

EXECUTIVE SUMMARY

After reviewing the staff analysis of Senate Bill 1057, the Mandated Benefits Review Committee of the Pennsylvania Health Care Cost Containment Council can not support this bill at this time. We were unable to find *needed proof* in the review of Senate Bill 1057 that coverage of bone density testing would provide corresponding *savings*, either in terms of saved health care dollars or improved quality of life. We conclude that, in as much as neither proponents nor opponents have submitted sufficient documentation pursuant to Act 34 of 1993, the Council did not receive the necessary and required information on the social and financial impact or the medical efficacy to warrant recommending approval of the mandated health benefits proposed under Senate Bill 1057.

The Committee also concludes that there is a **serious and significant need for public education regarding osteoporosis prevention**. Medical professionals and experts agree that the most effective way to deal with osteoporosis is to prevent it, and education is an essential component in prevention. While the benefits of osteoporosis prevention and early detection on improved quality of life and future health care savings are indisputable, we found there to be no consensus in medical literature that broad-based osteoporosis screening via bone density testing would necessarily achieve these results. Had there been such definitive information or a consensus on the benefits of broad-based bone mineral density screening, the Committee may have concluded differently regarding recommending passage of the bill.

While not required as part of mandated benefits reviews, Council staff undertook significant efforts in conducting independent research to better understand osteoporosis in general, including an examination of the Council's own hospitalization and average charge data, and the projected costs of Senate Bill 1057. Using numerous internet and library resources and by contacting state and federal personnel, staff applied some broad, and perhaps gross, assumptions to estimate that the implementation of Senate Bill 1057 could cost between \$199 million and \$275 million yearly. If only 50% of the eligible population would utilize the benefits mandated under the bill and undergo bone density testing in any year, the costs for the mandate could reach as high as from \$99 million to \$137 million per year. While staff were able to provide these broad cost estimates, no information was received or found that allowed us to estimate the potential cost savings of the measure.

In addition to the conclusion that there is a need for improvement in public education and awareness of osteoporosis prevention; the Mandated Benefits Review Committee finds the following upon reviewing the staff analysis of Senate Bill 1057:

- The Council recognizes the importance of preventing osteoporosis and is sympathetic to the burden this disease places on affected Pennsylvanians and their family members. Clearly, osteoporosis and related fractures are extremely costly to the Commonwealth in terms of direct health care expenditures, lost productivity, and diminished quality of life for Pennsylvanians—and the disease will only become more prevalent among our increasingly elderly population if current trends are not addressed.
- We conclude, however, that neither supporters nor opponents of the bill provided sufficient information to warrant a full review of the proposal; nor, given the documentation received, do we believe a panel of experts would come to conclusions different than the ones reached here.
- Council staff research has found there to be no universal level of bone mineral density at which osteoporosis is defined;

- There does not appear to be sufficient proof that coverage of bone density testing actually improves preventive efforts or reduces the incidence of osteoporotic fractures;
- We assert that using perimenopausal status as a definition for the clinical indication of bone density testing would result in very broad-based screening using methods for which there does not appear to be solid research to support efficacy. (Even the National Osteoporosis Foundation does not recommend universal screening.); and
- The potential cost of the proposal could reach as high as \$275 million annually, and while it is likely that an increase in prevention and early detection of osteoporosis could result in saved health care dollars from fractures, no information was provided that could be used to determine the degree to which the long-term *savings* from prevention would outweigh the cost of the benefit.

Numerous studies have shown legislative mandates to be a significant contributing factor to rising health care costs. Insurance Commissioner Koken stated in testimony before the House Insurance Committee that, "While the Department believes that the services provided under mandated benefits may be important, we are concerned that this trend toward increasing mandated benefits has a negative impact on the consumers and purchasers of health insurance." The Mandated Benefits Review Committee has similar concerns. As a Council, we are charged with the responsibility to "promote the public interest by encouraging the development of competitive health care services in which *health care costs are contained* and to assure that all citizens have reasonable access to quality health care" (Act 34 of 1993).

