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A Report to the Joint Standing Committee on Banking and Insurance of the 118th Maine Legislature

Review and Evaluation of Proposed L.D. 1556, An Act to Establish the Breast Care Patient Protection Act - Additional Screening Mammogram Provision

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EXECUTIVE SUMMARY

The Maine Legislature previously mandated coverage for mammogram screenings at least once every two years for women between the ages of 40 to 49 and once a year for women age 50 and older. A provision in LD 1556 "An Act to Establish the Breast Care Patient Protection Act" changes the screening mammogram mandated coverage to be at least once a year for women age 40 and over. This new mandated coverage would additionally affect HMOs; the current mandate did not affect HMOs.

Medical experts and professional cancer organizations have different perspectives on the cost and benefits of annual mammogram screenings for women between the ages of 40 to 49 who do not have high risk characteristics. Professional organizations are in consensus as to the value of annual screening mammograms for women age 50 and higher. The American Cancer Society and National Alliance of Breast Cancer Organizations recently changed their guidelines to recommend annual screening mammograms for all women age 40 and higher. This change is in response to recent clinical trials which indicated a 15% to 18% reduction in deaths from breast cancer as a result of regular screening mammograms for women between the ages of 40 to 49. The National Cancer Institute, the National Cancer Advisory Board and the National Institute of Health have guidelines recommending that women between the ages of 40 to 49 should be screened every one to two years with mammography. These organizations currently do not support annual screenings for women between the ages of 40 to 49 due to concerns with the statistical relevance of the above mentioned clinical trials, the relatively lower incidence of breast cancer for women under age 50, the anxiety caused by the higher proportion (30%) of 'false positive' test results and radiation risks from the mammogram examinations.

President Clinton has proposed that Medicare, Medicaid and all federal employee health plans cover annual screening mammograms for women between the ages of 40 to 49. The President has also called on private-sector health plans to provide similar coverage.

Forty-four states currently mandate screening mammograms. The majority of state mandates as of October, 1996 are similar to the current Maine statute. Only eight states at that time mandate annual screenings for women between the ages of 40 to 49 who do not have high risk characteristics. Three states mandate that the frequency of the screening mammogram be at the discretion of the physician.

The cost impact from changing the current screening mammogram mandate is extremely small. The estimated premium increase is .03%. A key consideration in whether or not to proceed with the mandate is the lack of consensus in the medical community regarding the desirability of encouraging annual screening mammograms for women between the ages of 40 to 49.

BACKGROUND

The Joint Standing Committee on Banking and Insurance of the 118th Maine Legislature requested that the Bureau of Insurance prepare a review and evaluation of LD 1556 "An Act to Establish the Breast Cancer Patient Protection Act." The Bureau of Insurance has contracted with William M. Mercer, Incorporated to prepare the review and evaluation. This review has been conducted consistent with the criteria outlined in 24-A M.R.S.A. § 2752. This criteria is to consider the social impact, financial impact and medical efficacy of the proposed act. The Joint Standing Committee on Banking and Insurance requested that the review reflect an amendment to LD 1556 which was proposed on April 11, 1997 and also address the impact of expanding the language to require coverage for breast disease instead of breast cancer. This report presents the findings from this requested review and evaluation for the screening mammogram provision. A separate report presents the findings for the LD 1556 provisions related to mastectomy, lumpectomy or lymph node dissection for breast disease.

Amended LD 1556 requires group and individual health insurance policies to provide reimbursement for screening mammograms performed at least once a year for women age 40 and over. The mammogram provision is consistent with previously proposed LD 785.

Additional provisions of LD 1556 require that written notice of the coverage be provided to each enrollee and that the terms and conditions of the coverage may not be modified by the enrollee to be less than the required minimum coverage.

Current Maine statutes 2320, 2745, 2837 and 4237 require that group and individual health insurance policies must provide reimbursement for screening mammograms performed at least once every 2 years for women between the ages of 40 and 49 and at least once a year for women age 50 and over. The incremental impact of LD 1556 with respect to the screening mammogram provision is that reimbursement will be provided for screening

mammograms performed every year, instead of at least once every two years, for women between the ages of 40 and 49.

SOCIAL IMPACT

The M.R.S.A. statute includes a list of specific questions which must be addressed in reviewing the social impact of mandated benefits legislation. Those questions and our findings are as follows:

1. "The extent to which the treatment or service is utilized by a significant portion of the population:"

Breast cancer is the most common form of cancer in women in the United States. The average woman faces a one in eight lifetime risk of being diagnosed with breast cancer. A chart displaying incidence rates by age is included in Appendix C, page 17 of this report. Breast cancer is the leading cause of death in the United States for women between the ages of 40 and 55. It is estimated that there were more than 185,000 new cases of female breast cancer in the United States in 1996. Approximately 18% (or 33,000) of these new breast cases is expected to occur in women between the ages of 40 to 49. Nearly 45,000 women have died from the disease in the United States in 1996. Approximately 10% of the women who die from breast cancer were aged between 40 to 49. According to research studies, a women age 40 has a 1.58% probability of developing invasive breast cancer before age 50.

The risk of women developing breast cancer has been increasing. According to the American Cancer Society, breast cancer incidence rates for women increased about 4% a year between 1982 and 1987 but recently have leveled off at about 110 per 100,000. Most of the recent increase in incidence rates is attributed to increases in mammograms. Mammograms allow the detection of early-stage breast cancer.

The number of women receiving mammograms has been increasing. The percentage of women older than age 40 who have had at least one mammogram

increased from 38% in 1987 to 60% in 1990. Another study showed that thirty-seven percent of women said they had a mammogram in the previous twelve months. Sixteen percent of the women age 55 and higher never had a mammogram.

2. "The extent to which the treatment or service is available to the population:"

Breast cancer can often be treated effectively if detected early with surgery that preserves the breast and followed by radiation therapy. Five-year survival after treatment for early-stage breast cancer is over 97 percent according to the National Alliance of Breast Cancer Organizations.

Mammography is the most common and currently effective detection method. New breast cancer detection techniques being studied include ultrasonography and magnetic resonance imaging.

Stationary mammography units are available throughout the State of Maine. However, there are shortages of units in rural areas of the state which create some relatively long waits. There are currently no mobile or portable mammography units licensed in Maine.

3. "The extent to which insurance coverage for this treatment or service is already available:"

With respect to screening mammograms, most individual and group policies currently cover no more than the current mandated benefit. Coverage is generally not provided for annual screening mammograms for women between the age of 40 to 49 who do not have high risk characteristics. Diagnostic mammograms are also currently covered by most individual and group policies within Maine. Diagnostic mammograms arise when a patient has symptoms of a disease. Some

insurance policies have defined diagnostic mammograms to include those for women who are at high risk based on personal or family history.

HMOs are not required currently to provide coverage for mammogram screenings. However, based on our telephone survey, most of them will cover mammogram screenings when requested by a physician. Results of our survey are shown in Appendix B.

4. "If coverage is not generally available, the extent to which the lack of coverage results in persons being unable to obtain necessary health care treatment:"

The lack of coverage is a consideration for some women who do not obtain an annual mammogram and are between the ages of 40 to 49. A national survey indicated that between 25% to 40% of women cited out-of-pocket costs as the reason they did not obtain a screening mammogram. However, the most significant factor appears not to be related to cost but is due to personal preference.

A survey performed in Maine in 1994 indicated that women cited lack of referral from their physician as the most significant barrier to mammography. Physicians would be influenced by changes in screening guidelines by national cancer organizations.

The availability of this mandated coverage will probably increase the number of insured women between the ages of 40 to 49 who obtain a screening mammogram annually by the 25% to 40% cited above.

5. "If the coverage is not generally available, the extent to which the lack of coverage results in unreasonable financial hardship on those persons needing treatment:"

Between 25% and 40% of women stated that cost was a barrier to obtaining a screening mammogram. The lack of coverage presents a financial hardship to approximately one-third of the women between the ages of 40 to 49 who desire an annual mammogram.

6. "The level of public demand and the level of demand from providers for the treatment or service:"

Public awareness of the frequency of breast cancer and the benefits of early detection has increased the demand of screening mammograms. The public demand is that screening mammograms be provided consistent with national guidelines. Several experts and professional organizations have reached different conclusions on the preferred frequency of screening mammogram for women between the ages of 40 to 49. Some experts recommend annual screening for all women age 40 and higher while others recommend annual screening every one to two years for women between ages 40 to 49 as long as they do not have high risk characteristics. Additional information on the guidelines of cancer organizations is provided in the Medical Efficacy section of this report.

7. "The level of public demand and the level of demand from the providers for individual and group insurance coverage of the treatment or service:"

The demand for the coverage was evident when the current mandate was enacted. As the guidelines change over time, the public and providers expect that the coverage would change to be consistent with the guidelines.

