

**PRESIDENT AND THE FIRST LADY ANNOUNCE NEW INITIATIVES TO IMPROVE
PREVENTION AND EARLY DETECTION OF BREAST CANCER**

October 24, 1997

Today the President and the First Lady announced new steps to ensure that more women get regular, high quality mammograms. Early detection, followed by prompt treatment, can reduce the risk of death by as much as 30 percent. However, a mammogram can fail to do its job because of poor medical techniques, processing or reading of the films; inadequate record keeping and reporting of results, and lack of effective quality assurance controls. In 1995, about 35 percent of mamography facilities that sought accreditation initially failed the quality requirements. Moreover, far too few women get regular mammograms. Thirty-three percent of women ages 50 to 64, and 45 percent of women over age 65 reported not receiving a mammogram in the last two years. The initiatives the President and the First Lady are announcing today include:

Improving Quality Standards of the Mammography Facilities Nationwide. The new FDA regulations announced today, authorized by the Mammography Quality Standards Act (MSQA), set new high standards for mammography facilities. They include important new clarifications that require facilities to hire capable technologists, to use equipment that produces clear and accurate images, and to ensure that physicians have the skills to interpret the rules. It also requires facilities to display their FDA certification, so women and their families know facilities have met the quality standards. They also require that patients be fully informed of results of a mammogram so that follow up testing and treatment can begin immediately. These new standards will ensure women receive high quality, accurate mammograms. The National Breast Cancer Coalition applauded the implementation of the final regulations stating that "this Rule will ensure that every woman in America will receive the highest quality mammography."

Initiating a New Mammography Education Campaign at the National Cancer Institute (NCI). Today, the NCI is initiating a new national education campaign that provides women and their families and health professionals clear, up-to-date information about steps they should take to detect mammography and breast cancer. The materials being released have been developed to educate women about the recommendations made by NCI this spring that women in their 40s and older should get regular screening mammograms. The NCI materials will be released to community organizations, doctor's offices, and other health care facilities around the country, providing education about the risk factors for breast cancer, the benefits and limitations of mammography, and the importance of regular mammograms for women in their 40s and older. They also highlight breast cancer incidence and mortality rates for women in different racial/ethnic groups.

Launching the First Lady's National Annual Medicare Mammography Campaign. Each year the First Lady has launched a mammography campaign to encourage older women to get mammograms. Despite the fact that mammography can significantly reduce mortality rates, 45 percent of women over age 65 have not had a mammogram in the last two years. To encourage more older women to get regular mammograms, this year the First Lady's campaign includes:

- **New Nationwide Public Service Announcements to Encourage More Older Women to Get Mammograms.** Today, the First Lady is announcing two new public service announcements to encourage older women to get mammograms. One of the PSAs features Candice Bergen and was aired this week at the close of the Murphy Brown Show. The second PSA includes breast cancer survivor and spokesperson Carol Baldwin and her sons, Alec, William, Daniel and Stephen. In addition to these PSAs, a number of corporations have made important new commitments to educate women about the importance of regular mammography and screening.
- **HORIZON Grants to Improve Mammography Rates Among Minority Women.** This year HCFA has focused the Medicare mammography campaign to reach minority Medicare beneficiaries who are even less likely to get mammography screenings. HCFA launched Horizon Project grants, a three-year initiative in six major cities which focuses efforts on increasing mammography rates among Hispanic and African-American Medicare beneficiaries. These comprehensive efforts will not only encourage more women in these areas to get regular mammograms but provide insight on how to overcome barriers that prevent women from getting mammograms. This week, we received the project's first report, and it is teaching us a great deal about how to identify barriers including lack of awareness about the Medicare mammography benefit, language barriers, and misconceptions that only women of childbearing age are at risk for breast cancer, and strategies to overcome them.

The Initiatives Being Announced Today Build on the President's Strong Record in the Fight Against Breast Cancer.

- **The Balanced Budget Act Made Medicare Mammograms More Affordable and Accessible.** The balanced budget the President signed into law this summer took steps to encourage more women to get regular mammograms by waiving deductibles for all mammograms and covering mammograms on an annual basis. Although Medicare has covered screening mammography since 1991, only 14 percent of eligible beneficiaries without supplemental insurance receive mammograms, indicating that cost can be a significant barrier. The balanced budget also expanded coverage to pay for annual screening mammograms all Medicare beneficiaries age 40 and over -- making coverage consistent with the new recommendations of national experts. Earlier in the year, President Clinton took action to bring Medicaid and Federal Employees Health Benefits in line with the new recommendations.
- **The President Has a Long Record in Fighting Breast Cancer.** The President has taken a number of important steps to fight breast cancer. Since the President took office funding for breast cancer research, prevention and treatment has nearly doubled to over \$500 million in 1997; the CDC breast and cervical program which provides screening low-income women has expanded nationwide; new space technology has been applied to research to gain valuable knowledge important about detection and treatment of breast and ovarian cancer; and funding has increased for an unprecedented partnership at the Department of Defense between the military, scientists, physicians and community members for grants to invigorate breast cancer research.

CLINTON ADMINISTRATION INITIATIVES TO FIGHT BREAST CANCER

- **Introduced Legislation to Prevent Discrimination Based on Genetic Information.** The President has urged Congress to pass bipartisan legislation to prohibit health plans from inappropriately using genetic screening information to deny coverage, set premiums, or to distribute confidential information. For many diseases, such as breast cancer, we are beginning to identify hidden genetic disorders which can spur early treatment. However, genetic testing also can be used by insurance companies and others to discriminate and stigmatize groups of people. In fact, studies show that a reason women do not get genetic testing for breast cancer is because they fear the information will be used to discriminate against them.
- **Expanded Medicare to Pay for Annual Screening Mammograms for all Medicare Beneficiaries Age 40 and Over.** The balanced budget expands coverage to pay for annual screening mammograms for all Medicare beneficiaries age 40 and over, enabling women to follow the National Cancer Institute's (NCI) recommendations to undergo regular mammogram screening at age forty. President Clinton has also taken action to bring Medicaid and federal employee health benefits in line with NCI recommendations.
- **Made Medicare Mammograms More Affordable and Accessible.** The balanced budget enacted by the President this August waived deductibles for all screening mammograms, making annual mammograms more affordable for older women. Costs can be a significant barrier for older women to get mammograms. Although Medicare has covered screening mammography since 1991, only 14 percent of eligible beneficiaries without supplemental insurance receive mammograms.
- **Built on HHS Commitment to Breast Cancer Research, Prevention and Training.** Since the President took office, funding for breast cancer research, prevention and treatment has nearly doubled, from about \$276 million in FY 1993 to an estimated \$513 million in the President's FY 1997 budget.
- **Continued Department of Defense Funding for Breast Cancer Research.** In FY 1997, the DOD will spend \$112 million on breast cancer research. This is an unprecedented partnership between the military, scientists, physicians, and the community to fund grants to invigorate breast cancer research. One of the most important and innovative aspects of the program is that breast cancer survivors are actively engaged in defining the program and serve on scientific panels which review grant proposals.
- **Increased Funding for Genetic Research.** HHS-funded research led to the discovery of two breast cancer genes -- BRCA-1 and BRCA-2 -- which holds great promise for the development of new prevention strategies. On October 26, 1996, President Clinton announced \$30 million in new funding for research into the genetic basis of breast cancer.

- Educated Older Women to Use the Medicare Mammography Screening Benefit.** The First Lady has launched a yearly mammography campaign to inform and encourage older women to use the Medicare mammography screening benefit. Despite evidence that early detection through mammography and clinical breast exams is essential, 45 percent of women over age 65 report they have not had a mammogram during the past two years. This year the First Lady's campaign focuses on encouraging women with particularly low mammography utilization rates to get mammograms.
- Improved Mammography Quality Standards.** The final regulations the President announced today strengthen and improve the program the FDA implemented for mammography standards in 1994 to ensure that they meet standards for equipment, personnel, record-keeping, and quality control. Women and their families can look for the FDA certificate as evidence that the facility meets quality standards. These new standards will ensure women high quality, accurate mammograms. Women can find a certified mammography facility by calling 1-800-4-CANCER.
- Supported Legislation That Prevents Women From Being Forced Out of the Hospital Only Hours After a Mastectomy.** In his State of the Union Address, President Clinton endorsed bipartisan legislation to ensure that women are not forced out of the hospital before they are ready because of pressure from their health plan. The Department of Health and Human Services also sent a letter to all Medicare managed care plans making it clear that they may not set ceilings for inpatient hospital treatment or set requirements for outpatient treatment, and that a woman and her doctor should make decisions about what is medically necessary.
- Provided Screening for Low-Income Women.** CDC's National Breast Cervical Cancer Early Detection Program offers free or low-cost mammography screening to low-income elderly and minority women. On October 1, 1996, Secretary Shalala announced the expansion of the program to all fifty states. The goal is to reduce breast cancer deaths among these women by 30% and cervical cancer deaths by 90% through increased mammography and pap testing.
- Applied Space Technology to Detect and Treat Breast Cancer.** NASA is applying cutting edge technology to improve ways to diagnose and treat breast cancer. For example, NASA uses the microgravity of space to grow human tissue for research and transplantation, gaining valuable knowledge important to the treatment of breast and ovarian cancer. Mars Pathfinder technology has been developed to enhance pictures is being modified to make three-dimensional models of breast tissue. This enables doctors to differentiate breast tissue more accurately without using painful invasive procedures.

QUOTES SUPPORTING THE PRESIDENT'S INITIATIVES ON BREAST CANCER

"Thank you for your continuing commitment to eradicating breast cancer. . .Over the past five years, your Administration has helped make finding the cause of and a cure for breast cancer a national priority by increasing research efforts and improving current breast cancer policy."

"We applaud the Administration's dedication to improving breast cancer screening and the promulgation of the final regulations implementing the Mammography Quality Standard Act (MQSA). This Rule will ensure that every woman in America will receive the highest quality mammography."

--National Breast Cancer Coalition

"The American Cancer Society (ACS) applauds President Clinton for his leadership on breast cancer issues. ACS supports the issuance of the final regulation of the Mammography Quality Assurance Standards Act (MQSA) because it will give women more confidence in the quality of their mammography."

"ACS also supports the investment in screening programs to reach poor and underserved women who may not otherwise receive health care."

"Finally, ACS supports the National Cancer Institute initiative to educate women about the need for annual mammograms beginning at age forty."

--American Cancer Society

"On behalf of the National Alliance of Breast Cancer Organizations' 375 member organizations and the many thousands of women under their care, please accept our appreciation for your leadership in the fight against breast cancer. With new plans and initiatives and through support of federal programs and legislation, all American families have felt your concern about this most common form of cancer in women in our country."

"With your guidance, millions of women are now hearing lifesaving messages, and poor and underserved women are linked to health care services they require and deserve."

--National Alliance of Breast Cancer Organizations

“I am pleased to join millions of other Americans in applauding your leadership in all areas of women’s health, especially breast cancer detection and treatment.”

“Your initiatives to broaden access to mammography for all American women and to ensure that mammograms are done only by trained personnel at properly equipped facilities will undoubtedly save many lives.”

“ We also applaud your efforts to increase funding for breast cancer research.”

--Society for the Advancement of Women’s Health Research

“The American College of Radiology (ACR) today strongly supported the Administration’s far-reaching efforts to bring high quality screening mammography to under-served women across the nation.”

“As a result of this private/public partnership with the ACR accreditation program and FDA certification women can be assured of getting the best mammography available, which can save their lives through early detection.”

--American College of Radiology

“The American Medical Women’s Association applauds the efforts of the Clinton Administration in the area of breast cancer research, education, detection, diagnosis, and treatment.”

“As a long-time advocates for women’s health, President and Mrs. Clinton are to be commended for their support of the FDA’s Mammography Quality Standards Act, which ensures that all mammography facilities in the United States are certified by the FDA as providing quality mammography in order to lawfully continue to provide mammography services.”

--American Medical Women’s Association

“I want to commend you for your leadership of a national effort to combat breast cancer.”

“The efforts of your Administration to expand Medicare coverage of mammograms are critical if elderly women are to take advantage of this important screening tool. Of equal significance is making women aware of the need for mammograms and that coverage is available.”

--American College of Obstetricians and Gynecologists

“Shaklee applauds the efforts of Hillary Clinton and the Clinton Administration to change Medicare guidelines to allow women over 50 access to annual mammogram testing.”

--Shaklee Corporation



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October 24, 1997

*File
in
President
and
Mrs. Clinton*

President Bill Clinton
and Hillary Rodham Clinton
The White House
Washington, DC 20500

Dear President and Mrs. Clinton:

On behalf of the National Alliance of Breast Cancer Organizations' 375 member organizations and the many thousands of women under their care, please accept our appreciation for your leadership in the fight against breast cancer. With new plans and initiatives and through support of federal programs and legislation, all American families have felt your concern about this most common form of cancer in women in our country. We admire your constant eagerness to learn about this rapidly-changing field, and your generous participation in issues of importance to national and local breast cancer organizations, advocates, patients and survivors.

As the country's leading non-profit education and information resource on breast cancer, NABCO believes that information is empowering, and that women can replace fear with facts about this disease. With your guidance, millions of women are now hearing lifesaving messages, and poor and underserved women are linked to health care services they require and deserve.

As we commemorate National Breast Cancer Awareness Month this October, I would like to add my personal thanks. Today, I celebrate my 13th year as a breast cancer survivor. We have come a long way toward a future without breast cancer for our daughters. With your continued support, we will win this fight.

Very truly yours,

Amy S. Langer
Executive Director



Society for the Advancement of
WOMEN'S HEALTH RESEARCH

October 23, 1997

The Honorable William J. Clinton
President
The White House
Washington, DC

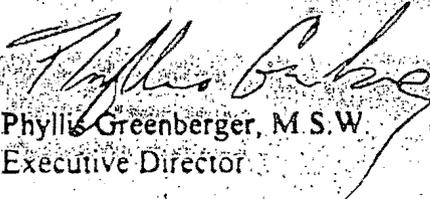
Dear President Clinton,

I am pleased to join millions of other Americans in applauding your leadership in all areas of women's health, especially breast cancer detection and treatment. Your initiatives to broaden access to mammography for all American women and to ensure that mammograms are done only by trained personnel at properly equipped facilities will undoubtedly save many lives. We also applaud your efforts to increase funding for breast cancer research.

Both you and the Society recognize that much more needs to be done in the way of prevention, early detection, and treatment. Certainly, the untimely death of your mother brought home the issue to you as it has for thousands of American families. Our goal should be to understand how and why some women develop breast cancer and then to develop ways to prevent it.

We look forward to your continuing support for research into the many diseases, disorders and conditions including osteoporosis and heart disease which shorten or diminish women's lives.

Sincerely,


Phyllis Greenberger, M.S.W.
Executive Director

NATIONAL BREAST CANCER COALITION

a grassroots advocacy effort October 23, 1997

The Honorable William Jefferson Clinton and Hillary Rodham Clinton
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear President and First Lady Clinton,

On behalf of the National Breast Cancer Coalition (NBCC) I would like to thank you for your continuing commitment to eradicating breast cancer. Since the beginning of your Administration you have supported the goals and mission of the NBCC. You recognize that breast cancer is not just a one month issue, but an ongoing crisis. Over the past five years, your Administration has helped make finding the cause of and a cure for breast cancer a national priority by increasing research efforts and improving current breast cancer policy.

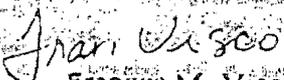
The NBCC is a grassroots advocacy organization dedicated to the eradication of breast cancer. We are made up of over 400 organizations and hundreds of thousands of individuals. The NBCC's goals are (1) to increase the money available for research into breast cancer and to focus research on prevention, on finding the cause of and a cure for this insidious disease, (2) to make certain that all women have access to the quality care and treatment they need, regardless of their economic circumstances and (3) to increase the influence of women with breast cancer in the decision making that affects their lives.

