3 and 4) to the referring provider. In addition, a Lay Letter is issued to the woman with the mammography results. For Spectrum Medical Group, modifications to this Lay Letter could be conducted for the Group's radiologists. We still have ongoing issue of changing addresses, and letters are returned despite efforts to obtain current contact info. Concerns about mandated reporting for one condition suggests other conditions less of a concern.
	Saber:	Regarding screening breast ultrasound, the community of radiologists and breast imaging providers has not come to consensus/specific recommendation on screening ultrasounds. The real issue for the referring provider is how to provide guidance in the absence of specific "next steps": this may produce stress and confusion for both patients and providers.
	Hayes:	Medical advice can be presented as options: understands there are no "black and white" scenarios. Recommends info not be withheld due to fear of increasing patient stress.
	Hardy:	Used example of screening women for ovarian cancer for which there is a lack of clear guidelines on "next steps." Very comfortable providing patient with options, and allowing them to make final decision on how to act on the screening results.
	Pietras:	I want to know how we are going to reach all the practicing physicians in Maine around this issue. Mammography is the gold standard for screening for breast cancer: it does not work as well in some patients because of their breast tissue. In these cases, we need to discuss if the woman has other risk factors for breast cancer; what things she can do on her own to reduce those risks; and what other tests may be appropriate to ensure we would find a developing cancer at the earliest stage. Radiologists are on board with sharing the information, but we need to have the discussion with referring providers as to how they are going to have informed conversations with their patients around this issue.
	Deschenes:	Asked for clarification: how can a mammogram result be "normal" when there is dense tissue? Are mammograms still beneficial for women with dense breasts? Shared her personal story: had a "normal" mammogram in November; in December she was diagnosed with a 4 cm breast tumor using ultrasound.

	Pietras:	Briefly commented on impact of dense tissue when reading a mammogram, as well as currently required follow-up testing for women with abnormal mammogram results. Noted even with dense tissue, breast cancers can be seen and detected and still should be recommended for women with dense tissue.
	McDonald:	Suggested the Work Group is in agreement that education around this issue is needed for primary care providers.
	Hayes:	Reviewed possible "tool" for achieving Work Group goal was "voluntary adoption of Lay Letter". If we recommend voluntary adoption of the Lay Letter with dense tissue language by Maine's approximate 200 radiologists, when and how can we measure if this is adequate and sufficient?
	Benson:	How are other states mandating the language enforcing the law?
	Pushkin:	Because it is law, identified non-compliance is fined. No infraction specifics were known.
	McDonald:	Desired outcome is really "educated and informed women": how are we going to measure that?
	Cappello:	Added we should also measure increase in early stage, node-negative cancers.
	Hayes:	Can we count the number of women with dense breasts who receive the letter, and how many did not - by imaging provider? That is more important than measuring what happened once they got the information.
	Pietras:	Yes, counting of letters is doable. Clarified the same Lay Letter with dense breast option would be sent to women with density of 3 and 4. Concern expressed about women with fatty breast tissue (density 1 and 2): should their Lay Letter have more clarification about limitations of mammogram?
	Robinson:	Expressed concern if Lay Letter to patients with density 1 and 2 does not make reference to the issue of breast density, doesn't this suggest to the woman her breasts are not dense and an adequate image of the breast was obtained to screen for cancer? Seems the only way to actually measure if "dense woman" got the information would be to conduct medical record review.
	Pinette:	Questioned if the radiologist's electronic reporting systems are able to be queried to assess the number of mammograms read with density 3, 4 and Lay Letters were issued?
	Benson:	Each facility has different electronic systems, and generally not able to be queried.
	Barnard:	Do we need to monitor the providers? If we give professional credibility to the practices to adopt the Lay Letter, perhaps a simple annual or biennial email asking practices if they are including the density information in their Lay Letter would be sufficient. Also, if patient education is also implemented, then this will also enforce the practice of including dense information in the Lay Letter.
	Rooney:	Reminded the Group that density determination is subjective, and this issue needs to be referenced as we develop recommendations. Also reminded the Group that the Lay Letter alone is not education.
	Pietras:	Confirmed that there is variability between providers in determining density, as well as variability within an individual woman over the course of her imaging years (40 – 74) depending on a variety of medical scenarios.
	Benson:	In response to Hayes request, reviewed the Mammography Quality Standards Act was signed into law in 1992 (and implemented in 1994). The Act mandated mammogram result reporting to both the referring provider and Lay Letter to woman because of inconsistent and poor quality practices among breast imagers.
	Pinette:	Suggested Lay Letter should be mailed to both patient and referring provider.
	Benson:	Work Group recommendation could include variety of suggestions to improve communication between patient and primary care provider including: ▪ Radiologist will issue Lay Letter to both patient and provider