8. "The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts:"

No information was available regarding the level of interest from collective bargaining organizations.

9. "The likelihood of achieving the objectives of meeting the consumer needs as evidenced by the experience of other states:"

Forty-four states have mandated screening mammogram coverage as of October, 1996. A variety of different mandated screening mammogram provisions are in place. Twenty-seven states have the same approach as is currently used in Maine. Five states designated mandated screening mammogram benefits explicitly for high risk patients. Eight states have mandated annual screening mammograms for all women between the ages of 40 to 49. Three states mandate that the frequency of the screening mammogram be at the discretion of the physician.

10. "The relevant findings of the state health planning agency or the appropriate health system agency relating the social impact of the mandated benefit:"

The Maine Bureau of Health provided information regarding the guidelines recommended by national cancer organizations. This information is included in Appendix C.

11. "The alternatives to meeting the identified need:"

An alternative approach to meet the need is to mandate screening mammograms based on a combination of risk characteristics and age. Another alternative is to target mammogram screening based on income or a combination of income and

risk characteristics. Poorer women have a more significant financial hardship with respect to paying for screening mammograms as a personal expense.

12. "Whether the benefit is a medical or a broad social need and whether it is consistent with the role of health insurance:"

The role of health insurance initially focused on financial protection from catastrophic illnesses. As the cost of health care escalated, the access to health care has become more linked to the availability of health insurance. The scope of benefits coverage has gradually expanded to include preventive services. Consumers have demanded preventive services and insurers have responded to this demand by generally including coverage for preventive services. Covering preventive services is also thought to eventually lead to fewer, more expensive acute treatments. The additional screening mammograms coverage does not appear to be inconsistent with the new evolving role of health insurance.

13. "The impact of any social stigma attached to the benefit upon the market:"

No apparent social stigma is attached to the screening mammogram benefit.

14. "The impact of this benefit upon the availability of other benefits currently being offered:"

The cost of this mandated benefit is extremely small. Any impact on the availability of other benefits would be too insignificant to detect.

15. "The impact of the benefit as it relates to employers shifting to self-insurance plans:"

Based solely on the impact of this mandate, the extremely small financial impact should not influence employers shifting to self-insurance plans.

FINANCIAL IMPACT

The M.R.S.A. statute includes a list of specific questions which must be addressed in reviewing the financial impact of mandated benefits legislation. Those questions and our findings are as follows:

1. "The extent to which the proposed insurance coverage would increase or decrease the cost of the treatment or service over the next five years:"

Mandating coverage for annual screening mammograms for women between the ages of 40 and 49 instead of once every other year will slightly increase the number of screening mammogram procedures in the state of Maine. The slight increase in volume could result in a very small reduction in unit costs of mammograms.

2. "The extent to which the proposed coverage might increase the appropriate or inappropriate use of the treatment or service over the next five years:"

The lack of consensus among medical experts makes it difficult to determine whether annual screening mammograms are appropriate or inappropriate for women between the ages of 40 to 49 who do not have high risk characteristics.

3. "The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service:"

There is currently no practical alternative other than screening mammograms to detect breast cancer for women between the ages of 40 to 49. Screening mammograms will not replace another diagnostic service.

4. "The methods which will be instituted to manage the utilization and costs of the proposed mandate:"

The frequency of screening mammograms specified in the mandate (i.e., annually) will manage the utilization. The objective is to increase appropriate utilization of treatments to detect breast cancer at an early stage. The cost would be managed through negotiations between insurers and providers as is the situation with the currently mandated screening mammogram coverage.

5. "The extent to which the insurance coverage may affect the number and types of providers over the next five years:"

The mandated coverage will only very slightly increase the number of screening mammogram procedures performed in the state of Maine. Any impact on the providers will be minimal.

6. "The extent to which insurance coverage of the health care service or provider may be reasonably expected to increase or decrease the insurance premium and administrative expenses of the policyholder:"

Increasing the frequency of mandated screening mammogram benefits for women between the age of 40 to 49 will result in an extremely small increase in insurance premium and administrative expenses. Data reported by Maine health insurers indicated that screening mammogram represents .15% of all claims. Based on the proportion of women aged 40 to 49 and their expected additional use of screening mammograms due to the LD 1556 mandate, our expectation is that the insurance premium would increase by .03% or three one-thousandths of all Maine claims.

7. "The impact of indirect costs, which are costs other than premiums and administrative costs, on the question of the costs and benefits of coverage:"

Improved early detection and treatment of breast cancer would reduce indirect costs associated with cancer treatment. Examples of indirect costs include lost work time and training new employees. Due to the limited scope of the additional mammogram mandate, any indirect cost reduction would be insignificant.

8. "The impact of this coverage on the total cost of health care:"

The additional cost of this mandate is extremely small and would be at least partially reduced by the benefits from the early detection of breast cancer.

9. "The effects on the cost of health care to employers and employees, including the financial impact on small employers, medium-sized employers, and large employers:"

The extremely small increase to the insurance premium (.03%) is not expected to lead to measurable decreases in the number of people insured or the range of benefits covered.

MEDICAL EFFICACY

The M.R.S.A. statute includes a list of specific questions which must be addressed in reviewing the medical efficacy of mandated benefits legislation. Those questions and our findings are as follows:

1. "The contribution of the benefit to the quality of patient care and the health status of the population, including the results of any research demonstrating the medical efficacy of the treatment or service compared to alternatives or not providing the treatment or service:"

The determination of whether the proposed coverage provides appropriate or inappropriate treatment is linked to national mammogram guidelines. National cancer organizations currently have different guidelines with respect to annual mammogram screening for women between the ages of 40 to 49. The National Cancer Institute and the National Cancer Advisory Board recommendation is that women between the ages of 40 to 49 should be screened every one to two years. The National Institute of Health deemed that the scientific evidence does not support annual mammograms for women between the ages of 40 to 49 who do not have a high risk of breast cancer. The American Cancer Society revised their breast cancer screening guidelines in March, 1997 to recommend that all women have annual screening mammograms and clinical breast examinations beginning at age 40. The National Alliance Breast Cancer Organizations advocate annual screenings for women age 40 and over.

The National Cancer Institute and the National Cancer Advisory Board stated in March, 1997 that mammography screening of women between the ages of 40 and 49 is beneficial and supported by current scientific evidence. This is a dramatic change from their previous recommendation with respect to screening

mammograms for women between the ages of 40 to 49. The current mammography recommendation is that:

- Women between the ages of 40 to 49 at average risk of breast cancer should be screened every one to two years.
- Women aged 50 and older should be screened every one to two years.
- Women who are at higher than average risk of breast cancer should seek expert medical advice about whether they should begin screening before age 40 and the frequency of screening.

The National Institutes of Health convened a Consensus Development Conference in January, 1997. This federal panel did not reach a consensus to recommend annual mammogram screening for women between the ages of 40 to 49. The NIH cited the inconclusive evidence of the demonstrated value from annual testing for women between the ages of 40 to 49 and the risks arising from annual mammograms. The American College of Radiology stated that these risks are too insignificant to keep women from obtaining mammograms.

Proponents of annual mammograms for women beginning at age 40 cite recent results from eight worldwide random, controlled trials of screening mammograms. The *International Journal of Cancer* stated that regular screening mammograms results in a 15% to 18% reduction in deaths from breast cancer for women between the ages of 40 to 49. There is medical evidence that breast tumors grow faster in younger women and that women under age 50 have higher survival rates than older women when breast cancer is detected early.

Medical experts who are opposed to routine annual mammogram screening for women age 40 to 49 raise concerns about the statistical accuracy of these clinical trials and cite the low rate of breast cancer in this age interval and the anxiety caused by excessive false positive results. These medical experts point out that the stated decline in mortality did not appear until many years after the testing and

may have been identified by other means (i.e., self examination, annual exams and mammograms after age 50). Breast cancer is much less common for younger women with 16 out of 1000 women ages 40 to 49 being diagnosed with breast cancer in comparison to 70 out of 1000 for women ages 60 to 79. It has been estimated that 20,000 women in ages 40 to 49 must be screened to save one life in comparison to 2,500 older women being screened to save one life. Excessive false alarms result from premenopause women having denser breasts which make it difficult to distinguish harmless tissue from malignant tumors on mammograms. The estimate is that women getting mammograms every year between 40 to 49 would have a 30% chance of receiving a 'false positive' result. Some medical experts state that the risks of overtreatment and emotional distress outweigh the very small benefit from routine mammograms for women between the ages of 40 to 49.