We appreciate your willingness to work with us at every opportunity from our first introduction with the First Lady in October 1992 to our work with the President on his Cancer Panel and the National Action Plan on Breast Cancer to our mutual commitment to finding quality health care for all Americans. Our relationship with the you and your Administration has been exceptional. Working together we have been able to achieve ground-breaking improvements in breast cancer which have benefitted thousands of women and their families. We know you share our understanding that much more needs to be done.

We applaud the Administration's dedication to improving breast cancer screening and the promulgation of the final regulations implementing the Mammography Quality Standard Act (MOSA). This Rule will ensure that every woman in America will receive the highest quality mammography.

It has been a pleasure and an honor to work with your Administration. Thank you for your past support -- we look forward to continuing to work with you over the next three years.

Sincerely,


Francis M. Visco
President



GOVERNMENT RELATIONS OFFICE

STATEMENT FROM THE AMERICAN CANCER SOCIETY

The American Cancer Society (ACS) applauds President Clinton for his leadership on breast cancer issues. ACS supports the issuance of the final regulation of the Mammography Quality Assurance Standards Act (MQSA) because it will give women more confidence in the quality of their mammography. ACS also supports the investment in screening programs to reach poor and underserved women who may not otherwise receive health care. Finally, ACS supports the National Cancer Institute initiative to educate women about the need for annual mamograms beginning at age forty.



AMERICAN MEDICAL WOMEN'S ASSOCIATION

FOR IMMEDIATE RELEASE

CONTACT: Anne Pritchett
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American Medical Women's Association Applauds Breast Cancer Efforts

Alexandria, VA (October 23, 1997). The American Medical Women's Association applauds the efforts of the Clinton Administration in the area of breast cancer research, education, detection, diagnosis, and treatment. It is particularly appropriate during National Breast Cancer Awareness Month that we recognize the efforts of the Clinton Administration in the area of breast cancer. As a long-time advocates for women's health, President and Mrs. Clinton are to be commended for their support of the FDA's Mammography Quality Standards Act, which ensures that all mammography facilities in the United States are certified by the FDA as providing quality mammography in order to lawfully continue to provide mammography services. We also applaud them for their support of the Breast Cancer Patient Protection Act of 1997, which would require health plans to allow women who have undergone mastectomies to remain in the hospital for at least 48 hours, and 24 hours for those undergoing lymph node dissections.

Almost 2 million women will be diagnosed with breast cancer in this decade, and approximately 450,000 will lose their lives to the disease within this same timeframe. The number of breast cancer deaths will likely be reduced as a result of early detection and appropriate management. The American Medical Women's Association applauds the efforts of President and Mrs. Clinton for their efforts to help increase access to quality mammography and to improve the health of the Nation's women.

Founded in 1915, the American Medical Women's Association represents more than 11,000 women physicians and medical students who are dedicated to promoting women's health and furthering the personal and professional development of women in medicine. AMWA has long focused on breast cancer as a key public health issue, and currently is providing training in breast cancer diagnosis and treatment to more than 6,000 primary care managers throughout the country.

Representing Women in Medicine Since 1915

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NEWS

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For Immediate Release
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Shaklee Corporation Goes to Bat for Breast Cancer Awareness Month

San Francisco, CA — Shaklee applauds the efforts of Hillary Clinton and the Clinton administration to change Medicare guidelines to allow women over 50 access to annual mammogram testing. Recognizing the importance of breast cancer education and early detection, Shaklee Corporation initiated three breast cancer awareness programs targeted to its nationwide base of independent distributors, employees and the public during October of 1997. The company alerted both its distributors and employees through publications and notices about ways to be involved in educating themselves and others in combating this epidemic disease. Shaklee also provided funding to programs that raised awareness and encouraged individual action.

Special bulletins in Shaklee's *Late breaking News* went to over 14,000 independent distributors that encouraged readers to have regular physical check-ups and to ask their doctors about preventive measures. The notices included the reminder that Medicare covers the cost for mammography every other year for women that qualify. As part of its Wellness Program, the Company also underwrote the entry fee for any employee participating in the *Race For the Cure*, a run benefiting the Susan B. Komen Foundation.

Additionally, Shaklee provided seed money to help fund the compelling documentary, *Rachel's Daughters: Searching for the Causes of Breast Cancer* which aired on HBO six times during October. Taking an original approach to exploring the broad spectrum of suspected causes, the film included interviews with twenty-one scientists and medical doctors by its lay investigators, women who are living with breast cancer. This powerful film is a fitting tribute to Rachel Carson, author of the landmark book, *Silent Spring*. A conservative estimate is that four to five million people will have seen *Rachel's Daughters* by the end of October.

Founded in 1956, Shaklee Corporation is an innovative global marketing company with operations in the United States and seven other countries. A diversified consumer products company, Shaklee includes multilevel marketing, research and technology development under the Shaklee name and direct mail and retail product operations through its Bear Creek Corporation subsidiary. The Shaklee Global Marketing Companies include Shaklee North America and Shaklee International. In 1989, Shaklee was purchased as a wholly-owned subsidiary by Yamanouchi Pharmaceutical Co., Ltd., one of the largest and most profitable pharmaceutical companies in Japan with operations worldwide. The combination of the two firms has created a global entity on the cutting edge of science and technology, offering high quality products that continue the tradition of health, wellness and sensitivity to the environment.

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Contact: Michael J. Bernstein (703) 648-8910
Carolyn J. Jones (703) 648-8928

Embargoed Until:
Noon October 25

American College of Radiology Praises White House For Strong Mammography Screening Initiatives

The American College of Radiology (ACR) today strongly supported the Administration's far-reaching efforts to bring high quality screening mammography to under-served women across the nation.

Today the White House announced a major initiative, to be led by First Lady Hillary Rodham Clinton, targeting minority and other under-served women. The major educational campaign is titled, "Get a Mammogram, a Picture That Can Save Your Life."

The campaign will emphasize that beginning January 1 Medicare will cover yearly screening mammograms for all women 40 and over covered by the program.

In addition to announcing the First Lady's initiative, the White House unveiled final rules for the Mammography Quality Standards Act (MQSA), the act which has been giving the Food and Drug Administration (FDA) the power to certify mammography facilities accredited by the ACR and other accrediting bodies.

"The ACR is delighted that Medicare will now be covering screening mammograms yearly," College Board Chairman Dr. Ronald G. Evens said today. "Scientific studies clearly show that the shorter the interval between mammograms the greater chance for detecting breast cancer at its earliest, most treatable stage."

Dr. Evens also highly praised the program for focusing on the under-served women of the nation. "Too few low income women and minorities are having screening mammograms and this effort by the First Lady can have a major educational impact on both groups," he said.

The ACR, Dr. Evens added, " created the nation's first mammography accreditation program 10 years ago to assure that the women of this country have the highest quality of mammography possible. As a result of this private/public partnership with the ACR accreditation program and FDA certification women can be assured of getting the best mammography available, which can save their lives through early detection." J

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October 24, 1997

William Jefferson Clinton
President of the United States of America
The White House
1600 Pennsylvania Ave, NW
Washington, DC 20100

Dear President Clinton,

On of the behalf American College of Obstetricians and Gynecologists (ACOG), an organization representing 38,000 physicians dedicated to improving women's health, I want to commend you for your leadership of a national effort to combat breast cancer. As with any serious challenge, breast cancer must be attacked on many fronts and your Administration has been in the forefront on several initiative.

One weapon in the war against breast cancer is early detection and treatment. The efforts of your Administration to expand Medicare coverage of mammograms are critical if elderly women are to take advantage of this important screening tool. Of equal significance is making women aware of the need for mammograms and that coverage is available. Here too, we have been pleased to partner with your Administration. As primary care physicians, obstetrician-gynecologists are critical to efforts expanding access to mammograms. Obstetricians-gynecologist have an excellent record of assuring that their patients know the importance of self-breast exam and mammogram, receive a clinical breast exam, and receive a referral for a mammogram. Thus, your continued support of obstetrician-gynecologists as primary care physicians is critical to the war on breast cancer. Furthermore, we urge you to assure that any "Consumer Bill of Rights" guarantees women's access to obstetrician-gynecologists.

For women with breast cancer, your support for banning clauses in physician contracts that prevent physicians from discussing all treatment options is essential. These women benefit from knowing that if they have a mastectomy their insurance will cover a hospital stay of the length their doctor believes is medically appropriate. We are pleased to join you in support of such legislation. We encourage you to go further and support legislation guaranteeing women with breast cancer access to second opinions and for those choosing mastectomies coverage for reconstructive surgery.

To be effective, women need a quality mammogram. The College's efforts in this area are long-standing. ACOG actively lobbied for the enactment of the Mammography Quality Standards Act. Our goal and the goal of its sponsors was to assure quality. Based upon the early experience with this law, we believe this goal has been achieved while encouraging the availability of mammography in community settings, including primary care physicians' offices. We trust the final regulations being announced today will maintain this balance.

While these efforts address women with breast cancer, we also need to look to the future. Your commitment to research on prevention and treatment does just this. ACOG is pleased to have worked with, and pledges to continue to work with, your Administration to improve the health of women with breast cancer.

Sincerely,

Ralph W. Hale, M.D.

Ralph W. Hale, MD
Executive Director

American Airlines®

CONTACT: Corporate Communications
Fort Worth, Texas
(817) 967-1577 (CDT)

FOR RELEASE: Saturday, Oct. 25, 1997

AMERICAN LAUDS PRESIDENT AND FIRST LADY FOR PROMOTING BREAST CANCER AWARENESS

Fort Worth, Texas—American Airlines today praised the President and First Lady for their outstanding and unprecedented efforts to create a heightened national awareness of the need for far greater use of mammography to prevent breast cancer deaths. In particular, American lauded the President and Mrs. Clinton for using their weekly radio address to generate public attention to this critical issue.

American is particularly proud to have been cited by the First Couple as a model of corporate support for breast cancer awareness. "Our corporate commitment to promoting self-exams and mammography has been long-standing and grows greater every year," said Dr. David McKenas, American's Corporate Medical Director.

As part of its commitment, American was one of the initial sponsors—and is now the official carrier—of the Susan G. Komen Foundation, the nation's largest privately funded breast cancer research organization.

-more-



NCPA news release

FOR IMMEDIATE RELEASE

National COMMUNITY PHARMACISTS Association

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703-683-8200

NCPA JOINS FORCES WITH WHITE HOUSE ON MAMMOGRAPHY INITIATIVE

Alexandria, Virginia, October 25, 1997 -- The National Community Pharmacists Association is working with the White House and First Lady Hillary Rodham Clinton on its Medicare Mammography Initiative, a campaign to increase public awareness of the fact that Medicare now covers the cost of annual mammograms for all women aged 65 and over.

"Breast cancer prevention and detection are crucial to women's health care," said Calvin J. Anthony, NCPA Executive Vice President. "We are pleased to join with the Clinton administration in promoting this public awareness program. Community pharmacists are the most accessible health professionals in every community in America, and are ideally positioned to boost mammography awareness with seniors."

Breast cancer is the second leading cause of cancer deaths among American women. One in eight women risk

NCPA News Release/ 2

developing breast cancer in their lifetime. Mammography screening is partly credited with the recent overall decline in breast cancer death rates. Breast cancer treatment is most effective and survival rates highest when the disease is diagnosed in its early stages.

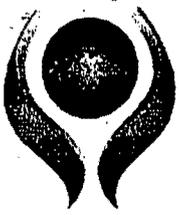
"Many women still don't know that mammograms are now covered by Medicare. If we can help get that information to our patients, we can help the U.S. Public Health Service save lives and improve cure rates," said Anthony.

Besides promoting the availability of materials on mammography screening to independent community pharmacists at its annual convention beginning this weekend in Denver, NCPA will broadcast public service announcements on the initiative on its new in-store television network, NPTV: Your Neighborhood Pharmacy Network.

Promotional materials, including ad slicks and posters, are available from the Office on Women's Health at 202-690-7650. The Medicare Mammography Initiative is being led by the United States Public Health Service Office on Women's Health.

The National Community Pharmacists Association, formerly NARD (the National Association of Retail Druggists), represents the pharmacist owners, managers, and employees of nearly 30,000 independent pharmacies across the country. Independent community pharmacists -- more than 75,000 nationwide -- dispense the majority of the nation's retail prescription drugs.

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American Association of
HEALTH PLANS

Press Release

EMBARGOED FOR RELEASE:
Saturday, October 25, 1997 12:00 Noon

Contact: Don White (202) 778-3274
John Murray (202) 778-8496

AAHP IS PROUD CO-SPONSOR OF NATIONAL MAMMOGRAPHY CAMPAIGN

WASHINGTON -- The American Association of Health Plans (AAHP) is a proud co-sponsor of the White House Medicare Mammography Initiative (MMI) and the 1997 Mammography Campaign. The program is designed to encourage American women, especially those over 65, to obtain mammograms.

"Our member health plans congratulate President and Mrs. Clinton for their commitment and dedication to educating women about the importance of obtaining regular mammograms," said AAHP President and CEO Karen Ignagni. "Regular screening and early detection of breast cancer are the best safeguards of women's health and our member health plans welcome the opportunity to build on their excellent track record in providing these very important preventive measures for women."

Health plans are committed to improving mammography screening rates, especially for older women and other underserved populations. AAHP members have designed innovative programs, including those that enable mobile mammography vans to come to communities that may have difficulty accessing health care. In addition, AAHP's Women's Health Initiative, a yearlong approach to identifying best practices in women's health, includes a focus on breast cancer treatment.

AAHP was also a proud co-sponsor of the Susan G. Komen Foundation's 1997 Race for the Cure, and partnered with the American Cancer Society (ACS) on a Mother's Day which stressed the importance of early detection and preventive screenings through television and radio public service announcements.

The American Association of Health Plans represents over 1,000 HMOs, PPOs and other similar health plans that provide health care for more than 150 million Americans nationwide.

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Draft

FOR IMMEDIATE RELEASE

**Contacts: Dagmar Farr, FMI
(202) 429-8238**

**Anne Hill, National Urban League
(212) 558-5300**

Washington, DC — October 21, 1997 — Organizations Join Forces to Fight Breast Cancer

The Food Marketing Institute (FMI) joins the many other organizations involved in women's health in support of National Breast Cancer Awareness Month. FMI, along with these other concerned organizations, is participating in efforts to educate women, especially African Americans, about the importance of regular mammography in the early detection of breast cancer and mammography Medicare benefits for women.

Breast cancer is the most commonly diagnosed cancer among American women, with 181,600 cases expected this year. While Black women are less likely than white women to develop breast cancer, they are more likely to die from the disease.

FMI, in collaboration with the National Cancer Institute, National Urban League and the U.S. Department of Health and Human Services (DHHS) developed the Take a Step Toward Good Health brochure specifically for African American women 65 and older. This easy-to-read pamphlet provides general information on mammograms and their importance in maintaining good health, as well as information about Medicare's coverage of mammograms. For information on breast cancer, you may contact the Medicare Hotline at 1-800-638-6839 or the National Cancer Institute's Information Service at 1-800-4-CANCER.

"FMI compliments the President and First Lady, the Department of Health and Human Services and the other partners, for their commitment to combat breast cancer. We are pleased to be part of this important educational effort," says Timothy Hammonds, president and CEO of the Food Marketing Institute.

"It is imperative that Black women over 65 years of age know that today, breast cancer is more treatable than ever, especially when it is detected early. Mammograms, along with regular clinical breast exams, are the most effective ways to detect breast cancer at its earliest stages," says Hugh B. Price, president and CEO, National Urban League, "The National Urban League is committed to women's health issues and communicating information to its audiences. The Take a Step Toward Good Health brochure is one means of reaching out and emphasizing the importance of regular mammograms."

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October 21, 1997
Take A Step Toward Good Health

The DHHS has set a goal of at least 60 percent of all women over 65 receiving mammograms and clinical breast exams every two years. Widespread distribution of these brochures will help in reaching that goal.