		▪ Educational opportunities for referring provider on breast density and other risk factors for breast cancer.
	Pinette:	Does the Group want to recommend radiologists adopt the ACR Sample Lay Letter and send to both patient and copy to referring provider?
	Chambers:	If provider report includes tissue composition (density rating), then not necessary to also send Lay Letter with dense language. Asked for primary care feedback from the Work Group.
	Pinette:	Speaking as a primary care provider, would find it helpful. Have seen patients who received their Lay Letter before mammography report was received by practice. Very helpful to always have copy of what patients are reading.
	Pietras:	Clarified radiologists must provide mammography report to referring provider within 30 days. Spectrum office used "auto-fax" method to provider office.
	Hayes:	Suggested radiologists could modify the report to include one line with a box checked off if a Lay Letter with dense information was sent to patient. Then referring provider would only need one copy of the dense Lay Letter to know what is said to the patient.
	Hardy:	Clarified radiologists in his health system have already incorporated specific language about breast density and impact on interpretation in their reports.
	Sirois:	Noted that the detailed mammography report used at her facility currently includes information on density, as well as the disclaimer about the impact of dense tissue when reading the mammogram. Perhaps additional screening/testing options could be incorporated into the report for follow-up options.
	Cappello:	Needs to get off call: what are the next steps regarding recommendations for Work Group report?
	Pinette:	Reviewed next steps discussed at beginning of call.
	Rooney:	Requested clarification: is there agreement among members regarding recommendation for a Lay Letter with information about breast density to be adopted by radiologists? And assuming there is agreement is the only remaining issue whether the Letter should be mandated or voluntary?
	Hayes:	How do we make decisions? If we are not of one mind, could we have a Minority and Majority Report? Suggest Work Group report clarify goals and intent, but also clarifies ongoing concerns that have been raised, such as: ▪ Lack of clarify around recommended "next steps" for women Negative/Benign mammograms and dense tissue (3, 4); ▪ If reporting voluntary, can we ensure every woman with dense breast be notified of this information. Encouraged members to reflect on the discussion from the two meetings, and send recommendations/ strategies to Zaremba who will compile and distribute to all members for comment.
	Zaremba:	Regarding the proposed "tool" to recommend a Lay Letter, is the Group embracing the ACR Sample Lay Letter, or was there a suggestion to draft new language?
	Benson:	The ACR Sample Lay Letter can be used as a model: but each radiologist should have the option of adapting the Letter as they deem appropriate for their patients.
	Hayes:	Might a recommendation be made to have the radiologists provide to a central repository a copy of the Lay Letter they adopted? Maine CDC? Maine Radiological Society? Is reporting necessary to verify voluntary adoption has been achieved? Might another recommendation be that the Work Group recommends to ACR that they include a Lay Letter for women with dense breasts in their reporting requirements?
	Pietras:	Asked Group for feedback on ACR Sample Lay Letter: is reading level appropriate? Is wording adequate? Feedback requested from female members of Group.