The mandate relates utilization only to the age of the patient. An alternative approach is to relate utilization to a combination of age and risk characteristics. This risk of breast cancer increases with increasing age and is also associated with several conditions. Screening mammogram utilization can be managed by focusing results on women having a higher risk of breast cancer. The National Cancer Advisory Board states that higher risks of breast cancer is associated with the following conditions:

1. having had previous breast cancer;
2. laboratory evidence that the woman is carrying a specific mutation or genetic change that increases susceptibility to breast cancer;
3. having a mother, sister or daughter with a history of breast cancer or having two or more close relatives, such as cousins, with a history of breast cancer;
4. having had a diagnosis of other types of breast disease (not cancer but a condition that may predispose to cancer) on a breast exam or having had two more breast biopsies for benign disease, even if no atypical cells are found;

5. having so much dense breast tissue (above 75 percent) on a previous mammographic examination that clear reading is difficult; and
6. having a first birth at age 30 or older.

2. "If the legislation seeks to mandate coverage of an additional class of practitioners:"

The proposed mandate would not provide insurance coverage for an additional class of practitioners.

a. The results of any professional acceptable research demonstrating the medical results achieved by the additional class of practitioners relative to the those already covered:

Not applicable

b. The methods of appropriate professional organization that assure clinical proficiency:

Not applicable

BALANCING THE EFFECTS

The effects of balancing the social, economic, and medical efficacy considerations in the evaluation of the screening mammogram provision in LD 1556 is addressed through the following comments.

1. "The extent to which the need for coverage outweighs the cost of mandating the benefit for all policyholders:"

The benefits and need for early cancer detection has been clearly demonstrated. The current screening mammogram mandate is an indication of the desirability of encouraging the early detection and treatment of this significant medical concern.

Determining the benefits of the screening mammogram provision in LD 1556 depends on which national guideline is appropriate. The choice is whether to be consistent with the national cancer organizations whose guidelines recommend annual mammogram screening for average risk women between the ages of 40 to 49 or the national care organizations whose guidelines do not recommend annual mammogram screenings for these women.

It should be kept in mind that there is an extremely small financial impact from this mandate. Since the costs are extremely small, only a small benefit is needed to more than offset it.

2. "The extent to which the problem of coverage may be solved by mandating the availability of the coverage as an option for policyholders:"

Mandating the availability of coverage may help solve the problem through informing consumers on the desirability of this coverage which in turn could subsequently lead to consumer demand and automatic inclusion.

However, the cost of this additional coverage is extremely small (i.e., .03%) and screening mammograms are already a mandated benefit. The complexities and related administrative expenses would make it impractical to mandate the availability of the coverage for this extremely limited benefit.

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118th MAINE LEGISLATURE

FIRST REGULAR SESSION-1997

Legislative Document No. 785

H.P. 594 House of Representatives, February 4, 1997

An Act to Require Certain Practices by Managed Care Plans.

Reference to the Committee on Banking and Insurance suggested and ordered printed.

JOSEPH W. MAYO, Clerk

Presented by Representative AHEARNE of Madawaska.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 24 MRSA §2320-C, as enacted by PL 1995, c. 295, §1, is repealed and the following enacted in its place:

§2320-C. Coverage for mastectomy surgery

1. Reconstructive surgery. All individual and group nonprofit and medical services plan contracts and all nonprofit health care plan contracts providing coverage for mastectomy surgery must provide coverage for reconstruction of the breast on which surgery has been performed and surgery and reconstruction of the other breast to produce a symmetrical appearance if the patient elects reconstruction and in the manner chosen by the patient and the physician.

2. Hospital stay. With respect to managed care plans, all individual and group nonprofit and medical services plan contracts and all nonprofit health care plan contracts providing coverage for mastectomy surgery must provide coverage for a minimum of 48 hours of in-patient hospital care following mastectomy surgery unless the patient and the physician elect a shorter hospital stay.

Sec. 2. 24-A MRSA §2745-C, as corrected by RR 1995, c. 1, §15, is repealed and the following enacted in its place:

§2745-C. Coverage for mastectomy surgery

1. Reconstructive surgery. All individual health policies providing coverage for mastectomy surgery, except those designed to cover only specific diseases, hospital indemnity or accidental injury, must provide coverage for reconstruction of the breast on which surgery has been performed and surgery and reconstruction of the other breast to produce a symmetrical appearance if the patient elects reconstruction and in the manner chosen by the patient and the physician.

2. Hospital stay. With respect to managed care plans, all individual health policies providing coverage for mastectomy surgery, except those designed to cover only specific diseases, hospital indemnity or accidental injury, must provide coverage for a minimum of 48 hours of in-patient hospital care following mastectomy surgery unless the patient and the physician elect a shorter hospital stay.

Sec. 3. 24-A MRSA §2837-C, as corrected by RR 1995, c. 1, §17, is repealed and the following enacted in its place:

§2837-C. Coverage for mastectomy surgery

1. Reconstructive surgery. All group health policies providing coverage for mastectomy surgery, except those designed to cover only specific diseases, hospital indemnity or accidental injury, must provide coverage for reconstruction of the breast on which surgery has been performed and surgery and reconstruction of the other breast to produce a symmetrical appearance if the patient elects reconstruction and in the manner chosen by the patient and the physician.

2. Hospital stay. With respect to managed care plans, all group health policies providing coverage for mastectomy surgery, except those designed to cover only specific diseases, hospital indemnity or accidental injury, must provide coverage for a minimum of 48 hours of in-patient hospital care following mastectomy surgery unless the patient and the physician elect a shorter hospital stay.

Sec. 4. 24-A MRSA §4237, as corrected by RR 1995, c. 1, §21, is repealed and the following enacted in its place:

§4237. Coverage for mastectomy surgery

1. Reconstructive surgery. All individual or group coverage subject to this chapter that provides for mastectomy surgery must provide coverage for reconstruction of the breast on which surgery has been performed and surgery and reconstruction of the other breast to produce a symmetrical appearance if the patient elects reconstruction and in the manner chosen by the patient and the physician.

2. Hospital stay. With respect to managed care plans, all individual or group coverage subject to this chapter that provides for mastectomy surgery must provide coverage for a minimum of 48 hours of in-patient hospital care following mastectomy surgery unless the patient and the physician elect a shorter hospital stay.

Sec. 5. 24-A MRSA §4303, sub-§5 is enacted to read:

5. Prohibition on incentives to providers. A carrier offering a managed care plan may not provide a payment or other financial incentive to a participating provider for not referring enrollees in the managed care plan to a specialist and for not disclosing the seriousness of an enrollee's condition.

SUMMARY

This bill requires managed care plan policies and contracts offered by nonprofit hospital, medical or health plan services

organizations, insurers and health maintenance organizations to provide in-patient hospital coverage following mastectomy surgery.

The bill also prohibits nonprofit hospital, medical or health plan services organizations, insurers and health maintenance organizations offering managed care plans from providing payments or other financial incentives to participating providers for not referring patients to specialists and for not disclosing the seriousness of a patient's condition.

118th MAINE LEGISLATURE

FIRST REGULAR SESSION-1997

Legislative Document **No. 1556**

H.P. 1113 House of Representatives, March 18, 1997

An Act to Establish the Breast Care Patient Protection Act

Reference to the Committee on Banking and Insurance suggested and ordered printed.

JOSEPH W. MAYO, Clerk

Presented by Representative DAVIDSON of Brunswick.
Cosponsored by Senator GOLDTHWAIT of Hancock and
Representatives: AHEARNE of Madawaska, BRUNO of Raymond, KONTOS of Windham, MAYO of Bath, MITCHELL of Portland, SAXL of Bangor, Senators: ABROMSON of Cumberland, LaFOUNTAIN of York.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 24 MRSA §2320-C, as corrected by RR 1995, c. 1, §13, is repealed and the following enacted in its place:

§2320-C. Coverage for mastectomy surgery

All individual and group nonprofit and medical services plan contracts and all nonprofit health care plan contracts providing coverage for mastectomy surgery must provide coverage for:

1. Inpatient care. Not less than 48 hours of inpatient care following a mastectomy.

Nothing in this subsection may be construed to require the provision of not less than 48 hours of inpatient coverage when the attending physician and patient determine that a shorter period of hospital stay is appropriate.

In implementing the requirements of this subsection, an individual and group nonprofit and medical services plan contract or a nonprofit health care plan contract may not modify the terms and conditions of coverage based on the determination by an enrollee to request less than the minimum coverage required under this subsection.

All individual and group nonprofit and medical services plan contracts and all nonprofit health care plan contracts must provide immediate written notice prominently positioned in any literature or correspondence to each enrollee under the contract regarding the coverage required by this subsection; and

2. Reconstruction. Reconstruction of the breast on which surgery has been performed and surgery and reconstruction of the other breast to produce a symmetrical appearance if the patient elects reconstruction and in the manner chosen by the patient and the physician.

Sec. 2. 24 MRSA §2320-F is enacted to read:

§2320-F. Coverage of lymph node dissection for treatment of breast cancer

All individual and group nonprofit medical services plan contracts and all nonprofit health care plan contracts providing coverage for lymph node dissection for treatment of breast cancer must provide not less than 24 hours of inpatient care following a lymph node dissection.