The National Urban League will distribute the Take a Step Toward Good health brochure to older African American women as part of an educational program on breast cancer awareness. FMI will distribute this brochure to its 1,500 member companies including subsidiaries, food retailers, wholesalers and their customers in communities across the country. You may order the Take A Step Toward Good Health brochure through the FMI website at <http://www.fmi.org>.

The Food Marketing Institute (FMI) is a nonprofit association conducting programs in research, education, industry relations and public affairs on behalf of its 1,500 members including their subsidiaries — food retailers and wholesalers and their customers in the United States and around the world. FMI's domestic member companies operate approximately 21,000 retail food stores with a combined annual sales volume of \$220 billion — more than half of all grocery store sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms and independent supermarkets. Its international membership includes 200 members from 60 countries.

The mission of the Urban League movement is to help African American and other people of color become economically self-reliant and equal citizens under the law. Building on the substantial work and influence of our 115 local affiliates, our three-prong agenda for achieving that goal is as follows: ● Ensuring the academic and social development of children so that they are equipped for self-reliance and citizenship in the 21st century; ● Fostering economic self-sufficiency for their families through gainful employment, business development and home ownership; and ● Promoting racial inclusion and harmony so the opportunity structure is open to those we serve.

care covered services, choice of plans, changes in enrollment, and other relevant factors. The Secretary would be required to periodically report to Congress on project progress.

e. Waiver Authority. The provision authorizes the Secretary to waive such requirements of Section 1876 (relating to Medicare risk, cost, and HCPP plans) and of MedicarePlus as may be needed to carry out the demonstration project.

f. Denver Demonstration. Except as specified above, the Secretary would be prohibited from conducting or continuing any ongoing demonstration project (i.e., the Denver demonstration) designed to demonstrate competitive bidding as an alternative to paying plans on the basis of the AAPCCs (as specified under current law) or the Medicare Plus capitation rates (as established under new Section 1853 of the provision).

SUBTITLE B—PREVENTION INITIATIVES

Section 4101. Screening mammography

Current Law. Medicare provides coverage for screening mammograms. Frequency of coverage is dependent on the age and risk factors of the woman. For women ages 35–39, one test is authorized. For women ages 40–49, a test is covered every 24 months, except, an annual test is authorized for women at high risk. Annual tests are covered for women ages 50–64. For women aged 65 and over, the program covers one test every 24 months. Medicare's Part B deductible and coinsurance apply for these services.

Explanation of provision. The proposal would authorize coverage for annual mammograms for all women ages 40 and over. It would also waive the deductible for screening mammograms. These provisions would be effective January 1, 1998.

Section 4102. Screening pap smear and pelvic exams

Medicare covers a screening Pap smear once every 3 years for purposes of early detection of cervical cancer. The Secretary is permitted to specify a shorter time period in the case of women at high risk of developing cervical cancer.

Explanation of provision. The provision would authorize coverage, every 3 years, for a screening pelvic exam which would include a clinical breast examination. It would modify the purpose of Pap smears to include early detection of vaginal cancer.

The provision would specify that for both Pap smears and screening pelvic exams, coverage would be authorized on a yearly basis for women at high risk of developing cervical or vaginal cancer (as determined pursuant to factors identified by the Secretary). Coverage would also be authorized on a yearly basis for a woman of childbearing age who had not had a test in each of the preceding 3 years that did not indicate the presence of cervical or vaginal cancer. The provision would waive the deductible for screening Pap smears and screening pelvic exams. The provisions would be effective January 1, 1998.

The provision would require the Secretary, within 6 months of enactment, to submit a report to Congress on the extent to which the use of supplemental computer-assisted diagnostic tests (consisting of interactive automated computer imaging of an exfoliative cy-

tology test) in conjunction with pap smears improves the early detection of cervical or vaginal cancer. The report must also consider cost implications.

Section 4103. Prostate cancer screening tests

Current law. Medicare does not cover prostate cancer screening tests.

Explanation of provision. The provision would authorize an annual prostate cancer screening test for men over age 50. The test could consist of any (or all) of the following procedures: (1) a digital rectal exam; (2) a prostate-specific antigen blood test; and (3) after 2001, other procedures as the Secretary finds appropriate for the purpose of early detection of prostate cancer, taking into account such factors as changes in technology and standards of medical practice, availability, effectiveness, and costs.

The provision would specify that payment for prostate-specific antigen blood tests would be made under the clinical laboratory fee schedule. The provisions would be effective January 1, 1998.

Section 4104. Coverage of colorectal screening

Current law. Medicare does not cover preventive colorectal screening procedures. Such services are covered only as diagnostic services.

Explanation of provision. The provision would authorize coverage of colorectal cancer screening tests. A test covered under the provision would be any of the following procedures furnished for the purpose of early detection of colorectal cancer: (1) screening fecal-occult blood test; (2) screening flexible sigmoidoscopy; (3) screening colonoscopy for a high-risk individual; (4) screening barium enema, if found by the Secretary to be an appropriate alternative to screening flexible sigmoidoscopy or screening colonoscopy; and (5) after 2002, other procedures as the Secretary finds appropriate for the purpose of early detection of colorectal cancer, taking into account such factors as changes in technology and standards of medical practice, availability, effectiveness, and costs. A high-risk individual (for purposes of coverage for screening colonoscopy) would be defined as one who faces a high risk for colorectal cancer because of family history, prior experience of cancer or precursor neoplastic polyps, a history of chronic digestive disease condition (including inflammatory bowel disease, Crohn's disease or ulcerative colitis), the presence of any appropriate recognized gene markers, or other predisposing factors. The Secretary would be required to make a decision with respect to coverage of screening barium enema tests within 2 years of enactment; the determination would be published.

The provision would establish frequency and payment limits for the tests. For screening fecal-occult blood tests, payment would be made under the lab fee schedule. In 1998, the payment amount could not exceed \$5; in future years the update would be limited to the update applicable under the fee schedule. Medicare could not make payments if the test were performed on an individual under age 50 or within 11 months of a previous screening fecal-occult blood test.

The provision would require the Secretary to establish a payment amount under the physician fee schedule for screening flexible

sigmoidoscopies that is consistent with payment amounts for similar or related services. The payment amount could not exceed the amount the Secretary specifies, based upon the rates recognized for diagnostic flexible sigmoidoscopy services. For services performed in ambulatory surgical centers or hospital outpatient departments, the payment amount could not exceed the lesser of the payment rate that would apply to such services if they were performed at either site. Medicare could not make payments for a screening flexible sigmoidoscopy if the test were performed on an individual under age 50 or within 47 months of a previous screening flexible sigmoidoscopy.

The provision would require the Secretary to establish a payment amount under the physician fee schedule for screening colonoscopy for high risk individuals that is consistent with payment amounts for similar or related services. The payment amount could not exceed the amount the Secretary specifies, based upon the rates recognized for diagnostic colonoscopy services. For services performed in ambulatory surgical centers or hospital outpatient departments, the payment amount could not exceed the lesser of the payment rate that would apply to such services if they were performed at either site. Medicare could not make payments if the test were performed on a high-risk individual within 23 months of a previous screening colonoscopy.

The provision would establish special payment rules, in the case of both a screening flexible sigmoidoscopy or screening colonoscopy, if a lesion or growth is discovered during the procedure which results in a biopsy or removal of the lesion or growth during the procedure. In these cases, payment would be made for the procedure classified as either a flexible sigmoidoscopy with such biopsy or removal or screening colonoscopy with such biopsy or removal.

The provision would require the Secretary to review from time to time the appropriateness of the amount of the payment limit for fecal-occult blood tests. The Secretary could, beginning after 2000, reduce the amount of the limit as it applies nationally or in a given area to the amount the Secretary estimates is required to assure that such tests of an appropriate quality are readily and conveniently available.

The provision would require the Secretary to review periodically the appropriate frequency for performing colorectal cancer screening tests based on age and other factors the Secretary believes to be pertinent. The Secretary may revise from time to time the frequency limitations, but no revisions could occur before January 1, 2001.

Nonparticipating physicians providing screening flexible sigmoidoscopies or screening colonoscopies for high risk individuals would be subject to limiting charge provisions applicable for physicians services. The Secretary could impose sanctions if a physician or supplier knowingly and willfully imposed a charge in violation of this requirement.

The provision would require the Secretary to establish payment limits and frequency limits for screening barium enema tests if the Secretary issues a determination that such tests should be covered. Payment limits would be consistent with those established for diagnostic barium enema procedures.

The provisions would be effective January 1, 1998.

Section 4105. Diabetes screening tests

Current law. In general, Medicare covers only those items and services which are medically reasonable and necessary for the diagnosis or treatment of illness or injury. In addition, Medicare covers home blood glucose monitors and associated testing strips for certain diabetes patients. Home blood glucose monitors enable diabetics to measure their blood glucose levels and then alter their diets or insulin dosages to ensure that they are maintaining an adequate blood glucose level. Home glucose monitors and testing strips are covered under Medicare's durable medical equipment benefit. Coverage of home blood glucose monitors is currently limited to certain diabetics, formerly referred to as Type I diabetics, if: (1) the patient is an insulin-treated diabetic; (2) the patient is capable of being trained to use the monitor in an appropriate manner, or, in some cases, another responsible person is capable of being trained to use the equipment and monitor the patient to assure that the intended effect is achieved; and (3) the device is designed for home rather than clinical use.

Explanation of provision. Effective January 1, 1998, the provision would include among Medicare's covered benefits diabetes outpatient self-management training services. These services would include educational and training services furnished to an individual with diabetes by a certified provider in an outpatient setting meeting certain quality standards. They would be covered only if the physician who is managing the individual's diabetic condition certifies that the services are needed under a comprehensive plan of care to provide the individual with necessary skills and knowledge (including skills related to the self-administration of injectable drugs) to participate in the management of the individual's condition. Certified providers for these purposes would be defined as physicians or other individuals or entities designated by the Secretary that, in addition to providing diabetes outpatient self-management training services, provide other items or services reimbursed by Medicare. Providers would have to meet quality standards established by the Secretary. They would be deemed to have met the Secretary's standards if they meet standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who participated in the establishment of standards of the Board, or if they are recognized by an organization representing persons with diabetes as meeting standards for furnishing such services. In establishing payment amounts for diabetes outpatient self-management training provided by physicians and determining the relative value for these services, the Secretary would be required to consult with appropriate organizations, including organizations representing persons or Medicare beneficiaries with diabetes.

In addition, beginning January 1, 1998, the provision would extend Medicare coverage of blood glucose monitors and testing strips to Type II diabetics and without regard to a person's use of insulin (as determined under standards established by the Secretary in consultation with appropriate organization). The provision would

also reduce the national payment limit for testing strips by 10 percent beginning in 1998.

The Secretary, in consultation with appropriate organizations, would be required to establish outcome measures, including glycosylated hemoglobin (past 90-day average blood sugar levels), for purposes of evaluating the improvement of the health status of Medicare beneficiaries with diabetes. The Secretary would also be required to submit recommendations to Congress from time to time on modifications to coverage of services for these beneficiaries.

The Committee notes the important role of registered dietitians and other qualified nutrition professionals in providing dietary counseling and education services related to diabetes self-management training. These health care professionals are trained and authorized by the States to perform these services and regularly do so in private sector health plans. While this section does not authorize direct reimbursement for these professionals to perform diabetes self-management services, nothing in this bill precludes them from providing services under arrangements with individuals or entities authorized to receive payment for services under this Title.

Section 4106. Standardization of Medicare coverage of bone mass measurements

Current law. Medicare does not include specific coverage of bone mass measurement.

Explanation of provision. The provision authorizes coverage of bone mass measurement for the following high risk persons: an estrogen-deficient woman at clinical risk for osteoporosis; an individual with vertebral abnormalities; an individual receiving long-term glucocorticoid steroid therapy, and an individual with primary hyperparathyroidism; or an individual being monitored to assess the response to or efficacy of an approved osteoporosis drug therapy. The Secretary would be required to establish frequency limits. Payments would be made under the physician fee schedule. The provision would be effective July 1, 1998.

Section 4107. Vaccines outreach expansion

Current law. The Health Care Financing Administration, in conjunction with the Centers for Disease Control and the National Coalition for Adult Immunization, conducts an Influenza and Pneumococcal Vaccination Campaign. The Campaign is scheduled to cease operations in 2000.

Explanation of provision. The provision would extend the campaign through the end of FY 2002. The provision would appropriate \$8 million for each Fiscal Year 1998 through 2002 to the Campaign; 60 percent of the appropriation would come from the Federal Hospital Insurance Trust Fund and 40 percent from the Federal Supplementary Medical Insurance Trust Fund.

Section 4108. Study on preventive benefits

Current Law. No provision.

Explanation of provision. The provision would require the Secretary to request the National Academy of Sciences, in conjunction with the United States Preventive Services Task Force, to analyze the expansion or modification of preventive services covered under

Medicare. The study would consider both the short term and long term benefits and costs to Medicare. The study would have to include specific findings with respect to the following: (1) nutrition therapy, including parenteral and enteral nutrition; (2) standardization of coverage for bone mass measurement; (3) medically necessary dental care; (4) routine patient care costs for beneficiaries enrolled in approved clinical trial programs; and (5) elimination of time limitation for coverage of immunosuppressive drugs for transplant patients. The Secretary would be required to provide such funding as may be necessary in FY 1998 and FY 1999.

SUBTITLE C—RURAL INITIATIVES

Section 4206. Informatics, telemedicine, and education demonstration project

Current law. No provision.

Explanation of provision. The provision would require the Secretary to begin, no later than 9 months after enactment, a 4-year demonstration project designed to use eligible health care provider telemedicine networks to apply high-capacity computing and advanced networks for the provision of health care to Medicare beneficiaries who are residents of medically underserved rural and inner-city areas. The project would focus on improvements in primary care and prevention of complications for those residents with diabetes mellitus. The objectives of the project would include: (1) improving patient access to and compliance with appropriate care guidelines for chronic diseases through direct telecommunications links with information networks; (2) developing a curriculum to train, and provide standards for credentialing and licensure of, health professionals (particularly primary care) in the use of medical informatics and telecommunications; (3) demonstrating the application of advanced technologies to assist primary care providers in assisting patients with chronic illnesses in a home setting; (4) applying medical informatics to residents with limited English language skills; (5) developing standards in the application of telemedicine and medical informatics; and (6) developing a model for the cost-effective delivery of primary and related care both in a managed care and fee-for-service environment.

The provision defines an eligible health care provider telemedicine network as a consortium that includes at least one tertiary care hospital, at least one medical school (but no more than two such hospitals), and at least one regional telecommunications provider, no more than four facilities in rural or urban areas, and meets certain additional requirements. The provision would define those services to be covered under Part B for the purposes of this demonstration project. Medicare payment for covered Part B services would be made at a rate of 50 percent of the reasonable costs of providing such services. The Secretary would be required to recognize the following project costs as permissible costs for coverage under Part B: (1) the acquisition of telemedicine equipment for use in patient homes; (2) curriculum development and training of health professionals in medical informatics and telemedicine; (3) payment of certain telecommunications costs, including costs of telecommunications between patients' homes and the eligible net-

Medicare Prevention File

Doc Sarah Kent?
[Handwritten initials]

**PREVENTION INITIATIVES INCLUDED IN THE
BALANCED BUDGET ACT OF 1997 (SUBTITLE B)**

Screening Mammography (Section 4101)

Current law

- o Current law provides coverage for annual screening mammography for women age 50-64 and for women age 40-49 at high risk for breast cancer. Screening mammography for women age 40-49 at normal risk, and women age 65 and over, is covered every 2 years. One baseline mammogram is also covered for women age 35-39. Beneficiaries must pay both 20 percent coinsurance and any unmet portion of the Part B deductible.

[Handwritten notes and signatures]

Provision

- o The new law provides coverage for annual screening mammograms for all women age 40 and over, and one baseline mammogram for women age 35-39. Application of the Part B deductible for is waived for screening mammography.

Effective date of changes

- o January 1, 1998.

