

United States Senate
WASHINGTON, DC 20510-2003

July 26, 2006

Dear Colleague:

Please join me in sending the attached letter to CMS Administrator McClellan. It calls to his attention, and raises questions about, a recently proposed rule, which would make substantial cuts in Medicare reimbursement for technologies used to screen for osteoporosis and breast cancer.

The proposed rule would cut central DXA, the gold standard for osteoporosis screening, by 75% over four years. Computer Aided Detection as an adjunct to mammography, which has led to substantial increases in the cancer detection rate, is slated for a 54% cut. Finally, stereotactic guided breast biopsy, a minimally invasive alternative to surgical biopsy, would be cut by 80%.

Attached, please also find a fact sheet that further describes these procedures and their importance.

These cuts to basic preventive services are directly at odds with public health messages encouraging women to get screened, as well as Dr. McClellan's commitment to disease prevention, and the "Welcome to Medicare" physical exam, which he instituted. Please join me in asking that Dr. McClellan review these proposed cuts to Medicare reimbursement, and resolve their inconsistency with his agency's preventive health perspective by withdrawing them.

Please call Ellen-Marie Whelan or Devin Lynch in my office (4-4654) if you have any questions or want to sign onto the letter by August 2, 2006.

Sincerely,



Barbara A. Mikulski
United States Senator

Fact Sheet

Osteoporosis

More than 10 million Americans, mostly women, have been diagnosed with osteoporosis, and another 45 million are at risk. The human cost is incalculable. Within one year of suffering a hip fracture, 20% of seniors die, and another 20% enter a nursing home. Annual expenditures related to hip fractures alone exceed \$18 billion.

Fortunately, within the last 10–15 years, we have seen the advent of screening technologies that can detect and monitor this “silent” disease, and more recently, the availability of drugs that can stop or even reverse the effects of bone loss. As a result, the U.S. Preventive Services Task Force recommended in 2002 that women aged 65 and older be screened routinely for osteoporosis. Two years later, the Surgeon General warned that, unless immediate action was taken, half of all Americans older than 50 would be at risk for fractures from osteoporosis and low bone mass by 2020.

The “gold standard” for bone mineral density testing is central DXA (axial dual-energy x-ray absorptiometry), the only method recognized by the International Society for Clinical Densitometry and the International Osteoporosis Foundation for the diagnosis of osteoporosis. At least 75% of all bone densitometry screening exams are performed using central DXA.

Despite the fact that screening rates for the Medicare population remain below 25%, CMS proposes to cut reimbursement for central DXA by 75%.

Breast Cancer

For the year 2004, except for non-melanoma skin cancers, breast cancer was the most common cancer among women, and the second leading cause of death after lung cancer. Mammography is the best screening procedure currently available for the detection of breast cancer, though far from perfect. Due to large caseloads, fatigue, the complex structure of the breast and the subtlety of early disease, radiologists fail to detect some 20% of breast cancers that are visible on the mammogram.

To address the problem of missed cancers, academic and industry research groups worked to develop sophisticated computer algorithms to identify features on mammograms that are suspicious for breast cancer. The result was **CAD (Computer Aided Detection)**, which has led to dramatic increases in the number of cancers detected, and detected at

an earlier stage of the disease. Women enjoy improved likelihood of survival and less aggressive treatment options.

CAD has been endorsed by the Blue Cross/Blue Shield TEC, the American Cancer Society and the American College of Radiology. It is now the standard of care at state-of-the-art facilities like Washington Radiology; Susan Komen Breast Cancer Center in Dallas; the Elizabeth Wende Breast Center in Rochester, NY; Stanford University; Brigham and Women's at Harvard; and the Mayo Clinic.

Despite the benefits CAD offers women in screening and diagnosis, the proposed rule would cut Medicare reimbursement for CAD by 54%.

Finally, the proposed rule cuts reimbursement for ***stereotactic guided breast biopsy***, a minimally invasive alternative to open surgical biopsies. Minimally invasive biopsies are performed as outpatient procedures, requiring only a local anesthesia, and can be completed in 30 to 40 minutes. Over the last 12-15 years, they have displaced more conventional surgery as the preferred approach.

Minimally invasive biopsies generally require some form of image guidance, either ultrasound, or stereotactic (x-ray based). Stereotactic is the predominant guidance technology used with vacuum assisted breast biopsy devices, due to device maneuverability and patient positioning requirements. In addition, stereotactic imaging, unlike ultrasound, makes it possible to see micro-calcifications -- sub-centimeter tissue abnormalities -- critical in determining the early presence of breast cancer.

The proposed rule would cut stereotactic guided biopsy by 80%.