Nothing in this section may be construed to require the provision of not less than 24 hours of inpatient coverage when

the attending physician and patient determine that a shorter period of hospital stay is appropriate.

In implementing the requirements of this section, an individual and group nonprofit medical services plan or nonprofit health care plan contract may not modify the terms and conditions of coverage based on the determination by an enrollee to request less than the minimum coverage required under this section.

All individual or group nonprofit and medical services plan contracts and all nonprofit health care plan contracts must provide immediate written notice prominently positioned in any literature or correspondence to each enrollee under the plan regarding the coverage required by this section.

Sec. 3. 24-A MRSA §2745-C, as corrected by RR 1995, c. 1, §15, is repealed and the following enacted in its place:

§2745-C. Coverage for mastectomy surgery

All individual health policies providing coverage for mastectomy surgery, except those designed to cover only specific diseases, hospital indemnity or accidental injury must provide coverage for:

1. Inpatient care. Not less than 48 hours of inpatient care following a mastectomy.

Nothing in this subsection may be construed to require the provision of not less than 48 hours of inpatient coverage when the attending physician and patient determine that a shorter period of hospital stay is appropriate.

In implementing the requirements of this subsection, an individual health policy may not modify the terms and conditions of coverage based on the determination by an enrollee to request less than the minimum coverage required under this subsection.

All individual health policies must provide immediate written notice prominently positioned in any literature or correspondence to each enrollee under the policy regarding the coverage required by this subsection; and

2. Reconstruction. Reconstruction of the breast on which surgery has been performed and surgery and reconstruction of the other breast to produce a symmetrical appearance if the patient elects reconstruction and in the manner chosen by the patient and the physician.

Sec. 4. 24-A MRSA §2745-E is enacted to read:

§2745-E. Coverage for lymph node dissection for treatment of

breast cancer

All individual health policies providing coverage for lymph node dissection must provide not less than 24 hours of inpatient care following a lymph node dissection for treatment of breast cancer.

Nothing in this section may be construed to require the provision of not less than 24 hours of inpatient coverage when the attending physician and patient determine that a shorter period of hospital stay is appropriate.

In implementing the requirements of this section, an individual health policy may not modify the terms and conditions of coverage based on the determination by an enrollee to request less than the minimum coverage required under this section.

All individual health policies subject to this section must provide immediate written notice prominently positioned in any literature or correspondence to each enrollee under the policy regarding the coverage required by this section.

Sec. 5. 24-A MRSA §2837-C, as corrected by RR 1995, c. 1, §17, is repealed and the following enacted in its place:

§2837-C. Coverage for mastectomy surgery

All group health policies providing coverage for mastectomy surgery, except those designed to cover only specific diseases, hospital indemnity or accidental injury must provide coverage for:

1. Inpatient care. Not less than 48 hours of inpatient care following a mastectomy.

Nothing in this subsection may be construed to require the provision of not less than 48 hours of inpatient coverage when the attending physician and patient determine that a shorter period of hospital stay is appropriate.

In implementing the requirements of this subsection, a group health policy may not modify the terms and conditions of coverage based on the determination by an enrollee to request less than the minimum coverage required under this subsection.

All group health policies subject to this subsection must provide immediate written notice prominently positioned in any literature or correspondence to each enrollee under the group health policy regarding the coverage required by this subsection; and

2. Reconstruction. Reconstruction of the breast on which surgery has been performed and surgery and reconstruction of the other breast to produce a symmetrical appearance if the patient

elects reconstruction and in the manner chosen by the patient and the physician.

Sec. 6. 24-A MRSA §2837-F is enacted to read:

§2837-F. Coverage for lymph node dissection for treatment of breast cancer

All group health policies providing coverage for lymph node dissection must provide not less than 24 hours of inpatient care following a lymph node dissection for treatment of breast cancer.

Nothing in this section may be construed to require the provision of not less than 24 hours of inpatient coverage when the attending physician and patient determine that a shorter period of hospital stay is appropriate.

In implementing the requirements of this section, a group health policy may not modify the terms and conditions of coverage based on the determination by an enrollee to request less than the minimum coverage required under this section.

All group health policies subject to this section must provide immediate written notice prominently positioned in any literature or correspondence to each enrollee under the group health policy regarding the coverage required by this section.

Sec. 7. 24-A MRSA §4237, as corrected by RR 1995, c. 1, §21, is repealed and the following enacted in its place:

§4237. Coverage for mastectomy surgery

All individual or group coverage subject to this chapter that provides for mastectomy surgery must provide coverage for:

1. Inpatient care. Not less than 48 hours of inpatient care following a mastectomy.

Nothing in this subsection may be construed to require the provision of not less than 48 hours of inpatient coverage when the attending physician and patient determine that a shorter period of hospital stay is appropriate.

In implementing the requirements of this subsection, an individual or group coverage contract may not modify the terms and conditions of coverage based on the determination by an enrollee to request less than the minimum coverage required under this subsection.

All individual or group coverage subject to this subsection must provide immediate written notice prominently positioned in any literature or correspondence to each enrollee under the

individual or group coverage contract regarding the coverage required by this subsection; and

2. Reconstruction. Reconstruction of the breast on which surgery has been performed and surgery and reconstruction of the other breast to produce a symmetrical appearance if the patient elects reconstruction and in the manner chosen by the patient and the physician.

Sec. 8. 24-A MRSA §4243 is enacted to read:

§4253. Coverage for lymph node dissection for treatment of breast cancer

All individual or group coverage subject to this chapter that provides coverage for lymph node dissection must provide not less than 24 hours of inpatient care following a lymph node dissection for treatment of breast cancer.

Nothing in this section may be construed to require the provision of not less than 24 hours of inpatient coverage when the attending physician and patient determine that a shorter period of hospital stay is appropriate.

In implementing the requirement of this section, an individual or group coverage contract may not modify the terms and conditions of coverage based on the determination by an enrollee to request less than the minimum coverage required under this section.

All individual or group coverage subject to this section must provide immediate written notice prominently positioned in any literature or correspondence to each enrollee under the individual or group coverage contract regarding the coverage required by this section.

SUMMARY

This bill requires that medical insurance coverage provide a patient with not less than 48 hours of inpatient care following a mastectomy and not less than 24 hours of inpatient care following a lymph node dissection for treatment of breast cancer.

Committee: BAN **PROPOSED COMMITTEE AMENDMENT**
LA: CMM
File Name:G:\OPLAGEA\COMMTTEE\BAN\AMENDMTS\033202.DOC
LR (item)#: 0332 (02)
New Title?: Y
Add Emergency?: N
Date: April 11, 1997

COMMITTEE AMENDMENT "." TO L.D. 1556, An Act to Establish the Breast Care Patient Protection.

Amend the bill by striking out title and inserting in its place the following:

An Act to Establish the Breast Care Patient Protection Act

Further amend the bill by striking out everything after the enacting clause and before the summary and inserting in its place the following:

Sec. 1. 24 MRSA § 2320-A, sub-§ 2 is repealed and the following enacted in its place:

2. Required coverage. All individual and group nonprofit medical services plan contracts and all nonprofit health care plan contracts must provide coverage for screening mammograms performed by providers that meet the standards established by the Department of Human Services' rules relating to radiation protection. The policies must reimburse for screening mammograms performed at least once a year for women age 40 and over.

Sec. 2. 24 MRSA §2320-C, as corrected by RR 1995, c. 1, §13, is repealed and the following enacted in its place:

§2320-C. Coverage for breast cancer treatment

1. Inpatient care. All individual and group nonprofit and medical services plan contracts and all nonprofit health care plan contracts providing coverage for medical and surgical benefits shall ensure that inpatient coverage with respect to the treatment of breast cancer is provided for a period of time as is determined by the attending physician, in consultation with the patient, to be medically appropriate following a mastectomy, a lumpectomy or a lymph node dissection for the treatment of breast cancer.

Nothing in this subsection may be construed to require the provision of inpatient coverage if the attending physician and patient determine that a shorter period of hospital stay is appropriate.

In implementing the requirements of this subsection, an individual and group nonprofit and medical services plan contract or a nonprofit health care plan contract may not modify the terms and conditions of coverage based on the determination by an enrollee to request less than the minimum coverage required under this subsection.

All individual and group nonprofit and medical services plan contracts and all nonprofit health care plan contracts must provide written notice to each enrollee under the contract regarding the coverage required by this subsection. The notice must be prominently positioned in any literature or correspondence made available or distributed by the plan and must be transmitted in the next mailing made by the plan to the enrollee or as part of any yearly information packet sent to the enrollee, whichever is earlier.