Screening Pap Smear and Pelvic Exams (Section 4102)

Current law

- o Current law provides coverage for a screening pap smear every 3 years, or more often for women at high risk for cervical cancer. Beneficiaries do not pay coinsurance or deductible for clinical laboratory tests (including pap smears).

Provision

- o The new law provides coverage for a screening pap smear and pelvic exam (including a clinical breast exam) every 3 years, or annual coverage for women (1) at high risk for cervical or vaginal cancer, or (2) of childbearing age who have had a pap smear during the preceding 3 years indicating the presence of cervical or vaginal cancer or other abnormality. The Part B deductible is waived for screening pap smears and pelvic exams. Pap smears will continue to be paid under the clinical laboratory fee schedule, and pelvic exams will be paid under the physician fee schedule.

Effective date of changes

- o January 1, 1998.

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL

of pages **11**

To Susan Bianchi	From Shawn Hanson
Dept./Agency	Phone # 260.4448
Fax # 456.5557	Fax #

Prostate Cancer Screening Tests (Section 4103)

Current law

- o Current law provides coverage for prostate cancer testing only when medically necessary for diagnostic purposes.

Provision

- o The new law provides coverage for annual prostate cancer screening for men over age 50. Covered procedures include (1) digital rectal exam, (2) prostate-specific antigen (PSA) blood test, and (3) after 2002, other procedures the Secretary finds appropriate. Payment for PSA blood test will be made under the clinical laboratory fee schedule, and other services will be paid under the physician fee schedule.

Effective date of changes

- o January 1, 2000.

Coverage of Colorectal Cancer Screening (Section 4104)

Current law

- o Current law provides coverage for colorectal cancer testing only when medically necessary for diagnostic purposes.

Provision

- o The new law provides coverage for colorectal cancer screening procedures including (1) fecal-occult blood tests for persons age 50 and over, (2) flexible sigmoidoscopy for persons age 50 and over, (3) colonoscopy for persons at high risk for colorectal cancer, and (4) other procedures (including screening barium enema) as the Secretary determines appropriate. By 90 days after enactment of the new law, the Secretary shall publish notice regarding a determination of coverage for screening barium enema.
- o The new law sets frequency limits for each covered procedure, except the Secretary sets frequency limits for procedures covered pursuant to determination by the Secretary.
- o Payment for each covered procedure is to be based on rates paid for the same procedure when done for diagnostic purposes, except the Secretary sets payment limits for procedures covered pursuant to determination by the Secretary. Fecal occult blood tests will be paid under the clinical laboratory fee schedule, and other procedures will be paid under the physician fee schedule.

- o Special payment rules (including limits on deductible and coinsurance) apply to flexible sigmoidoscopies and colonoscopies performed in hospital outpatient departments or ambulatory surgical centers beginning January 1, 1999, and in cases where such procedures result in biopsy or removal of a lesion.

Effective date of changes

- o Determination of coverage for barium enemas to be made by 90 days after enactment. Rules regarding payment for flexible sigmoidoscopies and colonoscopies in hospital outpatient departments and ambulatory surgical centers are effective January 1, 1999. Other provisions effective January 1, 1998.

Diabetes Self-Management Benefits (Section 4105)

Current law

- o Under current law, Medicare covers outpatient diabetes self-management training furnished by hospital-based programs.
- o Under current law, Medicare covers blood glucose monitors and testing strips for insulin-dependent diabetics.

Provision

- o The new law provides coverage for outpatient diabetes self-management training furnished in both hospital-based and non-hospital-based programs. Services may be provided by physicians or other entities designated by the Secretary if they also provide other services paid for by Medicare and meet quality standards established by the Secretary. A physician managing the patient's condition must certify that the services are needed under a comprehensive plan of care. Services will be paid under the physician fee schedule in amounts set by the Secretary in consultation with appropriate organizations.
- o The new law provides coverage for blood glucose monitors and testing strips for all diabetics (without regard to insulin use). Payment for testing strips used with blood glucose monitors will be reduced by 10 percent.
- o The new law requires the Secretary to establish outcome measures for evaluating improvements in the health status of Medicare beneficiaries with diabetes, and to periodically submit recommendations to Congress on modifications to coverage of services for diabetics.

Effective date of changes

- o Reduction in payment for testing strips effective January 1, 1998. Other provisions effective July 1, 1998.

Standardization of Medicare Coverage of Bone Mass Measurements (Section 4106)**Current law**

- o Medicare initiated coverage for bone mineral density studies in 1984 according to a national coverage policy. Given subsequent changes in technology, coverage decisions are now made by local Medicare contractors, resulting in some regional variation in coverage policies.

Provision

- o The new law provides coverage for procedures to identify bone mass, detect bone loss, or determine bone quality, including a physician's interpretation of the results, at frequencies determined by the Secretary. Persons qualifying for these procedures include estrogen-deficient women at risk for osteoporosis, and persons (1) with vertebral abnormalities, (2) receiving long-term glucocorticoid steroid therapy, (3) with primary hyperparathyroidism, and (4) being monitored to assess response to, or efficacy of, an approved osteoporosis drug. Services will be paid under the physician fee schedule.

Effective date of changes

- o July 1, 1998.

Vaccines Outreach Expansion (Section 4107)**Provision**

- o The new law extends through fiscal year 2002 the existing Influenza and Pneumococcal Vaccination Campaign conducted by HCFA in conjunction with CDC and the National Coalition for Adult Immunization. It authorizes \$8 million for each fiscal year from 1998 through 2002 (60 percent payable from the Part A Trust Fund and 40 percent from the Part B Trust Fund).

Effective date of changes

- o Covers activities from October 1, 1997 through September 30, 2002.

Study on Preventive and Enhanced Benefits (Section 4108)**Provision**

- o The new law requires the Secretary to request the National Academy of Sciences (in conjunction with the U.S. Preventive Services Task Force, as appropriate) to analyze the expansion or modification of preventive or other services covered by Medicare, considering both short and long term costs and benefits. The Secretary shall submit a

report to Congress within 2 years of enactment of the new law on the findings of the analysis including (but not limited to) specific findings about coverage for (1) nutrition therapy, including enteral and parental nutrition and services provided by registered dietitians, (2) skin cancer screening, (3) medically necessary dental care, (4) routine patient care costs for beneficiaries enrolled in approved clinical trials, and (5) elimination of time limit for coverage of immunosuppressive drugs for transplant patients. Funding for the study will come from funds appropriated to DHHS for fiscal years 1996 and 1999 as the Secretary determines appropriate.

Effective date of changes

- o Report to be submitted to Congress within 2 years of enactment.

Adults/Older Adults — SCREENING

33. Fecal Occult Blood

There will be approximately 149,000 new cases of colorectal cancer and 56,000 deaths caused by it in 1994. On average, clinically diagnosed colorectal cancer deprives its victims of 6 to 7 years of life. Principal risk factors for colorectal cancer include a history of one of the familial polyposis syndromes, familial cancer syndromes, colorectal cancer in first-degree relatives, or a personal history of ulcerative colitis, adenomatous polyps, or endometrial, ovarian, or breast cancer. If detected at an early stage, colorectal cancer can be successfully treated with surgery.

Malignancies and, to a lesser extent, polyps bleed intermittently. This bleeding can be detected by tests that identify occult blood or breakdown products of blood in fecal material. Recent evidence indicates that the sensitivity of commonly used fecal occult blood tests for detecting colorectal cancer in low-risk, asymptomatic patients may be as low as 25%. (Rehydration of dried samples before testing can increase sensitivity, at the cost of producing more false-positive results.) The predictive value of a positive fecal occult blood test for colorectal cancer in general populations is only 5% to 10%. Thus, up to 75% of cancers will be missed and up to 20 patients will undergo workups that will be negative for every case of colorectal cancer detected by fecal occult blood testing.

Until recently, no studies had shown decreased mortality as a result of fecal occult blood testing. In 1993, however, Mandel et al found that yearly fecal occult blood testing using rehydrated stool specimens decreased mortality from colorectal cancer by about one third. In that study, guaiac-impregnated paper slides were used to test for fecal blood.

For information about other methods of screening for colorectal cancer, refer to chapters 29 and 40.

Recommendations of Major Authorities

- **American Academy of Family Physicians (AAFP), Canadian Task Force on the Periodic Health Examination, and U.S. Preventive Services Task Force (USPSTF)**—There is insufficient evidence to recommend either initiating or terminating the routine provision of fecal occult blood testing in low-risk, asymptomatic individuals (see above). These recommendations are currently under review. AAFP and USPSTF recommend that it may be clinically prudent to offer screening, including fecal occult blood testing, to individuals 50 years of age or older who are at increased risk for disease.
- **American Cancer Society (ACS), American College of Physicians (ACP), American Gastroenterological Association, American Society for Gastrointestinal Endoscopy, and National Cancer Institute (NCI)**—Annual fecal occult blood testing should be done for all asymptomatic individuals without known risk factors beginning at 50 years of age. ACP recommends annual fecal occult blood testing beginning at 40 years of age for individuals at high risk for disease. ACS and NCI recommend that special surveillance be considered for individuals at high risk for disease, without specifically designating fecal occult blood testing.

Adults — SCREENING

Adults/Older Adults — SCREENING

35. Mammography

Breast cancer is the most common type of cancer in women and the second leading cause of cancer death in American women (after lung cancer). There will be an estimated 182,000 new cases and 46,000 deaths in 1994. The average lifetime risk for a woman in the United States of developing breast cancer is approximately 1 in 9. Breast cancer mortality increases with age, with first deaths occurring at approximately 30 years of age. Mortality from breast cancer does not plateau, even in extreme old age. Aside from age, the next strongest risk factor is a family history of breast cancer in a first-degree relative (sister or mother). Very modest increases in risk are also associated with nulliparity, first pregnancy after 30 years of age, menarche before 12 years of age, menopause after 50 years of age, postmenopausal obesity, some types of benign breast disease, high socioeconomic status, and a personal history of ovarian or endometrial cancer.

Mortality from breast cancer is strongly influenced by stage at detection. The 5-year survival rate is 93% for women found to have localized disease. The 5-year survival rate for women with distant spread is only 18%. African-American women have somewhat lower survival rates than white women at every stage of diagnosis. Mammography is the most effective means of early detection for breast cancer, with sensitivity estimates of 70% to 90% and specificity estimates of 90% to 95%. Although mammography can detect small tumors in younger women, there has been controversy about whether mammography screening actually reduces mortality in women less than 50 years of age.

Well-maintained, modern mammography equipment is very safe, using very low levels of radiation. Screening does, however, carry the added risk of morbidity from unnecessary biopsies performed to follow up false-positive mammograms.

For information about clinical breast examination to detect breast cancer, refer to chapter 29.

Recommendations of Major Authorities

■ For women 50 and older: All major authorities, including American Academy of Family Physicians, American Cancer Society, American College of Obstetricians and Gynecologists, American College of Physicians, Canadian Task Force on the Periodic Health Examination, and U.S. Preventive Services Task Force (USPSTF)—Routine mammography screening is recommended. Yearly screening is recommended by all these authorities, with the exception of USPSTF, which recommends a frequency of 1 to 2 years. American Geriatrics Society recommends that women over 65 years of age receive mammograms at least every two or three years until at least 85 years of age. National Cancer Institute states that experts agree that routine mammography and clinical breast examination screening every 1 to 2 years can reduce breast cancer mortality by about one-third in women aged 50 and over.

■ For women under 50: American Cancer Society and American College of Obstetricians and Gynecologists—Women 40-49 years of age should receive screening mammograms every 1 to 2

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Adults/Older Adults — SCREENING**36. Papanicolaou Smear**

Approximately 15,000 cases of invasive cervical cancer will be diagnosed and 4600 women will die of cervical cancer in the United States in 1994. Risk factors for cervical cancer include early age at first intercourse, having multiple sexual partners, and smoking. Rates for carcinoma in situ reach a peak for both black and white women between 20 and 30 years of age. After the age of 25, however, the incidence of invasive cancer in black women increases dramatically with age while in white women the incidence rises more slowly. Over 25% of invasive cervical cancers occur in women older than 65, and 40% to 50% of all women who die from cervical cancer are over 65 years of age.

The effectiveness of early detection through Papanicolaou (Pap) smear testing and early treatment has been impressive, resulting in a marked decrease in mortality from cervical cancer. The incidence of invasive cervical cancer has been estimated to have been decreased 70% by screening. However, a large proportion of women, particularly elderly black women and middle-aged poor women, have not had regular Pap smears. In some areas, as many as 75% of women over 65 have not had a Pap smear within the previous five years.

Depending on the technique used, Pap testing has a sensitivity of 50% to 90% and a specificity of 90% to 99%. A large proportion of false-negative pap smears are thought to be due to poor technique in performance (as many as half of all false negatives) and inadequate laboratory interpretation. Because of the long lead time from development of precancerous changes to invasive carcinoma (8 to 9 years by some estimates), almost all precancerous or early stage malignancies initially missed can still be detected by repeat testing.

Recommendations of Major Authorities

■ **American Academy of Family Physicians**—Women who are sexually active or (if the sexual history is thought to be unreliable) are 18 years of age or older should have annual Pap tests. After a woman has had three or more consecutive satisfactory normal annual examinations, the Pap test may be performed at the discretion of the physician and the patient, but not less frequently than every 3 years.

■ **American Cancer Society, American College of Obstetricians and Gynecologists, and National Cancer Institute**—All women should begin having annual Pap tests at the onset of sexual activity or at 18 years of age, whichever occurs first. After a woman has had three or more consecutive satisfactory normal annual examinations, the Pap test may be performed less frequently at the discretion of the patient and clinician.

■ **American College of Physicians**—Sexually active women between 25 and 65 years of age should be screened with a Pap smear every 3 years. Women 66 to 75 years of age who have not been screened within the 10 years prior to age 66 should be screened every 3 years. Women at increased risk for cervical cancer should be screened every 2 years. Initial screening tests may be done as frequently as annually for two or three examinations to ensure diagnostic accuracy.

Adults — SCREENING

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Adults/Older Adults — SCREENING

40. Sigmoidoscopy

Colorectal cancer is the second leading cause of death from cancer in the United States, afflicting people mainly over the age of 40 years. Of the three widely used methods of screening for colorectal cancer (digital rectal examination and fecal occult blood testing being the other two), examination using a sigmoidoscope is the most specific and sensitive. Because it enables the examiner to perform a biopsy during the procedure, the specificity of sigmoidoscopy approaches 100%. Sensitivity is largely determined by the skill of the examiner and the length of the instrument. Approximately 30% of colorectal cancers are within reach of the 25-cm rigid sigmoidoscope. The 35-cm flexible sigmoidoscope can reach 45% to 50% of cancers, and the 60-cm flexible sigmoidoscope can reach 50% to 60%. Screening with sigmoidoscopy has been limited by costs, patient and provider noncompliance, and controversy about effectiveness. Patient compliance problems have been somewhat diminished by the advent of the more comfortable flexible instruments. The 35-cm sigmoidoscope is particularly well-accepted by patients, and the 60-cm sigmoidoscope is relatively well-accepted. The controversy about effectiveness has revolved around a lack of evidence that screening with sigmoidoscopy decreases mortality from colorectal cancer. Two recently published case-control studies (Selby et al., 1992, and Newcomb et al., 1992) have demonstrated significant decreases in risk (59% and 79%, respectively) of death from colorectal cancer for screened patients. In the Selby study, significant benefit was suggested from rigid sigmoidoscopy screening performed as infrequently as every 10 years.

For information about colorectal cancer and about other methods of screening for it, refer to chapters 29 and 33.

Recommendations of Major Authorities

Normal Risk

- American Academy of Family Physicians, Canadian Task Force on the Periodic Health Examination, and U.S. Preventive Services Task Force (USPSTF)—There is insufficient evidence to recommend either initiating or terminating the provision of sigmoidoscopy screening for low-risk, asymptomatic individuals. This recommendation is currently under review by USPSTF.
- American Cancer Society, American College of Obstetricians and Gynecologists, American College of Physicians (ACP), American Gastroenterological Association, American Society for Gastrointestinal Endoscopy, and National Cancer Institute—Patients at normal risk should be screened with sigmoidoscopy every 3 to 5 years beginning at 50 years of age. ACP has stated that performance of an air-contrast barium enema every 5 years is an acceptable alternative to sigmoidoscopy.