	Chambers:	Work Group recommendations should include resources for primary care providers to reference when their patients say "…so what does this mean that I have dense breasts and more screening tests might be useful..."
	Pietras:	Radiologists have access to resources and web sites that could be shared. Proactive education with referring providers would be necessary. Work would be needed before implementing the Lay Letters.
	Rooney:	Shared that a National Komen representative reported there is interest at National to develop activities to educate primary care providers on this issue. Will reach out to National and get more information.
	Chambers:	Does Connecticut have on-line CME opportunities for primary care providers on this issue? Lay Letters will ensure patient has the information: next step is to ensure her doctor is provided the needed resources to have a conversation with her about follow-up options.
	Pushkin:	Reminded Group that Cappello left: but not aware of resource, but agreed it was a good idea.
	Pinette:	Reported how pathologists have included web links to ACOG recommendations on HPV testing on cytology reports, and similar approach could be used on mammography report.
	Zimmerman:	Recommended education activities go beyond primary care provider/referring provider and include entire care team members (RN, other health educators and support staff).
	Barnard:	Supported suggestion of including reference links on mammography reports to assist in dissemination of education references around dense breast tissue. CME opportunities are valuable, but one-time education activities.
	Pinette:	At this point in time, educational activities should be limited to the primary care provider/ordering provider due to the scope of the request. Ask members if they had recommendations in addition to (1) Lay Letter and (2) inclusion of reference links and suggested next steps on mammography report?
	Benson:	In response to a question, clarified Maine Radiological Society is a voluntary professional society not an enforcement body. Regarding enforcement of mandated MQSA requirements, staff from State of Maine conducts annual site visits to assess compliance with MQSA requirements.
	McDonald:	Suggested the topic be included as agenda item for the annual meetings of the Maine Academy of Family Physicians and Maine Osteopathic Association.
	Pinette:	Once consensus is reached, Work Group recommendations can be posted on the Maine CDC website. Asked Work Group how to address #7 from the 7/19th Meeting Summary Highlight: *To ensure consistent and appropriate referrals across the state, recommendations are needed for follow-up testing when mammogram reported as normal with dense tissue*?
	Benson:	At this time, screening ultrasounds are not universally accepted as the recommended follow-up modality. Suggested the Work Group not make recommendations on follow-up testing.
	Zaremba:	Noted #7 did represent the Group's discussion on 7/19th, but the Group has made great progress in understanding the issues associated with follow-up testing, and this issue is not appearing as a highlight in today's meeting.
	Pinette:	Summarized the Work Group recommendations made today: ▪ Lay Letter to patient ▪ Inclusion of reference guidelines in mammography report that goes to ordering provider ▪ Continuing Medical Education opportunities for primary care providers ▪ Inclusion of Work Group recommendations on Maine CDC website
	Hayes:	Concerned that the Lay Letter, if recommended, remains as voluntary. Over a period of time, how do we know the information is getting to every woman with dense breasts? Should there be an implementation timeframe to ensure all women get the information? History about the MQSA