2. Reconstruction. All individual and group nonprofit and medical services plan contracts and all nonprofit health care plan contracts providing coverage for mastectomy surgery must provide coverage for reconstruction of the breast on which surgery has been performed and surgery and reconstruction of the other breast to produce a symmetrical appearance if the patient elects reconstruction and in the manner chosen by the patient and the physician.

Sec. 3. 24 MRSA §2745-A, sub-§2 is repealed and the following is enacted in its place:

2. Required coverage. All individual insurance policies that cover radiologic procedures, except those designed to cover only specific diseases, accidental injury or dental procedures, must provide coverage for screening mammograms performed by providers that meet the standards established by the Department of Human Services' rules relating to radiation protection. The policies must reimburse for screening mammograms performed at least once a year for women age 40 and over.

Sec. 4. 24-A MRSA §2745-C, as corrected by RR 1995, c. 1, §15, is repealed and the following enacted in its place:

§2745-C. Coverage for breast cancer treatment

1. Inpatient care. All individual health policies providing coverage for medical and surgical benefits, except those designed to cover only specific diseases, hospital indemnity or accidental injury, shall ensure that inpatient coverage with respect to the treatment of breast cancer is provided for a period of time as is determined by the attending physician, in consultation with the patient, to be medically appropriate following a mastectomy, a lumpectomy or a lymph node dissection for the treatment of breast cancer.

Nothing in this subsection may be construed to require the provision of inpatient coverage if the attending physician and patient determine that a shorter period of hospital stay is appropriate.

In implementing the requirements of this subsection, an individual health policy may not modify the terms and conditions of coverage based on the determination by an enrollee to request less than the minimum coverage required under this subsection.

All individual health policies must provide written notice to each enrollee under the contract regarding the coverage required by this subsection. The notice must be prominently positioned in any literature or correspondence made available or distributed by the plan and must be transmitted in the next mailing made by the plan to the enrollee or as part of any yearly information packet sent to the enrollee, whichever is earlier.

2. **Reconstruction.** All individual health policies providing coverage for mastectomy surgery must provide coverage for reconstruction of the breast on which surgery has been performed and surgery and reconstruction of the other breast to produce a symmetrical appearance if the patient elects reconstruction and in the manner chosen by the patient and the physician.

Sec. 5. 24-A MRSA §2837-A, sub-§2 is repealed and the following is enacted in its place:

2. **Required coverage.** All group insurance policies that cover radiologic procedures, except those policies that cover only dental procedures, accidental injury or specific diseases, must provide coverage for screening mammograms performed by providers that meet the standards established by the Department of Human Services relating to radiation protection. The policies must reimburse for screening mammograms performed at least once a year for women age 40 and over.

Sec. 6. 24-A MRSA §2837-C, as corrected by RR 1995, c. 1, §17, is repealed and the following enacted in its place:

§2837-C. Coverage for breast cancer treatment

1. **Inpatient care.** All group health policies providing coverage for medical and surgical benefits, except those designed to cover only specific diseases, hospital indemnity or accidental injury, shall ensure that inpatient coverage with respect to the treatment of breast cancer is provided for a period of time as is determined by the attending physician, in consultation with the patient, to be medically appropriate following a mastectomy, a lumpectomy or a lymph node dissection for the treatment of breast cancer.

Nothing in this subsection may be construed to require the provision of inpatient coverage if the attending physician and patient determine that a shorter period of hospital stay is appropriate.

In implementing the requirements of this subsection, a group health policy may not modify the terms and conditions of coverage based on the determination by an enrollee to request less than the minimum coverage required under this subsection.

All group health policies must provide written notice to each enrollee under the contract regarding the coverage required by this subsection. The notice must be prominently positioned in any literature or correspondence made available or distributed by the plan and must be transmitted in the next mailing made by the plan to the enrollee or as part of any yearly information packet sent to the enrollee, whichever is earlier.

2. Reconstruction. All group health policies providing coverage for mastectomy surgery must provide coverage for reconstruction of the breast on which surgery has been performed and surgery and reconstruction of the other breast to produce a symmetrical appearance if the patient elects reconstruction and in the manner chosen by the patient and the physician.

Sec. 7. 24-A MRSA §4237, as corrected by RR 1995, c. 1, §21, is repealed and the following enacted in its place:

§4237. Coverage for breast cancer treatment

1. Inpatient care. All individual or group coverage subject to this chapter that provides for mastectomy surgery providing coverage for medical and surgical benefits, except those designed to cover only specific diseases, hospital indemnity or accidental injury, shall ensure that inpatient coverage with respect to the treatment of breast cancer is provided for a period of time as is determined by the attending physician, in consultation with the patient, to be medically appropriate following a mastectomy, a lumpectomy or a lymph node dissection for the treatment of breast cancer.

Nothing in this subsection may be construed to require the provision of inpatient coverage if the attending physician and patient determine that a shorter period of hospital stay is appropriate.

In implementing the requirements of this subsection, an individual or group coverage contract may not modify the terms and conditions of coverage based on the determination by an enrollee to request less than the minimum coverage required under this subsection.

All individual or group coverage subject to this subsection must provide written notice to each enrollee under the contract regarding the coverage required by this subsection. The notice must be prominently positioned in any literature or correspondence made available or distributed by the plan and must be transmitted in the next mailing made by the plan to

the enrollee or as part of any yearly information packet sent to the enrollee, whichever is earlier.

2. Reconstruction. All individual or group coverage subject to this chapter that provides coverage for mastectomy surgery must provide coverage for reconstruction of the breast on which surgery has been performed and surgery and reconstruction of the other breast to produce a symmetrical appearance if the patient elects reconstruction and in the manner chosen by the patient and the physician.

Sec. 7. 24-A MRSA § 4237-A is enacted to read:

§ 4237-A. Screening mammograms

1. Definition. For purposes of this section, "screening mammogram" means a radiologic procedure that is provided to an asymptomatic woman for the purpose of early detection of breast cancer and that consists of 2 radiographic views per breast.

2. Required coverage. All individual and group coverage subject to this chapter must provide coverage for screening mammograms performed by providers that meet the standards established by the Department of Human Services' rules relating to radiation protection. The policies must reimburse for screening mammograms performed at least once a year for women age 40 and over.

SUMMARY

This amendment replaces the bill and requires that medical insurance coverage provide inpatient coverage for a period of time as determined by the physician and patient to be medically appropriate following a mastectomy, lumpectomy or a lymph node dissection for treatment of breast cancer.

The amendment also requires insurance coverage for annual mammograms for women age 40 and over and extends the provisions requiring coverage for annual mammograms to health maintenance organizations.

Summary of Health Maintenance Organizations Coverage of Mammogram Screenings

Company	Type of Coverage
Healthsource	They have guidelines on practices that physicians should follow, but coverage is completely based on physician recommendations. Literature recommends every 1 to 2 years at age 50.
Harvard/Pilgrim Health Plan	Coverage is based solely on physician's recommendations.
NYL Care of Maine	Physician recommendation is required for services to be covered.
Blue Cross HMO	They cover these screenings if recommended by a physician.

Summary of Commercial Insurance Organizations Coverage of Mammogram Screenings

Company	Type of Coverage
Blue Cross Blue Shield	Ages 40 to 49 are covered once every two years. Ages 50 and over are covered once every year.
The Guardian	Coverage as required by current mandate. Offer a rider to groups for preventive services that would cover mammograms under age 50.
Allmerica Financial	Ages 40 to 49 are covered once every two years. Ages 50 and over are covered once every year.
CIGNA	Besides mandated coverage, covers screenings as ordered by physicians.

STATE OF MAINE
DEPARTMENT OF HUMAN SERVICES
11 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0011

ANGUS S. KING, JR.
GOVERNOR

KEVIN W. CONCANNON
COMMISSIONER

ADDRESS REPLY TO

April 24, 1997

Don Hamm
William M. Mercer, Inc.
411 East Wisconsin Avenue
Milwaukee, WI 53202

Dear Don:

Enclosed are materials related to screening guidelines for mammography for women age 40-49. I hope you will find these helpful. I am continuing to search for information related to hospital stays following mastectomy, and will be contacting CDC for information from other states tomorrow.

As I mentioned yesterday, I would be very happy to review your impact study once it is available in draft form, and will pan it by our program's technical and medical consultants for their review as well. Because breast cancer is such a complicated disease, we can lend our clinical and programmatic experience to assure that the assumptions made in the study are appropriate.

Please feel free to call me at 207-287-5387 if you have any questions.

Sincerely,

Barbara Leonard/pmk

Barbara A. Leonard, MPH
Program Director
Maine Breast and Cervical Health Program

BAL/pmk
Enclosures

cc: Dora Anne Mills, MD, MPH, Director, Maine Bureau of Health

March 27, 1997

National Cancer Institute
Press Office
(301) 496-6641

American Cancer Society
Joann Schellenbach
(212) 382-2169

Joint Statement on Breast Cancer Screening for Women in Their 40s
The National Cancer Institute and the American Cancer Society

The National Cancer Institute (NCI) and the American Cancer Society (ACS) agree that mammography screening of women in their 40s is beneficial and supportable with the current scientific evidence.