Adults/Older Adults — IMMUNIZATION/PROPHYLAXIS

48. Influenza (Including Childhood Immunization)

Influenza is a significant cause of mortality and morbidity in the United States. Between 1977 and 1988, at least 10,000 deaths occurred in each of seven separate influenza epidemics in the United States. More than 40,000 deaths occurred in three of these epidemics. Approximately 80% to 90% of deaths occur in individuals 65 years of age or older. Older adults with underlying health problems, such as pulmonary or cardiovascular disorders, are particularly at risk of death and serious illness from influenza. Nonelderly adults and children with certain chronic medical problems are also at increased risk for influenza-related complications (see Table 48-1).

Influenza vaccine is approximately 30% to 40% effective in preventing clinical illness and 80% effective in preventing death in older adults. Approximately 40% of noninstitutionalized older adults receive immunization annually. Amantadine prophylaxis is 70% to 90% effective for preventing influenza type A illness in adults, but it does not prevent influenza type B illness.

Recommendations of Major Authorities

Immunization

- **Advisory Committee on Immunization Practices, American Academy of Family Physicians, American College of Physicians, Canadian Task Force on the Periodic Health Examination, and U.S. Preventive Services Task Force**—Influenza immunization should be provided annually to all individuals 65 years of age or older. Immunization should also be provided to adults and children at least 6 months of age who are at increased risk for influenza-related complications due to certain medical conditions, such as chronic pulmonary and cardiovascular disorders (see Table 48-1), or who may transmit influenza to individuals at increased risk, such as health-care workers and household members (see Table 48-2).
- **American College of Obstetricians and Gynecologists**—All women 60 years of age and older should receive immunization against influenza yearly.

Prophylaxis

- **Advisory Committee on Immunization Practices, American College of Physicians, American Geriatrics Society, Canadian Task Force on the Periodic Health Examination, and U.S. Preventive Services Task Force**—Amantadine should be given prophylactically to the following individuals: residents of institutions housing high-risk patients in which an influenza A outbreak occurs; older adults and others at high risk for whom immunization is contraindicated; older adults and other high-risk patients who have been recently exposed to influenza A, but are unimmunized or only recently immunized; immunocompromised patients and others expected to have a suboptimal response to immunization.

Adults/Older Adults — IMMUNIZATION/PROPHYLAXIS

49. Pneumococcus (Including Childhood Immunization)

Streptococcus pneumoniae infections are a major cause of morbidity and mortality in the United States, causing 15% to 20% of all cases of pneumonia. Pneumococcal infection causes approximately 40,000 deaths annually in the United States. As many as 20% of patients with pneumococcal pneumonia develop bacteremia. Older adults are particularly at risk of mortality from pneumococcal infection. In older adults, mortality from pneumococcal bacteremia may be as high as 60%. Other groups at increased risk include the very young and individuals with chronic cardiovascular and pulmonary conditions, organ transplants, diabetes mellitus, alcoholism, cirrhosis, functional or anatomic asplenia (e.g. sickle cell disease or splenectomy), Hodgkin's and non-Hodgkin's lymphomas, multiple myeloma, renal failure, nephrotic syndrome, and HIV infection (see Table 49-1).

The current 23-valent pneumococcal vaccine, which replaced a 14-valent vaccine in 1983, contains antigens for 88% of the serotypes of *S. pneumoniae* causing bacteremia in the United States. Human antibody studies demonstrate cross-reactivity with an additional 8% of serotypes causing bacteremia. The vaccine has a protective efficacy of approximately 60% (for included serotypes) for all patients. Efficacy of the vaccine may decrease with increasing age and time since vaccination. Among older adults, antibody levels may decrease after 6 years to levels that are not protective. In immunocompromised patients and patients with certain chronic illnesses, the initial antibody response to pneumococcal vaccine is lower and declines more rapidly.

Implementation of immunization recommendations has been poor, with only about 20% of patients at risk for pneumococcal disease, including older adults, receiving the vaccine. Many opportunities for vaccination are missed, such as during hospitalization or on discharge. Two thirds of patients with serious pneumococcal disease have been hospitalized at least once within the preceding 5 years. Recent research indicates that pre-discharge vaccination of patients hospitalized for pneumonia of any etiology decreases their rates of subsequent hospitalization for pneumococcal disease.

Recommendations of Major Authorities

- Advisory Committee on Immunization Practices (ACIP), American Academy of Family Physicians, American College of Physicians (ACP), American College of Obstetricians and Gynecologists, and U.S. Preventive Services Task Force (USPSTF)—All people 65 years of age or older should be immunized at least once with pneumococcal vaccine. Patients with medical and living conditions putting them at high risk for pneumococcal disease (including immune compromise) should also be immunized (see Table 49-1). ACIP and USPSTF recommend that revaccination be strongly considered for patients who received the 14-valent vaccine and who are at highest risk of serious or fatal pneumococcal infections (such as patients with surgical or functional asplenia). ACP recommends revaccination for such patients. ACIP, ACP, and USPSTF recommend that adults who received the 23-valent vaccine 6 or more years ago and who are at the highest

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Part B. Neoplastic Diseases

7. Screening for Breast Cancer

RECOMMENDATION

Routine screening for breast cancer every 1-2 years, with mammography alone or mammography and annual clinical breast examination (CBE), is recommended for women aged 50-69. There is insufficient evidence to recommend for or against routine mammography or CBE for women aged 40-49 or aged 70 and older, although recommendations for high-risk women aged 40-49 and healthy women aged ≥70 may be made on other grounds (see Clinical Intervention). There is insufficient evidence to recommend for or against the use of screening CBE alone or the teaching of breast self-examination.

Burden of Suffering

In the U.S. in 1995, there were an estimated 182,000 new cases of breast cancer diagnosed and 46,000 deaths from this disease in women.¹ Approximately 32% of all newly diagnosed cancers in women are cancers of the breast, the most common cancer diagnosed in women.¹ The annual incidence of breast cancer increased 55% between 1950 and 1991.² The incidence in women during the period 1987-1991 was 110/100,000.² In 1992, the annual age-adjusted mortality from breast cancer was 22/100,000 women.³ The age-adjusted mortality rate from breast cancer has been relatively stable over the period from 1930 to the present.^{1,2} For women, the estimated lifetime risk of dying from breast cancer is 3.6%.² Breast cancer resulted in 2.2 years of potential life lost before age 65 per 1,000 women under age 65 in the U.S. during 1986-1988.⁴ This rate was surpassed only by deaths resulting from motor vehicle injury and infections. Breast cancer is the leading contributor to cancer mortality in women aged 15-54,¹ although 48% of new breast cancer cases and 56% of breast cancer deaths occur in women age 65 and over.² As the large number of women in the "baby boom" generation age, the number of breast cancer cases and deaths will increase substantially unless age-specific incidence and mortality rates decline.

Important risk factors for breast cancer include female gender, residence in North America or northern Europe, and older age.⁵ In American women, the annual incidence of breast cancer increases with age: 127

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FAX TRANSMITTAL

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GENERAL SERVICES ADMINISTRATION
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TION 1: SCREENING

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cases/100,000 for women aged 40-44; 229/100,000 for women aged 50-54; 348/100,000 for women aged 60-64; and 450/100,000 for women aged 70-74.² The risk for a woman with a family history of breast cancer in a first-degree relative is increased about 2-3-fold, and for women under 50 it is highest when the relative had premenopausally diagnosed breast cancer.⁶⁻⁹ Women with previous breast cancer or carcinoma in situ and women with atypical hyperplasia on breast biopsy are also at significantly increased risk.^{6,7,10-12} Other factors associated with increased breast cancer risk include a history of proliferative breast lesions without atypia on breast biopsy, late age at first pregnancy, nulliparity, high socioeconomic status, and a history of exposure to high-dose radiation.^{6,7,10-12} Associations between breast cancer and oral contraceptives, long-term estrogen replacement therapy, obesity, and a diet high in fat have been suggested, but causal relationships have not been established.^{13,14}

Accuracy of Screening Tests

The three screening tests usually considered for early detection of breast cancer are clinical breast examination (CBE), x-ray mammography, and breast self-examination (BSE). Estimates of the sensitivity and specificity of these maneuvers depend on a number of factors, including the size of the lesion, the characteristics of the breast being examined, the age of the patient, the extent of follow-up to identify false negatives, the skill and experience of the examiner or radiographic interpreter, and (in the case of mammography) the quality of the mammogram. Because multiple clinical trials have demonstrated the effectiveness of screening, measures of screening test performance (such as sensitivity and specificity) are primarily helpful in comparing trials, screening programs, and community practice. Uniform definitions, however, are necessary for such comparisons. For example, different studies may use similar definitions of sensitivity, such as the number of screen-detected cancers compared to the total of screen-detected cancers plus interval cancers, but one may use a fixed interval (e.g., 12 months)¹⁵ and another a variable interval (e.g., time to next screen),¹⁶ making direct comparisons difficult. The ability to detect interval cancers may also vary and will affect such estimates.

A review¹⁷ of the current clinical trial data, published and unpublished, summarized screening test performance for mammography using uniform definitions. Sensitivity of mammography did not dramatically differ across the trials. Estimates from three Swedish trials using mammography alone averaged about 75%, while estimates for mammography combined with CBE ranged from 75% in the Health Insurance Plan of Greater New York (HIP) to 88% in the Edinburgh trial and the Canadian National Breast Cancer Screening Study in women aged 50-59 (NBSS 2).

Specificity estimates ranged from 75% to 95% in the Canadian NBSS 2. Sensitivity of combined screening with CBE and mammography for women aged 40-49 compared to mammography alone. Preliminary results from two trials suggest improved sensitivity of combined screening with CBE. In preliminary trials, agreement was about 80% between radiologists at five screening centers.²¹

The effectiveness of CBE compared to mammography. Comparisons of the sensitivity of mammography can be considered. The incremental value of a 5-10 minute CBE.^{24,25} Pfeiffer highlighted the fact that the sensitivity of CBE plus CBE vs. 63% for CBE alone. Specificity was comparable for CBE for women aged 40-49. Initial screen compared to NBSS 2).²⁶ Specificity estimates were 75%.

Data regarding the accuracy of CBE. Data calculated an upper limit of 10% for all interval cases in the similar approach. The overall sensitivity was 26% in women also screened with CBE. Cancer Detection Demonstration Study. Sensitivity decreased with age, from 75% for women aged 60-74.²⁷ Thus, the sensitivity of screening with CBE remains uncertain. The effectiveness of CBE as measured by the proportion of interval cancers detected in models and artificial lumps. The effectiveness of this improved detection on overall performance is unknown.

Adverse effects of screening. Adverse effects of screening with positive tests, resulting from false positive tests, have negative consequences. In Canadian trials there were 7% of women with mammography and CBE. Among those aged 50-59.²⁸ The effectiveness of graphic screening among

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Specificity estimates ranged from 98.5% in the HIP trial to 83% in the Canadian NBSS 2. Sensitivity estimates for mammography alone and for combined screening with CBE have generally been 10-15% lower for women aged 40-49 compared with women greater than age 50.^{15,17-19} Preliminary results from two North American demonstration projects suggest improved sensitivity of mammography, especially for women in their forties, with current mammographic techniques.²⁰ Significant variations in interpreter performance have also been observed.²¹⁻²³ In the Canadian trials, agreement was about 50% beyond that attributable to chance between radiologists at five screening centers and a single reference radiologist.²¹

The effectiveness of CBE alone has not been evaluated directly, but comparisons of the sensitivity and specificity of this maneuver to that of mammography can be considered. The Canadian NBSS 2 was designed to assess the incremental value of mammography above a careful, thorough (5-10 minutes) CBE.^{24,25} Preliminary results showing no incremental benefit highlighted the fact that higher sensitivity (88% for mammography plus CBE vs. 63% for CBE alone)¹⁷ may not guarantee improved effectiveness. Specificity was comparable or slightly better for CBE alone. Sensitivity of CBE for women aged 40-49 (Canadian NBSS 1) was about 10% lower at initial screen compared to the estimate for women aged 50-59 (Canadian NBSS 2).²⁶ Specificity estimates were similarly lower for younger women.

Data regarding the accuracy of BSE are extremely limited. One report calculated an upper limit of sensitivity ranging from 12 to 25% by assuming all interval cases in the clinical trials were detected by BSE.¹⁷ Using a similar approach, the overall sensitivity of BSE alone was estimated to be 26% in women also screened by mammography and CBE in the Breast Cancer Detection Demonstration Project (BCDDP).²⁷ Estimated BSE sensitivity decreased with age, from 41% for women aged 35-39 to 21% for women aged 60-74.²⁷ Thus, as currently practiced, BSE appears to be a less sensitive form of screening than is CBE or mammography, and its specificity remains uncertain. The sensitivity of BSE can be improved by training as measured by the proportion of benign lumps²⁸ detected on human models and artificial lumps²⁹ on silicone breast models, although whether this improved detection on models translates into improved personal BSE performance is unknown.

Adverse effects of screening tests are an important consideration. False-positive tests, resulting from the effort to maximize disease detection, may have negative consequences including unnecessary diagnostic tests. In the Canadian trials there were 7-10% false positives from combined screening with mammography and CBE among women aged 40-49 and 4.5-8% among those aged 50-59.^{24,30} In a study of the yield of a first mammographic screening among women, half as many cancers per 1,000 first

screening mammograms were diagnosed in women aged 40-49 (3/1,000) compared to women aged 50-59 (6/1,000).³¹ Yet, women aged 40-49 underwent twice as many diagnostic tests per cancer detected compared to women aged 50-59 (43.9 vs. 21.9). Women aged 60-69 had a higher yield from screening, with 13 breast cancers diagnosed per 1,000 first screening mammograms and 10.2 diagnostic tests performed per cancer detected.

Mammographic screening may also adversely affect psychological well-being. Increased anxiety about breast cancer after a false-positive mammogram has been reported both at short- and long-term follow-up in studies surveying groups of screened women.^{32,33} No impact on compliance in obtaining future screening examinations was observed, however. Women who underwent a surgical biopsy as a result of a false-positive screening mammogram were more likely to report the workup as a stressful experience than were those who did not have a biopsy.³²

Excess breast cancers in populations that received doses of ionizing radiation significantly greater than those normally delivered by mammography, such as survivors from atomic bombings in Japan³⁴ and patients with benign breast disease,³⁵ have raised concerns about the potential radiation risk from screening mammograms. There is no direct evidence of an increased risk of breast cancer from mammographic screening, however. Assuming a mean breast dose of 0.1 rad from a mammogram and extrapolating from higher doses of radiation, modeling suggests that in a group of 100,000 women receiving annual screening from ages 50 to 75, 12.9 years would be lost due to radiogenic cancers but 2,623 years would be gained through a 20% reduction in breast cancer mortality as a result of that screening.³¹

Fewer data are available regarding adverse effects associated with CBE and BSE. A dramatic increase in false-positives was observed after instruction in BSE in a nonrandomized controlled trial evaluating performance on human models,²⁸ although no increase was found in a randomized controlled trial evaluating performance on silicone breast models.²⁹ The latter study also assessed the impact of training on variables other than detection performance on models. Adverse effects, such as unnecessary physician visits, heightened anxiety levels, or increased radiographic and surgical procedures, were not observed.²⁹

Effectiveness of Early Detection

Seven randomized controlled trials^{16,30,36-40} have evaluated the effectiveness of screening for breast cancer in women by either mammography alone or combined with CBE compared to no periodic screening. The age of participants at date of first invitation ranged from 40 to 74. The six trials^{16,36-40} that included women aged ≥ 50 showed a reduction in breast cancer mortality of 20-30% in the intervention group. The reduction was

statistically significant in (HIP),³⁷ the Swedish trials,⁴⁰ and two meta-analyses.