		requirements suggests there may be benefit to requiring the dense information be incorporated into the Lay Letter.
	Saber:	Agreed we should keep the "door open" on the discussion: the science on the topic is evolving, and accordingly screening and follow-up recommendations will be evolving.
	Benson:	In response to a question about his opinion on voluntary versus mandated reporting, noted he does not think the Lay Letter should be mandated: instead "recommended." Suggested mandating every woman in Maine get a mammogram may go further to increase early detection efforts.
	Pushkin:	On behalf of woman who received annual screening mammograms with "normal" results and then went on to be diagnosed with late stage breast cancer, supported that the informational Lay Letter about dense tissue be mandated.
	Hayes:	Clarified the Work Group can make any recommendation, but it will ultimately be up to the Legislature as to what recommendations are implemented. Solutions that address a variety of interests on this topic are the goal of the Legislature. As sponsor of the Resolve, wants "certainty" in the recommendations to know the information is getting to the woman with dense breasts.
	McDonald:	Suggested question be inserted in Maine Behavioral Risk Factor Surveillance Survey to determine if woman have been informed via the Lay Letter that they have dense breast tissue.
	Sirois:	Noted FDA/ MQSA have reporting standards, and State of Maine has Maine standards and conducts annual site visits. Could the State inspection process include an assessment of the sites' Lay Letter? Would that include additional costs to the inspection? Comments generated questions regarding the difference between FDA/MQSA standards and Maine standards? Zaremba will contact Maine CDC Radiation Control Program regarding clarification of these issues.
	Benson:	ACR grants accreditation to the facility: FDA certifies the ACR accreditation is valid in respect to the MQSA standards.
	Pinette:	In response to a question about her opinion on voluntary versus mandated reporting, she did not think it would hurt to mandate the reporting.
	Pinette:	Facilitated discussion to create plan for production of Work Group recommendations: ▪ Zaremba will prepared Minutes and compile discussed recommendations, and send electronically to Work Group members for review by 9/7/2012. ▪ Work Group members will review and comment/edit recommendations and return feedback to Zaremba by 9/21/2012 ▪ Zaremba will compile all feedback and summarize: "majority" and "minority" recommendations may be a summary option. Summary will be sent electronically to Work Group members by 10/5/2012 ▪ Final meeting of Work Group will be held: ➢ Thursday October 11, 2012 ➢ 7 am – 9 am at Maine Medical Association (Webex will be offered) ➢ Agenda will include review, discussion and vote on final Work Group recommendations.
	Pinette:	Action: Adjourning meeting
Next Meeting of LD 1886 Work Group:	• Thursday October 11, 2012 from 7:00 – 9:00am – Maine Medical Association • Webex will again be offered for members who cannot attend in person	

Appendix C

American College of Radiology

Sample Lay Letter for Negative of Benign Finding(s)

Sample Lay Letter for Negative or Benign Finding(s) (to be used with BI-RADS® 1-2)

Name of Facility, Address and Phone Number
Name of Patient/ID
Date of Breast Imaging

Dear Patient:

We are pleased to let you know that the results of your recent [mammogram or breast ultrasound or breast MRI] shows no sign of breast cancer.

Even though mammograms are the best method we have for early detection, not all cancers are found with mammograms. If you feel a lump or have any other reasons for concern, you should tell your health care provider.

[Optional, if the woman has dense breasts] *The mammogram shows that your breast tissue is dense. Dense breast tissue is very common and is not abnormal. But dense breast tissue can make it harder to find cancer on a mammogram. Also, dense breast tissue may increase your breast cancer risk. This information about the result of your mammogram report is given to you to raise your awareness. Use this report when you talk to your doctor about your own risks for breast cancer, which includes your family history. At that time, ask your doctor if more screening tests might be useful, based on your risk.*

A report of your results was sent to: [referring health care provider].

Your images will become part of your medical record at [facility name]. They will be on file for your ongoing care. If, in the future, you change health care providers or go to a different location for a mammogram, you should tell them where and when this mammogram was done.

Thank-you for allowing us to help meet your health care needs.

Sincerely,

Jane Smith, M.D.
Interpreting Radiologist

American Cancer Society Guidelines for Early Breast Cancer Detection in Women without Symptoms

Mammogram: Yearly mammograms are recommended starting at age 40 and continuing for as long as a woman is in good health.

Clinical breast exam: a clinical breast exam is recommended every 3 years for women in their 20s and 30s and every year for women 40 and over.

Breast awareness and breast self-exam: Women should know how their breasts normally look and feel and report any breast change promptly to their health care provider. Breast self-exam (BSE) is an option for women starting in their 20s.

Breast MRI: Some women, because of their family history, a genetic tendency, or certain other factors, should be screened with MRI in addition to mammography. (The number of women who fall into this category is small: less than 2% of all the women in the US.) Talk with your doctor about your history and whether you should have additional tests at an earlier age.