Both organizations recognize the importance of basing their guidance on currently available scientific evidence that shows a benefit of screening with mammography for women in their 40s. The NCI and the ACS will work together to provide clear guidance to women concerning the risk of developing breast cancer and the value and limitations of screening mammography.

Risk factors vary for each person. Women and their physicians need clear and understandable information that explains what is known about the risk of developing the disease They also need to know that incidence of breast cancer rises with increasing age.

The ACS and the NCI will develop educational tools to enable a woman to understand her own risk for developing the disease, as well as the benefits and limitations of mammography for finding breast cancer early. As in older women, screening women in their 40s provides the opportunity to find breast cancer early, when less aggressive treatments may be more feasible and more likely to provide long-term freedom from this disease.

Both the NCI and ACS are committed to a goal of providing the best possible guidance to women of all ages.

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APR

National Cancer Advisory Board

9000 Rockville Pike, Bethesda, Maryland 20892 Tel (301) 496-5147 Fax (301) 402-0956

FOR IMMEDIATE RELEASE
10:30 a.m. EST
Thursday, March 27, 1997

NCI Press Office
(301) 496-6641

National Cancer Advisory Board Issues Mammography Screening Recommendations

Members of the National Cancer Advisory Board (NCAB) concurred 17 to 1 in recommending that the National Cancer Institute (NCI) advise women 40 to 49 to get screening mammograms every one to two years if they are at average risk for breast cancer. For women 50 years and older, the Board said NCI should recommend mammograms every one to two years.

The NCAB said that women who are at higher than average risk should seek expert medical advice about beginning mammography before age 40 and about their screening frequency when they are in their 40s.

The Board defined higher risk women as those who have had breast cancer; women carrying identified genetic alterations that may make them more susceptible to breast cancer; women in families in which multiple family members are affected with breast cancer, generally at younger ages; those with breast disease that may predispose them to cancer or those having had two or more breast biopsies for benign disease; women with 75 percent or more dense breast tissue on previous mammograms that made mammography reading difficult; or women having a first birth at age 30 or older. Women without these risk factors are considered to be at average risk of developing breast cancer.

Because of the limitations of mammography, the Board stated that a clinical breast examination by a health care provider is an important part of regular, routine health care for women.

The Board stated that health insurers, including managed care organizations, should pay for mammography for higher-risk women at any age and for all women beginning at 40.

"The Board concluded that there is enough evidence to support a woman's decision to begin screening in her 40s," said Barbara Rimer, Dr. P.H., board chair, professor and director of cancer prevention, detection, and control research at Duke University, Durham, N.C.

"But the Board also wanted women and their providers to be informed fully about both the benefits and limitations of mammography so they can make informed decisions," Rimer added.

The NCI decided in 1993 not to recommend universal mammography screening beginning at age 40 because at that time there was not clear scientific evidence that women in their 40s undergoing regular screening have a reduced risk of dying of breast cancer. For many years, the evidence for women age 50 and older has shown clear benefit.

In reaching its conclusions, the National Cancer Advisory Board, a presidentially appointed committee that advises and consults with the director of the NCI, considered updated findings from breast cancer screening studies presented in January at an National Institutes of Health Consensus Development Conference. These new data show that regular screening mammography of average risk women in their 40s reduces deaths from breast cancer by about 17 percent.

In addition to the benefits of screening, the Board outlined the limitations of mammography. In particular, it referred to the high percentage (compared to women over age 50) of abnormal mammograms that are not cancer, but require further testing -- another mammogram, fine needle aspiration, ultrasound, or biopsy. Estimates are that a women who has a yearly mammogram in her 40s has about a 30 percent chance of having a "false-positive" mammogram.

Another limitation of mammography for women in their 40s is the difficulty of detecting tumors in the denser breasts of younger women. About 25 percent of breast tumors are missed in women in their 40s compared with 10 percent of tumors for women in their 50s.

Research is under way in imaging technology such as magnetic resonance imaging, breast ultrasound, and breast-specific positron emission tomography to overcome these limitations.

In addition to imaging technologies, NCI-supported scientists are exploring methods to detect traces of breast cancer in blood, urine, or nipple aspirates, and to detect genetic alterations in women who are at increased risk for breast cancer.

NCAB also recommended that the NCI take the following actions:

- Develop, in partnership with other professional and advocacy organizations innovative methods of educating women, physicians, and other providers regarding the benefits and limitations of mammography as well as the risk factors for breast cancer.

- Create a uniform database that will encourage all investigators conducting large-scale randomized screening studies for women ages 40 to 49 to provide primary data for combined analyses.

- Convene an independent Mammography Data Monitoring Board to review on an ongoing basis the data from randomized mammography trials and, to report regularly to the NCAB and the public on the progress of the trials.

# # #

The Board statement and a list of its members are attached.

-4-

National Cancer Advisory Board (NCAB)
Mammography Recommendations For Women Ages 40 to 49

Introduction

The risk of developing breast cancer is not the same for all women. Several expert groups and professional organizations have examined the available data on mammography screening in women ages 40 to 49, and have reached different conclusions. Current mammography recommendations for women 40 to 49 are, of necessity, interim in nature and subject to change as new data continue to be collected. This statement reflects the perspective of the National Cancer Advisory Board.

Recommendations

To assist women ages 40 to 49 who seek definitive advice on mammography, the National Cancer Institute (NCI) should recommend regular screening mammograms between ages 40 and 49 years for women at **average risk**. (All women who do not fulfill criteria for higher risk, as defined on the next page, are assumed to be at average risk.) For women 40 to 49 years of age, it is prudent to have mammograms every one to two years.

Some women are at **higher risk** (also see next page) than others. Women of higher risk should seek expert medical advice about beginning mammography before age 40 and to determine their mammography schedule in the 40s. Mammography for women at higher risk is described in more detail below.

The NCI should continue to recommend regular (every one to two years) mammograms for women in their 50s and older, as advised by all professional organizations.

Benefits

The benefit of mammography is detection of cancer early when it is more easily treated with a better outcome. Regular screening mammography in **average risk** women ages 40 to 49 reduces deaths from breast cancer by about 17 percent. By early detection of breast cancer, treatment is not only more effective but potentially less disfiguring and toxic. Women whose breast cancers are found by mammography may also be able to have surgery that spares part of the breast.

Limitations of Mammography

No medical test is always 100 percent accurate, and mammography is no exception. Research is underway to improve the technology which will lead to better accuracy in screening with mammography.

(more)

While women 40 to 49 and older may benefit from having regular mammograms, some cancers will be missed by this test (as many as 25 percent of breast cancers for women ages 40 to 49). That is why it is important that a clinical breast examination by a health care provider should be included as part of regular, routine health care.

Distinguishing early cancers from suspicious, but not cancerous, breast abnormalities found on a mammogram is more difficult in younger women. These "false positive" mammograms require careful attention, including breast biopsies, to assure a woman that she does not have breast cancer. It is estimated that if a woman got mammograms every year between 40 to 49, she would have about a 30 percent chance of having a "false positive" mammogram result. Current research is directed towards improving the accuracy of mammograms to reduce the still high proportion of "false positives" among women 40 to 49 and, for that matter, other ages.

Who Pays for Mammograms?

For women within the age and risk groups recommended to have mammograms, all third party payers (e.g., health insurers and managed care organizations) should pay for mammography.

Mammograms for Women at Higher Risk of Breast Cancer

Women who have a higher risk of breast cancer, or who suspect that they may be prone to breast cancer, should seek good medical advice about when and how often to have mammograms, and should also practice other approaches, including examinations by health professionals, to detect this disease early when treatment is most effective. Elevated risk of breast cancer is associated with the following conditions: (1) having had a previous breast cancer; (2) laboratory evidence that the woman is carrying a specific mutation or genetic change that increases susceptibility to breast cancer; (3) having a mother, sister or daughter with a history of breast cancer or having two or more close relatives, such as cousins, with a history of breast cancer; (4) having had a diagnosis of other types of breast disease (not cancer but a condition that may predispose to cancer) on a breast exam or having had two or more breast biopsies for benign disease, even if no atypical cells are found; and (5) having so much dense breast tissue (above 75 percent) on a previous mammographic examination that clear reading is difficult; and (6) having a first birth at age 30 or older. Women will need to consult a health professional to determine if some of these conditions are present.