The results of these studies have consistently demonstrated the effectiveness of screening (with or without CBE) for breast cancer in screened women aged 40-74. The reduction in breast cancer mortality from breast cancer was lower than in the control group after 18 years of follow-up in women aged 45-64 from 84 general practices and CBE on the initial screening view mammography. The relative risk was 0.80 (95% confidence interval 0.65-0.99) and older at entry. The absolute risk reduction was 2.1% per 1,000 women per year.¹⁷ An overview of Swedish randomized controlled trials of mammography alone,⁴⁰ all of which were conducted in women aged 50 and older,⁴² and within screening mammography alone, reduced breast cancer mortality by 20%.

There are few data on the effectiveness of screening in this age group. Although there are many groups, an analysis of the data provides little evidence that an interval of screening every 2 years is as effective as mammography alone. The results are similar to that seen in the trials of screening with similar mortality reductions ranging from 12 to 33% for screening intervals are 12-33 months. The trials evaluating screening with CBE showed breast cancer mortality reductions of 18-33 months.

There is limited data on the effectiveness of screening women aged 40-49. The time series included women

statistically significant in the Health Insurance Plan of Greater New York (HIP),³⁷ the Swedish two-county trials,¹⁶ an overview of the Swedish trials,⁴⁰ and two meta-analyses of the trials.^{41,42}

The results of these six trials including women aged ≥ 50 have convincingly demonstrated the effectiveness of mammographic screening (with or without CBE) for breast cancer in women aged 50-69. The HIP trial screened women aged 40-64 with annual CBE and two-view mammography.³⁷ For women who were over age 50 at the time of entry into the study, mortality from breast cancer in the intervention group was more than 50% lower than in the control group at 5 years, decreasing to a 21% difference after 18 years of follow-up. The Edinburgh trial³⁶ screened women aged 45-64 from 84 general medicine practices with two-view mammography and CBE on the initial screen followed by annual CBE and biennial single-view mammography. Preliminary results at seven years found a relative risk of 0.80 (95% confidence interval [CI], 0.54 to 1.17) for women aged 50 and older at entry. The results from 10-year follow-up showed little change.¹⁷ An overview pooled the data through 1989 from the four Swedish randomized controlled trials of breast cancer screening with mammography alone.⁴⁰ All women diagnosed with breast cancer before randomization were excluded and endpoints were independently reviewed. Breast cancer mortality was reduced by about 30% for women aged 50-69 at entry using an endpoint of breast cancer as the underlying cause of death. A meta-analysis that included the most recently published results of these trials reported a 23% reduction in breast cancer mortality for women aged 50 and older.⁴² A meta-analysis of European case-control studies done within screening mammography programs also reported significantly reduced breast cancer mortality among women aged 50 and older.⁴²

There are few data regarding the optimal periodicity of screening in this age group. Although an annual interval has been recommended by many groups, an analysis of data from the Swedish two-county study found little evidence that an annual interval would confer greater benefit than screening every 2 years for women over the age of 50.¹⁹ This trial used mammography alone, but the reduction in breast cancer mortality was similar to that seen in the trials combining CBE with mammography.^{36,37} The similar mortality reductions found in screening trials using periodicities ranging from 12 to 33 months in women aged ≥ 50 suggests that biennial screening intervals are as effective as annual intervals. In a meta-analysis of the trials evaluating screening mammography,⁴² the estimated reduction in breast cancer mortality was the same (23%) for screening intervals of 12 months and 18-33 months in women aged 50-74.

There is limited and conflicting evidence regarding the benefit of screening women aged 70-74. The Swedish two-county trial and BCDDP time series included women up to age 74 at entry, and each found a re-

duction of breast cancer mortality for the intervention group as a whole.^{16,44} The Swedish overview, however, reported a relative risk of 0.98 (95% CI, 0.63 to 1.53) at 12-year follow-up for the age subgroup 70-74.⁴⁰ The wide confidence interval, due to small numbers in this subgroup analysis, does not preclude the possibility of a substantial benefit from screening in this age group. No clinical trials have evaluated screening in women over 74 years of age at enrollment.

Although all six trials found a benefit of screening among the total group of enrolled women who were 40-74 years at entry,^{16,36-40} there is uncertainty about the effectiveness of screening women between the ages of 40 and 49. The Canadian NBSS I was specifically designed to address this uncertainty.³⁰ This trial compared combined annual mammography and CBE to an initial CBE among women aged 40-49 at entry. At 7-year follow-up, no benefit of annual screening was observed (RR = 1.36; 95% CI, 0.84 to 2.21). This Canadian trial has been the subject of much criticism.⁴⁵⁻⁴⁷ Possible irregularities with randomization have been refuted by its investigators.⁴⁸ An independent review conducted by the National Cancer Institute of Canada to determine whether randomization was compromised. Although mammography quality issues have also been a concern, there is little evidence to suggest that the practices were inconsistent with the standards of the other clinical trials or community practice at the time of the study.⁴⁸ In addition, improvement in mammographic quality over the course of the study period was noted by both inside and outside observers.⁴⁸ The proportion of controls receiving mammography, 26%, can be compared to available estimates of 13% in the two-county trial, 24% in the Malmo trial (35% for women 45-49), and 24% in the Stockholm trial.^{38,39,49} This contamination may nevertheless have reduced the trial's ability to detect a benefit from the screening intervention. An excess of node-positive cancers detected in the intervention group raised concerns about subject randomization.³⁰ While this may have been the result of chance, other contributing factors suggested by the investigators include under-ascertainment secondary to lower surgical dissection rates in the control group and incomplete breast cancer ascertainment at preliminary follow-up (although these possibilities are unlikely to account for all of the observed excess).⁴⁸ Although the effect of these factors should diminish with long-term follow-up, the results are unlikely to achieve statistical significance because sample size calculations were based on an estimated 40% reduction in breast cancer mortality, which is greater than the typical reduction in mortality observed in the other six trials that included women in this age group.³⁰

Subgroup analyses of the other trials that included women under 50 have yielded conflicting evidence regarding the benefit of screening women aged 40-49. No benefit was observed in the Stockholm trial or in

one arm of the two-county significant benefits of about pooled the results from 7-year out adjustment for variation reduction in breast cancer mortality (95% CI, 0.85 to 1.39).⁴¹ In this analysis, the estimate changed in the Swedish trial (0.87; 95% CI, 0.63 to 1.20) group.⁴⁰ More recent meta-analyses reported nonsignificant 8-women aged 40-49.^{42,43} One of the Canadian trial was excluded with a greater reduction in mortality due to chance.⁴² Thus, the meta-analyses, primarily based on screening women aged 40-49, suggest the effectiveness of annual mammography at 40 or 41.

A recent analysis of data from BCDDP, a U.S. screening program for CBE, suggests comparable benefits for women 50-59.⁵¹ A similar analysis of the two-county trial confirms the results of comparisons of survival from the trial, and subgroup analyses have suggested that annual mammography results in a reduction in breast cancer mortality for women 40-49.^{19,20,52} In a meta-analysis, estimated mortality reduction was similar for 12- and 18-33-month follow-up (respectively, 12% and 12%).⁴²

There is no direct evidence comparing annual mammography to no screening. In the two-county trial, two thirds of the effectiveness of screening was due to the result of CBE.⁵³⁻⁵⁶ The Canadian meta-analysis found a minimal value of annual mammography for women aged 50-59 at study entry. This result suggests that thorough screening compared to CBE results in a small benefit in breast cancer mortality. This result suggests that thorough screening in this age group

one arm of the two-county trial, while the remaining trials reported non-significant benefits of about 22% or more.^{17,50} One meta-analysis, which pooled the results from 7-year follow-up of six published clinical trials without adjustment for variation in screening method or interval, found no reduction in breast cancer mortality for women in their forties (RR = 1.08; 95% CI, 0.85 to 1.39).⁴¹ When the Canadian trial was excluded from the analysis, the estimate changed little (RR = 0.99; 95% CI, 0.74 to 1.32). The overview of the Swedish trials found a nonsignificant 13% reduction (RR = 0.87; 95% CI, 0.63 to 1.20) only after 8–12 years of follow-up in this age group.⁴⁰ More recent meta-analyses of published mammography trial data reported nonsignificant 8–10% reductions in breast cancer mortality in women aged 40–49.^{42,43} One meta-analysis reported a significant benefit for women in this age group when unpublished data were included and the Canadian trial was excluded.⁴³ Longer duration of follow-up was associated with a greater reduction in mortality, although this finding may have been due to chance.⁴² Thus, there is conflicting evidence from clinical trials and meta-analyses, primarily based on subgroup analyses, regarding the benefit of screening women aged 40–49. An ongoing British trial is evaluating the effectiveness of annual mammography screening in women enrolled at age 40 or 41.

A recent analysis of data by tumor size, nodal status, and stage from the BCDDP, a U.S. screening project using annual two-view mammography and CBE, suggests comparable 14-year survival rates for women 40–49 and women 50–59.⁵¹ A similar analysis of breast cancers detected in the Swedish two-county trial confirms this finding.⁵² Based on these data, time series comparisons of survival, frequency of interval cancers in the two-county trial, and subgroup analysis of available clinical trial data, some experts have suggested that annual screening intervals may be necessary to achieve a reduction in breast cancer mortality from screening for women aged 40–49.^{19,20,52} In a meta-analysis of published trial results, however, the estimated mortality reduction from screening women in this age group was similar for 12- and 18–33-month screening intervals (1% and 12%, respectively).⁴²

There is no direct evidence that assesses the effectiveness of CBE alone compared to no screening. Modeling studies of the HIP trial estimated that two thirds of the effectiveness of the combined screening may have been a result of CBE.^{53–56} The Canadian NBSS 2 was designed to test the incremental value of annual mammography over a careful annual CBE among women aged 50–59 at study entry.²⁴ At 7-year follow-up, there was no difference in breast cancer mortality for the group receiving combined screening compared to CBE alone (RR = 0.97; 95% CI, 0.62 to 1.52). This result suggests that thorough CBE may be as effective as mammography for screening in this age group. The confidence interval is wide, however, and

substantial benefit or harm from screening is not excluded by the preliminary data. Concerns regarding the early quality of mammography of Canadian NBSS I also apply to this trial.⁴⁸ Long-term follow-up and additional studies are needed to confirm this apparent lack of an incremental benefit of mammography above a careful, thorough annual CBE. It is also unclear whether CBE adds benefit to screening with mammography. A meta-analysis of mammography trial results reported similar reductions in breast cancer mortality with and without the addition of CBE.⁴²

Evidence for effectiveness of BSE alone is also limited. In the United Kingdom Trial of Early Detection of Breast Cancer, a nonrandomized community trial, 40–50% of women living in two districts participated in BSE instruction that included a home visit and a lecture by a specially trained health provider.⁵⁷ At 7-year follow-up there was no reduction in breast cancer mortality in the BSE community compared with the control districts. Baseline comparability of intervention and control districts, treatment variation by community, and confounding by other screening modalities were not assessed; however, a World Health Organization (WHO) population-based randomized controlled trial in Leningrad comparing formal BSE instruction to no intervention in women aged 40–64 has reported increases in physician visits, referral for further screening tests, and excisional biopsies in the intervention group at 5-year follow-up.⁵⁸ Breast cancer patients in the two groups did not differ in number, size, or nodal status of their tumors. Completeness of endpoint assessment is a concern in this study, given the lack of a national tumor registry. Follow-up through 1999 is planned for reporting mortality results. In a case-control study of women who had been diagnosed with advanced stage (TNM III or IV) breast cancer, there was no association between disease status and self-reported BSE.⁵⁹ Proficiency in practicing BSE, however, was reported as poor by both cases and controls. For the small group of women reporting thorough BSE compared to all others, the relative risk was 0.54 (95% CI, 0.30 to 0.98). A meta-analysis of pooled data from 12 descriptive studies found that women who practiced BSE before their illness were less likely to have a tumor of 2.0 cm or more in diameter, or to have evidence of extension to lymph nodes.⁶⁰ The studies from which these data were obtained, however, suffer from important design limitations and provide little information on clinical outcome (i.e., breast cancer mortality). Retrospective studies of the effectiveness of BSE have produced mixed results.^{27,61–63}

Recommendations of Other Groups

The American Cancer Society (ACS),⁶⁴ American College of Radiology,⁶⁵ American Medical Association,⁶⁶ American College of Obstetricians and Gynecologists (ACOG),⁶⁷ and a number of other organizations⁶⁸ recom-

mend screening with mammography beginning at the age of 40 and continuing every 1–2 years until age 50.

The American Academy on Breast and Cervical Health recommends annual mammography every 1–3 years for women aged 40–74, and mammography every 2–3 years for women older than 75. Mammography recommendations are currently unclear. The American College of Physicians (ACP) recommends annual mammography for women aged 50–74 and biennial mammography for women under 50 or over 75 years of age. The American Cancer Society recommends the same recommendation for women aged 40–74. Mammography presses great anxiety about the benefits of screening. The Canadian Cancer Society recommends annual mammography for women aged 40–74 and biennial mammography for women aged 75 and older. The American Cancer Institute states that mammography at age 40–74 can reduce breast cancer mortality, but that the benefit has not shown a statistically significant benefit at the age of 50.⁷¹

Organizations that currently recommend mammography include the AAFP,⁶⁸ ACC,⁶⁹ and the American Cancer Society.⁷⁰ These organizations are currently under re-

Discussion

At this time, there is little evidence that mammography with or without CBE reduces breast cancer mortality for women aged 40–74. The incremental value of mammography from biennial screening to annual screening is likely to be small. The incremental value of mammography with CBE is likely to be small, although the Canadian data suggest that it may be more effective as mammography alone.

Evidence does not support mammography for women aged 40–49. Only the limited effectiveness of screening in women aged 40–49 has adequate power for statistical significance. For younger women, one of the major limitations of mammography include suboptimal adherence. The benefits of mammography in younger women may be offset by the treatment offered to

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The American Academy of Family Physicians (AAFP) recommends CBE every 1-3 years for women aged 30-39 and annually for those aged 40 and older, and mammography annually beginning at age 50;⁶⁸ these recommendations are currently under review. The American College of Physicians (ACP) recommends screening mammography every 2 years for women aged 50-74 and recommends against mammograms for women under 50 or over 75 years and baseline mammograms.⁶⁹ The ACP makes the same recommendations for high-risk women unless the woman expresses great anxiety about breast cancer or insists on more intensive screening. The Canadian Task Force on the Periodic Health Examination recommends annual CBE and mammography for women aged 50-69 and recommends against mammograms in women under 50.⁷⁰ The National Cancer Institute states there is a general consensus among experts that routine mammography and CBE every 1-2 years in women aged 50 and over can reduce breast cancer mortality, and that randomized clinical trials have not shown a statistically significant reduction in mortality for women under the age of 50.⁷¹

Organizations that presently recommend routine teaching of BSE include the AAFP,⁶⁸ ACOG,⁶⁷ and ACS.⁶⁴ The recommendations of the AAFP are currently under review.

Discussion

At this time, there is little doubt that breast cancer screening by mammography with or without CBE has the potential of reducing mortality from breast cancer for women aged 50 through about 70. The benefit derived from biennial screening appears to be quite similar to the benefit derived from annual screening. Given this similarity in effectiveness, biennial screening is likely to have the added benefit of increased cost-effectiveness. The incremental value of CBE above mammography or vice versa is uncertain, although the Canadian NBSS²⁴ suggests that careful CBE may be as effective as mammography.