Background

The controversy over mammography for women 40 to 49 is not new. In 1993, the NCI made the difficult decision to withdraw its prior recommendation for routine screening for women at these ages. Since then, new studies have found additional scientific evidence of a reduction in breast cancer mortality from screening mammography. Currently available data are from seven randomized studies in which women were assigned to either routine mammography or usual care, and thereafter, followed for cancer occurrences and mortality from breast cancer.

By combining available data from the seven randomized studies around the world, about a 17 percent reduction in breast cancer mortality was found for those who were invited for screening. To many, but not all experts this is statistically significant. This level of mortality reduction appears impressive, but is actually difficult to detect with a high level of certainty because the seven mammography studies differ with regard to study design and implementation, age composition of participants and other factors. The currently observed beneficial effect of mammography might increase, decrease or disappear over time. There may be unexpected late beneficial or harmful effects of screening mammography that cannot be detected presently.

In 1996, in the United States, 184,000 women were diagnosed with breast cancer; about 31,000 of these women were aged 40 to 49. The chance of being diagnosed with breast cancer over the decade of 40 to 49 is one in 66 women, or about 2 percent. In 1996, 44,000 women died from breast cancer; of those, 4,700 women were aged 40 to 49. A woman 40 to 49 has a 0.3 percent chance of dying from breast cancer before age 50.

Future Research

To improve the quality, analyses, interpretation and dissemination of data from the seven randomized studies of screening mammography (and other future studies), the NCAB recommends that the following actions be undertaken as soon as possible:

- The NCI, professional, voluntary, and public interest organizations should develop innovative methods to educate women, their physicians and other health professionals regarding the established benefits of mammography screening in women ages 50 and over, and the current recommendations and state of knowledge regarding screening at earlier ages.

- The NCI should make every effort to encourage and assist all investigators conducting randomized mammography screening studies that include women 40 to 49 to provide primary data for combined analyses. NCI can assist these groups in defining a uniform data set that will be periodically updated and submitted to a common database.

- The NCI should convene an independent Mammography Data Monitoring Board of clinicians, trialists, statisticians and other experts to prospectively define the analytic procedures and regularly review and report on the progress of the mammography trials to NCAB and the public.

National Cancer Advisory Board
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(more)

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Silver Spring, MD 20910

Charles B. Wilson, M.D.
Director, UCSF Neurosurgery
Brain Tumor Research Center
University of California at
San Francisco
San Francisco, CA 94143

Cancer Information Service

The Cancer Information Service (CIS), a national information and education network, is a free public service of the National Cancer Institute (NCI), the federal government's primary agency for cancer research. The CIS meets the information needs of patients, the public, and health professionals. Specially trained staff provide the latest scientific information in understandable language. CIS staff answer questions in English and Spanish and distribute NCI materials.

Toll-free phone number: 1-800-4-CANCER (1-800-422-6237)
TTY: 1-800-332-8615

CancerFax®

For NCI information by fax, dial 301-402-5874 from the telephone on a fax machine and listen to recorded instructions.

CancerNet™

For NCI information by computer:

CancerNet Mail Service (via E-mail)

To obtain a contents list, send E-mail to cancernet@icicc.nci.nih.gov with the word "help" in the body of the message.

Internet

Information is also accessible via the Internet through the World Wide Web at (http://rex.nci.nih.gov) and (http://cancernet.nci.nih.gov) servers.

NATIONAL CANCER INSTITUTE

Office of Cancer Communications

Building 31, Room 10A-24
Bethesda, Maryland 20892

For Response to Inquiries

National Institutes of Health

March 27, 1997

NCI Press Office
(301) 496-6641

Statement from the National Cancer Institute on the National Cancer Advisory Board Recommendations on Mammography

The National Cancer Institute (NCI) accepts the recommendations of the National Cancer Advisory Board on screening mammography.

As a result, NCI will recommend that:

- Women in their 40s should be screened every one to two years with mammography.
- Women aged 50 and older should be screened every one to two years.
- Women who are at higher than average risk of breast cancer should seek expert medical advice about whether they should begin screening before age 40 and the frequency of screening.

The board also stated that because of mammography's limitations, it is important that a clinical breast examination by a health care provider be included as part of regular, routine health care. NCI will include that statement in its recommendations.

Richard Klausner, M.D., NCI director, expressed his gratitude to the board for coming to closure on the issue quickly and for helping to bring clarity to this important issue. He said the board also made important recommendations for future research on breast cancer screening and education, and that NCI would address those research recommendations.

Klausner said the institute will immediately begin to develop new educational materials to communicate the screening recommendations and to help women and health professionals determine an individual's breast cancer risk. He said that NCI also will work with the American Cancer Society, other government agencies, advocacy organizations, cancer centers, and other

(more)

groups to educate the public and health professionals about the benefits, limitations, and risks of screening mammography.

# # #

Cancer Information Service
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Toll-free phone number: 1–800–4–CANCER (1–800–422–6237)
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For NCI information by computer:

CancerNet Mail Service (via E-mail)
To obtain a contents list, send E-mail to cancernet@icicc.nci.nih.gov with the word "help" in the body of the message.

Internet
Information is also accessible via the Internet through the World Wide Web at (http://rex.nci.nih.gov) and (http://cancernet.nci.nih.gov) servers.

STATEMENT

American Cancer Society
Workshop on Guidelines for Breast Cancer Detection
Chicago, March 7-9, 1997

On March 7-9, 1997, the American Cancer Society (ACS) convened a workshop to consider new scientific findings related to breast cancer screening, and to determine whether these new findings warrant a change in the existing ACS guidelines for the early detection of breast cancer. This meeting was proposed in June, 1995, but postponed twice in order to benefit from new data related to screening women ages 40-49 presented at a meeting in Falun, Sweden in March, 1996, and an NIH Consensus Development Conference that was announced just after the Falun meeting and held in January, 1997 (1,2). Although data presented at these meetings provided further support for the benefit of mammography for women ages 40-49, these new data have not been universally persuasive (3). In fact, even though there is growing acknowledgement that the accumulated results from the randomized clinical trials do show a benefit from screening for this age group, there are differences of opinion on the value of including women ages 40-49 in recommendations for regular breast cancer screening. This difference in opinion regarding breast cancer screening policy largely is due to different criteria for evidence-based medicine. However, the ACS had concluded that the new data accumulated since the last review of the guidelines in 1993 had potentially positive implications for the overall question of benefit from mammography in women ages 40-49 and in particular, recommendations for periodicity of mammography in ACS guidelines.

*After one and a half days of scientific presentations and workgroup discussions, workshop participants concluded that the new data warranted the following succinct recommendation regarding mammography: **the American Cancer Society recommends annual mammography for women beginning at age 40.** Cessation of annual screening is not age-dependent, but a function of co-morbidity. Previously, the ACS recommended that women begin mammographic screening for breast cancer by age 40, with intervals of 1-2 years between the ages of 40-49, and annual screening beginning at age 50. Also, there was no upper age limit for this recommendation--as long as a woman is in good health, regular mammographic screening is recommended.*

At present, there are limited data to guide recommendations for screening intervals for older women. Workshop participants concluded that cost-effectiveness research for women in these age groups was an important area for investigation, as were factors related to barriers to compliance with screening recommendations, and ways to improve public and provider education related to screening older women. Therefore, no age at which screening should be terminated is specified. The Workgroup assigned to evaluate recommendations for clinical breast examination and breast self-examination concluded that there were no new data to warrant a change in the current guidelines. However, the Workgroup recommended that to the extent possible, the clinical breast examination should be conducted close to the time of the regularly scheduled mammogram.

The risk of breast cancer increases with age. Between the ages of 40-49, a woman has a 1.52% (1 in 66) risk of developing breast cancer at some time during the decade (4). In successive decades, risk is higher: between the ages of 50-59, risk increases to 2.48%(1 in 40); between the ages of 60-69, risk increases to 3.43%(1 in 29). As measured by number of new cases per 100,000 women, age-specific

incidence increases until the age-group 75-79 (480.7 per 100,000 women), after which it declines slightly to 431.4 per 100,000 women ages 85+. By convention, women ages 40+ were included in the early studies of breast cancer screening because women diagnosed in their 40's accounted for a considerable proportion of the premature mortality attributed to deaths from breast cancer (5).

Results from the most recent meta-analysis of all 8 randomized clinical trials yields an 18% (95% C.I., 0.71 - 0.95) mortality reduction among the 40-49 group, and a 26% (95% C.I., 0.63 - 0.88) mortality reduction for the 7 population-based randomized clinical trials (6). Results from two individual trials in Sweden also reveal statistically significant reductions in mortality among women ages 40-49. After 12 years of follow-up, the Gothenberg trial has shown a 44% reduction in mortality (95% C.I., 0.32 - 0.98), and the Malmo trial has shown a 36% reduction in mortality (95% C.I., 0.45 - 0.89) (7-8). Data for this age group now meet the same criteria of benefit that has been the basis for concluding that mammography was beneficial for women ages 50+ at randomization, i.e., that the observed mortality reduction achieves statistical significance at the 95% confidence level.