Evidence does not establish a clear benefit from screening in women aged 40-49. Only the Canadian NBSS¹³⁰ was designed to test the effectiveness of screening in this age group, however, and none of the trials had adequate power for subgroup analysis. If screening is in fact ineffective in younger women, one possible explanation is a lower sensitivity of mammography in younger women (see *Accuracy of Screening Tests*). Other possibilities include suboptimal screening intervals, differential (less aggressive) treatment offered to women with mammographically detected cancer, and

varying biologic characteristics of breast tumors.^{52,72} The Swedish overview,⁴⁰ HIP,³⁷ and Edinburgh³⁹ trials suggest some benefit in women aged 40–49 after 8–12 years of follow-up. It is possible that the delayed benefit is due to screening women in their forties who entered the trials in their middle to late forties.^{72a} The final results of the Canadian NBSS I may provide important information. An ongoing British trial and a proposed trial in Europe which will enroll women only in their early forties and compare mammography to no screening could also clarify this issue.⁷³ Until further information is available, it is unclear whether any potential improvement in breast cancer mortality achieved by screening women aged 40–49 is of sufficient magnitude to justify the potential adverse effects that may occur as a result of widespread screening.

Because breast cancer incidence increases with age, the burden of suffering due to breast cancer in elderly women is substantial. In addition, there is no evidence (as there is in younger women) that sensitivity of mammography in older women is not comparable to that in women aged 50–69. This is an age group, moreover, in which the utilization of breast cancer screening is common.^{71–76} In a decision analysis of the utility of screening women over 65 for breast cancer, screening saved lives at all ages, but the savings decreased substantially with increasing age and comorbidities.⁷⁷ In the oldest women, those aged ≥85, short-term morbidity such as anxiety or discomfort from the screening may have outweighed the small benefits. Until more definitive data become available for elderly women, it is reasonable to concentrate the large effort and expense associated with screening mammography on women in the age group for which benefit has been most clearly demonstrated: those aged 50–69. Screening women aged 70 and older might be considered on an individual basis, depending on general health and other considerations (e.g., personal preference of the patient).

The age range of 50–69 years for which mammography has been proven effective, is to a large extent based on artificial cutpoints chosen for study purposes rather than on biologic cutpoints above or below which the ratio of benefits to risks sharply decreases. Both the incidence of breast cancer and the sensitivity of mammography increase with age. Thus, it is logical that women in their seventies (for whom only limited clinical trial experience is available, benefit from breast cancer screening. For women aged <50 years, evidence has been insufficient to establish a clear benefit from breast cancer screening. This age cutpoint may be a marker for biologic changes that occur with age, especially menopause. It is therefore plausible that women in their late forties, particularly postmenopausal women, might derive some intermediate benefit from screening. The risks and benefits of mammography and CBE may be best considered as changing on an age continuum rather than as specific chronologic age-

Guidelines for breast cancer mind.

No large study has quantifying by either CBE or mammography developing breast cancer the incidence of disease in high-risk (PPV) of screening tests used in a screening program, the PPV for women with a family history of breast cancer. Important consideration for women with a family history of breast cancer has not been established for benefit from screening younger women. Confirming this effect are lacking. The benefits of suffering, screening high-risk women on an individual basis for women with a family history of breast cancer screening.

Data regarding the effectiveness of BSE as currently practiced is similar to that of CBE and mammography in younger women in whom the benefits of necessary anxiety and diagnostic procedures in a clinical trial²⁹ did not find a net benefit. The conclusion is that time devoted to breast cancer prevention efforts with procedures that are not well known and the potential for harm. A recommendation for or against breast cancer health examination cannot be made.

CLINICAL INTERVENTION

Screening for breast cancer with mammography and annual clinical breast examination is recommended for women aged 50–69. For women aged 50–69, refer patients to mammography facilities that meet high standards of quality established by the Mammography Quality Standards Act, including that all mammography facilities must have a process approved by the FDA. There is insufficient evidence to recommend mammography aged 50–69 ("C" recommendation). There is conflicting evidence of fair to good benefit from mammography with or without clinical breast examination compared to benefit from CBE alone; d

Guidelines for breast cancer screening should be interpreted with this in mind.

No large study has quantitated the effectiveness of breast cancer screening by either CBE or mammography for women who are at higher risk of developing breast cancer than the general population. The increased incidence of disease in high-risk women increases the positive predictive value (PPV) of screening tests used in this group. For example, in a community screening program, the PPV of mammography was increased 2-3-fold for women with a family history of breast cancer.⁷¹ This is an especially important consideration for women under 50, in whom the benefit of screening has not been established for the general population. There may be a benefit from screening younger women in high-risk groups, but studies confirming this effect are lacking. Nevertheless, given their increased burden of suffering, screening high-risk women under age 50 may be considered on an individual basis for women who express a strong preference for such screening.

Data regarding the effectiveness of BSE are extremely limited, and the accuracy of BSE as currently practiced appears to be considerably inferior to that of CBE and mammography. False-positive BSE, especially among younger women in whom breast cancer is uncommon, could lead to unnecessary anxiety and diagnostic evaluation, although a small randomized clinical trial²⁹ did not find such adverse effects. A point also worth consideration is that time devoted to teaching BSE may reduce time available for prevention efforts with proven effectiveness. Given the present state of knowledge and the potential adverse effects and opportunity cost, a recommendation for or against inclusion of teaching BSE during the periodic health examination cannot be made.

CLINICAL INTERVENTION

Screening for breast cancer every 1-2 years, with mammography alone or mammography and annual clinical breast examination (CBE), is recommended for women aged 50-69 ("A" recommendation). Clinicians should refer patients to mammographers who use low-dose equipment and adhere to high standards of quality control. Such standards have recently been established by the Mammography Quality Standards Act, a federal law mandating that all mammography sites in the U.S. be accredited through a process approved by the Department of Health and Human Services.⁷⁸ There is insufficient evidence to recommend annual CBE alone for women aged 50-69 ("C" recommendation). For women aged 40-49, there is conflicting evidence of fair to good quality regarding clinical benefit from mammography with or without CBE, and insufficient evidence regarding benefit from CBE alone; therefore, recommendations for or against rou-

tine mammography or CBE cannot be made based on the current evidence ("C" recommendation). There is no evidence specifically evaluating mammography or CBE in high-risk women under age 50; recommendations for screening such women may be made on other grounds, including patient preference, high burden of suffering, and the higher PPV of screening, which would lead to fewer false positives than are likely to occur from screening women of average risk in this age group. There is limited and conflicting evidence regarding clinical benefit of mammography or CBE for women aged 70-74 and no evidence regarding benefit for women over age 75; however, recommendations for screening women aged 70 and over who have a reasonable life expectancy may be made based on other grounds, such as the high burden of suffering in this age group and the lack of evidence of differences in mammogram test characteristics in older women versus those aged 50-69 ("C" recommendation). There is insufficient evidence to recommend for or against teaching BSE in the periodic health examination ("C" recommendation).

The draft update of this chapter was prepared for the U.S. Preventive Services Task Force by Marisa Moore, MD, MPH, and Carolyn DiGiuseppe, MD, MPH.

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Part C. Metabolic, Nutritional, and Environmental Disorders

19. Screening for Diabetes Mellitus

RECOMMENDATION

There is insufficient evidence to recommend for or against routine screening for diabetes mellitus in asymptomatic adults. There is also insufficient evidence to recommend for or against universal screening for gestational diabetes. Although the benefit of early detection has not been established for any group, clinicians may decide to screen selected persons at high risk of diabetes on other grounds (see Clinical Intervention). Screening with immune markers to identify persons at risk for developing insulin-dependent diabetes is not recommended in the general population.

Burden of Suffering

Approximately 14 million persons in the U.S. have diabetes mellitus.¹ Non-insulin-dependent diabetes mellitus (NIDDM) or Type II diabetes accounts for 90-95% of all cases of diabetes in the U.S., while insulin-dependent diabetes mellitus (IDDM) or Type I diabetes accounts for the remaining 5-10%.¹⁻⁴ An estimated half of all persons with diabetes (primarily patients with NIDDM) are currently unaware of their diagnosis.² Diabetes may cause life-threatening metabolic complications, and is the seventh leading cause of death in the U.S., contributing to roughly 160,000 deaths each year.^{1,5} It is also an important risk factor for other leading causes of death such as coronary heart disease and cerebrovascular disease.¹ Diabetes is the most common cause of polyneuropathy, with approximately 50% of diabetics affected within 25 years of diagnosis,⁵ and is responsible for over 50% of the 120,000 annual nontraumatic amputations in the U.S.⁶ Diabetic nephropathy is now the leading cause of end-stage renal disease in the U.S.⁷ and, if current trends continue, will soon account for 50% of all patients with renal failure.⁸ Diabetes is the leading cause of blindness in adults ages 20-74 and accounts for over 8,000 new cases of blindness each year.⁹ Infants born of diabetic women are at increased risk of fetal malformation, prematurity, spontaneous abortion, macrosomia, and metabolic derangements.^{10,11} Compared to persons without diabetes, diabetic pa-

tients have a higher hospitalization rate, longer hospital stays, and increased ambulatory care visits.¹² The total annual economic burden of diabetes is believed to approach \$100 billion in the U.S.¹³

The onset of NIDDM is usually after age 30, and the prevalence steadily increases with advancing age. It is estimated that nearly 20% of the U.S. population aged 65-74 has diabetes.² The prevalence of NIDDM is markedly increased in Native Americans and is also higher among black and Hispanic populations.³ The prevalence of NIDDM is greater than 70% in Pima Indians 55 years of age and older.¹⁴ Other risk factors for diabetes include family history, obesity, and a previous history of gestational diabetes or impaired glucose tolerance. IDDM has an earlier onset (usually before age 30), a much shorter asymptomatic period, and a more severe clinical course than NIDDM.

Gestational diabetes mellitus (GDM), the development of glucose intolerance during pregnancy, occurs in 3-5% of all pregnancies and is the most common medical problem of pregnancy.^{9,15} Risk factors for GDM include obesity, increased maternal age, hypertension, glucosuria, a family history of diabetes, and a history of a macrosomic, stillborn, or congenitally malformed infant. GDM is a risk factor for fetal macrosomia and is associated with other neonatal complications, such as hyperbilirubinemia and hypoglycemia. Macrosomia—most commonly defined as birth weight above 4,000 or 4,500 g—is not itself a morbid condition but is associated with increased risk of operative delivery (cesarean section or vacuum or forceps delivery) and birth trauma (e.g., clavicular fracture, shoulder dystocia, and peripheral nerve injury).¹⁶⁻¹⁹ In some series, the incidence of shoulder dystocia in infants over 4,000 g is close to 2%.²⁰ Women with a history of GDM are also at increased risk for developing NIDDM later in life.²¹

Accuracy of Screening Tests

The diagnosis of diabetes in many nonpregnant patients is based on typical symptoms (polyuria, polydipsia) in association with clear elevation of glucose (fasting plasma glucose > 140 mg/dL [7.8 mM]). Many asymptomatic persons, however, may have abnormal glucose metabolism and be at increased risk for complications of diabetes.

Diagnosis of Diabetes in Asymptomatic Persons. The National Diabetes Data Group (NDDG)²² and World Health Organization (WHO)²³ have issued similar criteria for diagnosing diabetes in asymptomatic persons, based on elevated fasting plasma glucose (> 140 mg/dL) or an abnormal plasma or serum glucose following an oral glucose tolerance test (OGTT). NDDG criteria for a positive OGTT (> 200 mg/dL at 2 hours and before 2 hours) differ slightly from WHO criteria (glucose > 200 mg/dL at 2 hours alone). Abnormal glucose measurements on more than one occasion are

required for a diagnosis. These criteria reflect both the difficulties of diagnosing diabetes on the basis of symptoms and the variability of the OGTT. In asymptomatic adults, the American Diabetes Association (ADA) requires two abnormal tests, one on an overnight fast and one on a 2-hour OGTT.

Both the NDDG and WHO criteria require a second abnormal glucose measurement. Intermediate results of OGTTs are at increased risk for being false positive and are highly variable. A significant number of patients require repeat testing,²⁵ and a second test is often necessary to obtain a diagnosis.

Diagnosis of Gestational Diabetes Mellitus. The diagnosis of GDM is based on two or more abnormal glucose measurements. The test used is a 100 g glucose tolerance test (OGTT) using 100 g glucose and 500 mL of a 10% glucose solution (O'Sullivan²⁸ to identify GDM). The test is followed by a 1-hour follow-up. The conversion of glucose measurements to millimoles per liter (mmol/L) is proposed as a modified criterion for diagnosis. The proposed modified criteria for diagnosis of GDM are based on whether the 100 g glucose test or the 100 g glucose test with a 1-hour follow-up are used.

Because diagnosis of GDM is expensive for routine screening, it is not recommended for routine screening of asymptomatic persons. However, it is recommended for women with GDM in previous pregnancies.

Screening for Non-Insulin-Dependent Diabetes Mellitus. Screening tests for NIDDM include fasting or postprandial glucose in fasting or postprandial plasma or urine, and proteinuria. The specificity of the fas-

Part H. Musculoskeletal Disorders**46. Screening for Postmenopausal Osteoporosis****RECOMMENDATION**

There is insufficient evidence to recommend for or against routine screening for osteoporosis with bone densitometry in postmenopausal women. Recommendations against routine screening may be made on other grounds (see Clinical Intervention). All postmenopausal women should be counseled about hormone prophylaxis (see Chapter 68) and be advised of the importance of smoking cessation, regular exercise, and adequate calcium intake (see Chapters 54-56). For those high-risk women who would consider estrogen only to prevent osteoporosis, screening may be appropriate to assist treatment decisions (see Clinical Intervention).

Burden of Suffering

An estimated 1.8 million osteoporosis-related fractures occur each year in the U.S.¹ About 70% of fractures in persons aged 45 or older are types that are related to osteoporosis.² Most of these injuries occur in postmenopausal women. Over half of all postmenopausal women will develop a spontaneous fracture as a result of osteoporosis.³ It has been estimated that about one quarter of all women over age 60 develop vertebral deformities and about 15% of women sustain hip fractures during their lifetime.^{4,5} The annual cost of osteoporosis-related fractures in the U.S. has been estimated to be over \$8 billion in direct and indirect costs.⁶ Osteoporosis-related fractures commonly involve the proximal femur, vertebral body, and distal forearm, but most fractures in elderly women are due in part to low bone mass.⁷ Of these sites, the proximal femur (hip) has the greatest effect on morbidity and mortality; there is a 15-20% reduction in expected survival in the first year following a hip fracture.⁸ Hip fractures are also associated with significant pain, disability, and decreased functional independence.⁹ Among persons living at home at the time of a hip fracture, about half experience a deterioration in social function within 2.5 years.¹⁰

Low bone density is strongly associated with an increased risk of fracture.¹¹ By one estimate, a 50-year-old woman in the 10th percentile of bone

density has a 25% lifetime risk of hip fracture (vs. 8% for those in the 90th percentile).¹² A World Health Organization study group has recommended that osteoporosis be defined as a bone density more than 2.5 standard deviations (SD) below the normal bone mass in young women, and that osteopenia (low bone mass) be defined as bone density 1–2.5 SD below the normal mean.¹³ Risk of postmenopausal osteoporosis is a function of rate of bone loss as well as peak bone mass. The principal risk factors for osteoporosis are female sex, advanced age, Caucasian race, low body weight, and bilateral oophorectomy before menopause.¹⁴ Other historical risk factors such as parity, lactation history, and caffeine intake have been shown to be poor predictors of bone mass.^{14–16} Smoking is a probable risk factor for hip fracture, but it is a less reliable predictor of bone mass.¹⁷ The lower weight and poorer health of smokers compared to nonsmokers may be responsible for the association between smoking and bone mass and fracture risk.¹⁸

Accuracy of Screening Tests

A number of radiologic screening tests have been proposed for both clinical and research purposes to detect low bone mass in asymptomatic persons. These include conventional skeletal radiographs, quantitated computed tomography, single photon absorptiometry, dual photon absorptiometry, and dual energy x-ray absorptiometry. Although skeletal x-rays can detect focal bone disorders and fractures, they do not reliably detect bone loss of less than 20–30%, and they are of limited value in estimating bone mass.¹⁹ The other techniques vary in their availability, cost, and convenience, and provide measures expressed as bone mineral content (BMC) in grams/cm or as bone mineral density (BMD) in grams/cm².