Data from these studies show that relative mortality reductions appear later in women ages 40-49 at randomization compared with women ages 50+. This observation has raised questions about whether the observed benefit may be attributable to women randomized during their 40's who were diagnosed with breast cancer after age 50. However, even though it is methodologically unsound to analyze trial data based on age at diagnosis rather than age at randomization, data from the HIP Swedish trials do not support this conclusion (9). Rather, the observation that mortality reductions in the trials required longer periods of follow-up is best explained by 1) lower incidence and mortality in women in their 40's; 2) small numbers of women in their 40's in the existing randomized trials; 3) a greater proportion of diagnosis of ductal carcinoma in situ (DCIS) in the group invited to screening (the greater lead time achieved from a diagnosis at this stage requires a longer period of follow-up); and 4) the observation that screening intervals in excess of 1 year in the majority of the trials were comparatively less effective in detecting the more aggressive tumors at favorable stages. More recent analysis indicates that longer periods of follow-up have been necessary to observe a benefit among women ages 40-49 because the wide screening interval in the majority of the trials contributed to mortality reductions only among women diagnosed with tumors of intermediate to good prognosis (1, 10). Survival is better among women diagnosed with less aggressive tumors, and therefore a relative difference in mortality in the invited compared with the non-invited group has taken longer to observe. These data are consistent with the conclusion that to achieve similar mortality reductions in younger women, compared with older women screened every 2 years, annual screening is necessary.

Results from randomized trials and large community-based screening programs (a.k.a. "service screening") have provided compelling evidence to support a revision in the existing ACS guidelines. Evaluation of interval cancers indicate that a greater proportion of breast cancers tend to grow faster in younger women compared with older women (10-12). Therefore, in order to achieve the maximal benefit from screening among women ages 40-49, it is important that the screening interval be the same in women under and over 50, i.e. annual screening. Further, it is clear from the data presented that it is artificial to compare women ages 40-49 with *all* women over the age of 50. There is an incrementally higher risk of breast cancer with increasing age, and therefore with increasing age there are incrementally greater benefits in the efficiency of screening programs (2). The magnitude of the potential reduction in mortality among women in different age groups who participate in regular screening with modern mammography (as contrasted with the older mammography used in the trials) is unclear, but it is believed to be potentially greater in each age group. Diagnosis at more favorable stages is the basis for the observed mortality reductions in the trials, and reports from modern screening programs have demonstrated similar distributions of prognostic factors in women ages 40-49 and the decades after age 50. Long-term follow-up also has shown similar survival. For the reasons listed above, there is no longer any reason to recommend different screening intervals for women under and over age 50.

New data were presented on the cost-effectiveness of modifying the current guidelines to annual

screening for women ages 40-49. The cost effectiveness of the new guideline is within the range of other commonly accepted screening procedures.

Workshop participants felt that it was very important that the benefits and limitations of breast cancer screening need to be more effectively communicated to women and health care providers. Communication of these recommendations, and information for informed decision making, is aresponsibility that the American Cancer Society must address and an *important area for further research.*

All of these recommendations require succinct but adequate explanation in the narrative portion of a guidelines document. This new recommendation should be accompanied by a background document clearly delineating the scientific evidence that supports the recommendation.

In the last day's general session, workshop participants made the following recommendations (some of which were covered above):

The stated "risks" and limitations of mammography should be quantified, and their validity, incidence, and significance documented;

A realistic statement of cancer risk, by decade and over the lifetime is needed;

Clarification of medical-legal considerations related to mammographic screening requires further evaluation, and interventions should be pursued that will reduce the adverse affects of "defensive medicine;"

Additional research is needed into the most effective screening interval for postmenopausal women in successive decades of life. Further, the influence of hormone replacement therapy on breast cancer risk, sojourn time, and mammographic image quality requires further investigation;

Research and professional education programs to improve the overall efficacy of mammography (accuracy and efficiency) should be pursued, including continuing medical education needs, double reading, self-assessment of interpretative skills, importance of access to previous films, tracking and follow-up etc.;

Research into new technologies for early detection and risk profile estimation, in particular identification of genetic susceptibility, is needed;

Evaluation of recruitment techniques and methods that improve compliance *with breast cancer screening guidelines; in particular, the effectiveness of reminder systems in women of all ages is a high priority for research;*

Improved communication to women of all ages about the relative importance of clinical breast examination and breast self-examination is needed.

The ACS should place greater emphasis on training of providers to conduct clinical breast examination;

References

1.Report of the Organizing Committee and Collaborators. Breast-cancer screening with mammography in women aged 40-49 years. Int. J. Cancer 1996; 68:693-699.

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CHANCES OF DEVELOPING BREAST CANCER

By age 25:	1 in 19,608
By age 30:	1 in 2,525
By age 35:	1 in 622
By age 40:	1 in 217
By age 45:	1 in 93
By age 50:	1 in 50
By age 55:	1 in 33
By age 60:	1 in 24
By age 65:	1 in 17
By age 70:	1 in 14
By age 75:	1 in 11
By age 80:	1 in 10
By age 85:	1 in 9
Ever:	1 in 8

Source: NCI Surveillance Program, 1993.

STATE OF MAINE

ONE HUNDRED AND EIGHTEENTH LEGISLATURE

COMMITTEE ON BANKING AND INSURANCE

April 16, 1997

Rick Diamond
Senior Life and Health Actuary
Life and Health Division
Bureau of Insurance
34 State House Station
Augusta, Maine 04333

Dear Mr. Diamond:

Title 24-A Maine Revised Statutes Annotated, Section 2752 requires the Joint Standing Committee on Banking and Insurance to submit legislation proposing health insurance mandates to the Bureau of Insurance for review and evaluation if there is substantial support for the mandate among the committee after a public hearing on the proposed legislation. Pursuant to that statute, we request the Bureau of Insurance prepare a review and evaluation of the following proposal:

LD 1556 An Act to Establish the Breast Cancer Patient Protection Act

A copy of the bill is enclosed. Also enclosed is a proposed amendment to the bill discussed by the committee in advance of its decision to ask the Bureau to conduct a review and evaluation of the legislation. The amendment replaces the language in the bill that requires coverage for inpatient care of 48 hours and 24 hours respectively with language that requires coverage for inpatient care of a length determined as medically appropriate by the physician and patient. The amendment also proposes to amend the current statutory requirements for screening mammograms to require coverage for annual mammograms for women over age 40. The committee would ask that the Bureau conduct its review and evaluation in relation to the proposed amendment and address the social and financial impact and medical efficacy of adding the mammogram provision to the bill.

In addition, a suggestion was made to expand the language to require coverage for inpatient care for the treatment of breast disease, not only the treatment of breast cancer.

The committee would request that the study address, if possible, the impact of this expanded language if it were included in the bill.

Please prepare the evaluation using the guidelines set out in 24-A § 2752 and submit the report to the committee during the week of May 5th if possible. The committee would also ask that the report on LD 1060 requested by the committee in a prior letter also be submitted within this time frame. The committee has a deadline of May 9th to complete its work on all bills in light of the statutory adjournment date of May 31st set by the President of the Senate and the Speaker of the House.

If you have any questions, please do not hesitate to contact us or our legislative analyst, Colleen McCarthy Reid.

Sincerely,

Lloyd P. LaFountain, III
Senate Chair

Jane W. Saxl
House Chair

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April 23, 1997

Senator Lloyd LaFountain, Chair
Representative Jane Saxl, Chair
Banking and Insurance Committee
115 State House Station
Augusta, ME 04333

Re: LD 1060 - An Act to Provide Health Insurance Coverage for Prostate Cancer Screening
LD 1556 - An Act to Establish the Breast Care Patient Protection Act
Requests for Review and Evaluation
Your Letters of March 11, 1997 and April 16, 1997

Dear Senator LaFountain and Representative Saxl:

The Bureau of Insurance would be pleased to provide the requested reports. As you know, we will employ a consultant, Tim Harrington of William M. Mercer, Inc., to prepare the reports.

When the Committee determined on April 9 that LD 1060 would be its top priority, Mr. Harrington indicated he could complete a report within four weeks, or by May 7. However, that did not include time for the Bureau's internal review of the report and any resulting changes to the report. We would like to add a week for this process, resulting in a final report by May 14. We will make every effort to provide the report sooner if possible.

For LD 1556, as amended, Mr. Harrington has again indicated that he can complete his report within four weeks, or by May 14. As with LD 1060, we would request an additional week for internal review and changes to the report, with a final report by May 21. Again, we will make every effort to provide the report sooner if possible.

Sincerely,

Richard H. Diamond, FSA, MAAA
Life & Health Actuary

cc: Colleen McCarthy-Reed