Single photon absorptiometry (SPA), in which radioisotopes are the photon source, can measure BMC or BMD in cortical bone in the radius or calcaneus.²⁰ Dual photon absorptiometry (DPA), dual energy x-ray absorptiometry (DXA), and quantitative computed tomography (QCT) provide direct measures of BMD and are most useful in evaluating the trabecular bone density in locations beneath large amounts of soft tissue (e.g., lumbar vertebrae, proximal femur). DPA and DXA use radioisotopes (DPA) or x-rays (DXA) to emit photons at two different energy levels, thereby correcting for the effect produced by layers of soft tissues.^{20–22} DXA is now widely used in the clinical setting, and provides more reproducible measures of bone density with shorter examination times (5–10 vs. 20–40 minutes) than DPA.^{20–22} The precision of DXA (variation in results on repeated measurement) is about 0.5–2%, compared to 1.5–4.0% for DPA.²³ Current data on the performance of these devices have been ob-

tained primarily agree that DX bone density th SPA is similar to than DXA. Evid dictive for futur

QCT is high verse sections a cal as a routine Ultrasound tec development a under investiga may be able to bone loss.²⁶

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OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL

To: Doyle Thorne From: Shawn # of pages: 3

Dept./Agency: (I forgot this) Phone #

Fax #

NSN 7540-01-317-7368 5099-101 GENERAL SERVICES ADMINISTRATION

Health Care Financing Administration

Press Office
Washington, DC 20201

FAX TRANSMISSION

TO: Regional Media Contacts

+ Darcy Jakopchek (Kansas City)
Jane Rosen (Philadelphia)

FROM: Shawn Hanson

Three pages total.

Attached is the **DRAFT** letter to the editor we talked about during this morning's phone call. Please run it by your Regional Administrator for comments. The body of the letter will be standard, but keep in mind that we need to localize a paragraph for each state it is going to. You should also get the number of beneficiaries in each of your states ready to insert in the letter.

What I had in mind was saying something about the number of beneficiaries in each state (for example, a letter to the Seattle Times would talk about the XXX number of Medicare beneficiaries living in Washington state). I don't have the exact language yet -- would any of you be willing to take a first crack at re-writing a generic fill-in-the-blank first paragraph?

I am working with the Secretary's press office on this project -- the same letter will be going out to different papers from all of the HHS Regional Directors so that is why we wanted to change the first and maybe the last paragraphs a bit. We're dividing up markets to target, so that news of these benefits can reach as wide an audience as possible.

Again, this is a draft letter but we may need to move quickly on it once we get the go ahead.

Thank you for your help.

FAX TRANSMITTAL

of pages

9

To <i>Susan Branch</i>	From <i>Shawn Hanson</i>
Dept./Agency	Phone # <i>260 4448</i>
Fax # <i>456 5557</i>	Fax #
NSN 7540-01-317-7368	GENERAL SERVICES ADMINISTRATION

9. Screening for Cervical Cancer

RECOMMENDATION

Routine screening for cervical cancer with Papanicolaou (Pap) testing is recommended for all women who are or have been sexually active and who have a cervix. Pap smears should begin with the onset of sexual activity and should be repeated at least every 3 years (see Clinical Intervention). There is insufficient evidence to recommend for or against an upper age limit for Pap testing, but recommendations can be made on other grounds to discontinue regular testing after age 65 in women who have had regular previous screenings in which the smears have been consistently normal. There is insufficient evidence to recommend for or against routine screening with cervicography or colposcopy, or for screening for human papilloma virus infection, although recommendations against such screening can be made on other grounds (see Clinical Intervention).

Burden of Suffering

Approximately 16,000 new cases of cervical cancer are diagnosed each year, and about 4,800 women die from this disease annually.¹ The lifetime risk of dying from cervical cancer in the U.S. is 0.3%.² Although the 5-year survival rate is about 90% for persons with localized cervical cancer, it is considerably lower (about 14%) for persons with advanced (Stage IV) disease. The incidence of invasive cervical cancer has decreased significantly over the last 40 years, due in large part to organized early detection programs. Although all sexually active women are at risk for cervical cancer, the disease is more common among women of low socioeconomic status, those with a history of multiple sex partners or early onset of sexual intercourse, and smokers. The incidence of invasive cervical cancer among young white women has increased recently in the United States. Infection with human immunodeficiency virus (HIV) and certain types of human papilloma virus (HPV) also increases the risk of cervical cancer.

Accuracy of Screening Tests

The principal screening test for cervical cancer is the Pap smear. Although the Pap smear can sometimes detect endometrial, vaginal, and other cancers,^{3,4} its use as a screening test is intended for the early detection of cer-

vical dysplasia and cancer. Other proposed cervical screening tests include cervicography, colposcopy, and testing for HPV infection. The role of pelvic examination, which usually accompanies the collection of the cervical specimen, is discussed in Chapter 10 in relation to ovarian cancer screening.

Precise data on the sensitivity and specificity of the Pap smear in detecting cancer and dysplasia are lacking due to methodologic problems. Depending on study design, false-negative rates of 1–80% have been reported; a range of 20–45% has been quoted most frequently, primarily in studies comparing normal test results with subsequent smears.^{5–11} Studies using cone biopsy results as the reference standard have reported false-negative rates as low as 10%.¹² Although reliable data are lacking, specificity is probably greater than 90%¹³ and may be as high as 99%.^{6,11} The detection of precursor cervical intraepithelial neoplasia (CIN) by Pap smears may have poor specificity for cervical carcinoma, however, because a substantial proportion of CIN-I lesions do not progress to invasive disease or may regress spontaneously. The test-retest reliability of Pap smears is influenced to some extent by variations in the expense and procedures of different cytopathology laboratories.

A large proportion of diagnostic errors may be attributable to laboratory error. In one study of over 300 laboratories given slides with known cytologic diagnoses, false-negative diagnoses were made in 7.5% of smears with moderate dysplasia or frank malignancy, and false-positive diagnoses were made in 8.9% of smears with less than benign atypia.¹⁴ A survey of 73 laboratories in one state revealed a false-negative rate of 4.4% and a false-positive rate of 2.7%.¹⁵ These data were reported in 1990, before the introduction of federal legislation designed to improve the accuracy of cytopathologic laboratory interpretation.¹⁶ With the adoption of the Bethesda system for classification of cervical diagnoses,¹⁷ a large proportion of benign smears are interpreted as "atypical," a finding that poses little premalignant potential but that often generates intensive follow-up testing.

Another cause of false-negative Pap smears is poor specimen collection technique. A 1991 survey of 600 laboratories found that 1–5% of specimens received were either unsatisfactory or suboptimal, generally because endocervical cells were absent from the smears.¹⁸ Another study found that poor sampling technique accounted for 64% of false-negative results.¹⁹ The Pap smear has traditionally been obtained with a spatula, to sample the ectocervix, and a cotton swab, to obtain endocervical cells. A 1990 survey found that about half of physicians used a spatula and cotton swab to collect Pap smears.²⁰ In recent years, new devices have been introduced to improve sampling of the squamocolumnar junction. Controlled studies have shown that using an endocervical brush in combination with a spatula is more

likely to collect endocervical cells.²¹ There is conflicting evidence that increases the detection rate of CIN. There is also concern about collecting endocervical cells. CIN is detected over 2 times more often when endocervical cells are present.^{31–33} There is also concern about the presence of endocervical cells in a more expensive than the ectocervix, and easily recovered by the red dye. The use of endocervical cell washes to improve the visibility of endocervical cells.

There are important problems with the interpretation of Pap smears. The cause of CIN or more advanced disease due to the adverse effects of false-positive results is the risk of cervical cancer.^{41,42} The discomfort, and expense of the procedure, and the distribution of abnormal results may be improved by the use of a better sampling technique and a better interpretation of the results.

Other tests, such as colposcopy, can help improve the sensitivity of the cervical examination. The requirements are similar to the Pap smear (approximately 50%); the specificity is only 1–26%, and about 10% of women undergo Colposcopy, in which the acetic acid washing and visualization of the cervix is performed on women with CIN (34–43%), specificity (68%) used as a screening test for CIN. Other disadvantages of colposcopy are the unavailability of the equipment, the cost of the procedure, and patient discomfort. One study reported a range of scores for the procedure.

Another proposed screening test is the HPV test. It is a known risk factor for cervical cancer that have been identified. The HPV test has a strong epidemiologic

likely to collect endocervical cells than using a spatula or cotton swab.²¹⁻³⁰ There is conflicting evidence, however, that the endocervical brush increases the detection rate for abnormal smears or affects clinical outcomes.³¹⁻³³ There is also conflicting evidence regarding the importance of collecting endocervical cells. Although some large series have reported that CIN is detected over 2 times more frequently when endocervical cells are present,^{34,35} other series^{36,37} have shown no association between the presence of endocervical cells and the detection rate for dysplasia. The brush is more expensive than the cotton swab, but studies suggest that this cost is easily recovered by the reduced need for repeat testing.³⁸ Other methods for improving the sensitivity of cervical cancer screening, such as acetic acid washes to improve the visibility of lesions, remain investigational.^{39,40}

There are important potential adverse effects associated with inaccurate interpretation of Pap smears. False-negative results are significant because CIN or more invasive lesions may escape detection and progress to more advanced disease during the period between tests. The potential adverse effects of false-positive results include patient anxiety regarding the risk of cervical cancer,^{41,42} as well as the unnecessary inconvenience, discomfort, and expense of follow-up diagnostic procedures. Studies have shown that the distribution of patient education materials that explain the meaning of abnormal results is associated with a reduction in patient anxiety and stress and a better patient understanding of test results.⁴³⁻⁴⁵

Other tests, such as cervicography and colposcopy, have been proposed to help improve the sensitivity of screening,⁴⁶ but their accuracy and technical requirements are suboptimal. Cervicography, in which a photograph of the cervix is examined for atypical lesions, has a sensitivity that is comparable to the Pap smear (approximately 60%) but a much lower specificity (approximately 50%); the reported positive predictive value in most studies is only 1-26%, and about 10-15% of cervigrams are unsatisfactory.⁴⁷⁻⁵¹ Colposcopy, in which the cervix is examined under magnification with acetic acid washing and suspicious lesions are biopsied, is widely performed on women with abnormal Pap smears, but has poor sensitivity (34-43%), specificity (68%), and positive predictive value (4-13%) when used as a screening test for cervical neoplasia in asymptomatic women.⁵²⁻⁵⁴ Other disadvantages of colposcopy screening include its cost, the limited availability of the equipment, the time and skills required to perform the procedure, and patient discomfort. Using a VAS (visual analog scale) for assessing pain, one study reported that women who underwent colposcopy gave the procedure a range of scores from 3 to 4.5.⁵⁵

Another proposed screening strategy is testing for HPV infection, a known risk factor for cervical cancer. Of the more than 70 types of HPV that have been identified, several oncogenic forms (e.g., types 16 and 18) have a strong epidemiologic association with cervical cancer. However, the



File Medicare Preventive
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Press Office
Washington, DC 20201

FAX TRANSMISSION

Benefits

To: Chris Jennings

Date: 12/9/97

Fax: (202) 456-5557

Pages: 3 (including cover)

From: Chris Peacock

Subject: Draft of the Medicare Preventive Benefits fact sheet

Comments: Nancy-Ann Min DeParle wanted you to see the attached draft.

HHS FACT SHEET

DRAFT

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

December XX, 1997

Contact: HCFA Press Office
(202) 690-6145

MEDICARE PREVENTIVE SERVICE BENEFITS

Overview: Physicians and other experts agree prevention and early detection of disease can lead to substantial reductions in life-threatening illness. Pap smears, for example, are responsible for dramatic reductions in the numbers of cervical cancer cases and deaths. The Clinton Administration is committed to making sure Medicare beneficiaries get recommended preventive screening tests. That is why the President worked with Congress to expand preventive benefits for Medicare's beneficiaries in the Balanced Budget Act of 1997.

Mammograms: As of January 1, 1998, Medicare coverage is being expanded to pay for annual screening mammograms for women age 40 and over. Medicare also covers a one-time initial, or baseline, mammogram for women age 35-39. Beneficiaries will only have to pay the usual 20 percent copayment, and Medicare will pay the other 80 percent. Beneficiaries will not have to pay the \$100 annual Part B deductible for this service. Routine screening mammography every 1 to 2 years is recommended for all women age 40-75. Women over 75 should consult with their doctor.

Until now, annual screening mammograms have been covered for women 50-64, and for women 40-49 at high risk for breast cancer. A screening mammogram for women 40-49 at normal risk, and women 65 and over, has been covered only every 2 years. One baseline mammogram also has been covered for women 35-39. Beneficiaries have had to pay both 20 percent coinsurance and any unmet portion of their Part B deductible.

Pap Smears: As of January 1, 1998, Medicare coverage is being expanded to pay for a screening pap smear and pelvic exam (including a clinical breast exam) every 3 years for most women. They are covered every year for women at high risk for cervical or vaginal cancer, and those of childbearing age who have had an abnormal pap smear during the preceding 3 years. Medicare will pay 100 percent of the lab tests. Beneficiaries must pay the usual 20 percent copay for the doctor's service, and Medicare will pay the other 80 percent. Beneficiaries will not have to pay the annual deductible for this service.

Until now, only screening pap smears have been covered, every three years (or more often for women at high risk), not the accompanying pelvic exam or clinical breast examination. Beneficiaries do not pay coinsurance or the Part B deductible for any clinical laboratory tests, including pap smears.

Total - Female 40+
54,600
45,850
65,749,997,000
75-84 698,000
85+ 2864

clinical
breast exam

screening 3 yr - clinical breast exam

now
→ pelvic exam

~~more~~

50-64 - annual
40-49 - high risk - 2 yr
65-over - 2 yr
→ annually
→ Medicare 100%

DRAFT

Glucose Monitoring: As of July 1, 1998, all Medicare beneficiaries with diabetes, whether or not they use insulin, will have coverage for blood glucose monitors and testing strips. By monitoring their blood glucose levels patients will have the information to better control their diabetes. This has the potential to reduce the risk of complications associated with diabetes, such as blindness and the need for amputation.

Until now, Medicare has only covered blood glucose monitors and testing strips for beneficiaries with diabetes who must use insulin.

Diabetes Education: As of July 1, 1998, Medicare will cover a wider range of education and training programs to help teach beneficiaries with diabetes how to control their blood glucose levels. These training programs do not have to be based in hospitals. A physician must certify that a patient needs the service under a comprehensive plan of care.

Until now, Medicare has only covered education and training furnished by hospital-based programs or incidental to the service of a physician.

Colorectal Cancer: As of January 1, 1998, Medicare will cover colorectal cancer screening including fecal-occult blood tests, flexible sigmoidoscopy, colonoscopy (for people at high risk for colorectal cancer), and in certain cases, barium enemas. Each of these tests are covered under different circumstances, so patients should check with their physician to determine which tests are best for them and how often they should be scheduled.

Until now, these tests have been covered only when a patient had symptoms that could indicate cancer or another disease and the physician was using them for diagnostic, rather than screening, purposes.

Bone Mass Measurement: As of July 1, 1998, Medicare will cover bone density measurement for beneficiaries at risk for osteoporosis and other bone abnormalities. Beneficiaries should consult with their doctors about whether and when they might need one of these tests.

Until now, coverage of bone mass measurement tests has varied, to some extent, across the country. The new law aims to standardize coverage of these tests.

Flu and Pneumococcal Vaccination Program: Medicare's existing flu and pneumococcal vaccine outreach program will continue through the year 2002. This program is a joint effort by Medicare, the Centers for Disease Control and the National Coalition for Adult Immunization.

Medicare has covered flu shots since 1993. Thanks to the outreach program, Medicare has already met, and is now working to exceed, the Department of Health and Human Services' goal of having 60 percent of all senior citizens immunized by the year 2000.

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show expanding outreach campaigns