In considering mandated benefits, the Committee contends that extreme caution must be used and recommendation reserved only for measures which are of proven efficacy and cost-effectiveness. Clearly, some mandates, such as child immunization, meet these standards. For some proposed mandates, however, the balance is not so clear. We were unable to find *needed proof* in the review of Senate Bill 1057 that coverage of bone density testing would provide corresponding savings, either in terms of saved health care dollars or improved quality of life. It appears that there is no research that draws a clear correlation between bone mineral density testing and reduced fracture incidence, or even improved compliance with recommended preventive behaviors, such as hormone replacement therapy or exercise. Without this needed proof, we cannot derive the clear "benefit" portion of a cost/benefit analysis of Senate Bill 1057.

Attachment to Executive Summary

Brief Synopsis of Requirements under Act 34, Section 9

Act 34, Section 9, requires that “persons proposing or opposing legislation mandating benefits coverage should submit documentation to the council ... which demonstrates the following” eight specific issues. A summary of the staff conclusions on each of these points follows.

(i) *The extent to which the proposed benefit and the services it would provide are needed by, available to and utilized by the population of the Commonwealth.*

We found that many Pennsylvanians have access to bone density testing through Medicare coverage under certain medical restrictions, and that it appears that insurers often cover the service when deemed medically appropriate. Council staff conclude that there is no consensus in the medical community on the efficacy of broad-based bone mineral density testing, as would be mandated under Senate Bill 1057, or when such testing is warranted for certain clinical indications. Therefore, the need for the benefit is not clear.

(ii) *The extent to which insurance coverage for the proposed benefit already exists, or if no such coverage exists, the extent to which this lack of coverage results in inadequate health care or financial hardship for the population of the Commonwealth.*

Again, Council staff found that many Pennsylvanians have access to bone density testing through Medicare coverage under certain medical restrictions, and that it appears that insurers often cover the service when deemed medically appropriate.

With regard to this category, we suggest that other solutions, rather than mandating benefits, might be appropriate. For example, in the submission from Mercy Hospital of Pittsburgh, it is claimed that, “Insurance companies often will not clearly state if they will cover a bone mass measurement until a claim is submitted, thus only retrospective data provide the answer for a given carrier. This has led physicians to screen only after fracture when morbidity has already occurred.” Perhaps clearer communication guidelines are in order rather than mandates.

Overall, we found that neither supporters nor opponents of the bill submitted sufficient, *specific* information regarding Issue ii. For example, reference to an informal survey discussed by the National Osteoporosis Foundation lacked *specific* information to help staff determine the extent to which lack of coverage results in inadequate health care or financial hardship. Similarly, while opponents provided some general information, it was not sufficiently specific to understand the true “picture” of this issue for the “population of the Commonwealth.”

(iii) *The demand for the proposed benefit from the public and the source and extent of opposition to mandating the benefit.*

Although it is clear from where the demand for the benefit arises, we did not receive sufficient information on which to conclude the *extent of that demand*. Likewise, opposition to the benefit was found to be from some payers of health care, although the Council did not receive sufficient information to come to conclusions regarding *the extent of that opposition*.

One particularly interesting point was made by the Managed Care Association in suggesting that osteoporosis is a “condition for which treatment modes continue to evolve.” Through independent research, Council staff note that bone density *measurement* techniques continue to evolve as well and cite the recent approval of a test that estimates bone density using ultrasound (Neergaard).

(iv) *All relevant findings bearing on the social impact of the lack of the proposed benefit.*

While Council staff recognize the social implications of osteoporosis and are sympathetic to the plight of those with this disease, perhaps solutions other than mandates would be more appropriate. Most medical professionals cite a need for more education regarding osteoporosis prevention and treatment.

The social impact of osteoporosis is clear, however, we contend that we did not receive information regarding “*the social impact of the lack of the proposed benefit*,” as required under Act 34. Council staff assert that the social impact of the lack of the benefit can not be proven because the proposed benefit is of unproven efficacy and, therefore, uncertain value.

(v) *Where the proposed benefit would mandate coverage of a particular therapy, the results of at least one professionally accepted, controlled trial comparing the medical consequences of the proposed therapy, alternative therapies and no therapy.*

Given the contradictory findings suggested in the documentation received, Council staff believe that further research focusing on controlled trials with regard to bone mass measurement might shed more conclusive light on this issue. Without more consistent, conclusive findings, Council staff suggest that the information submitted is not sufficient, nor specific enough, for full review of this category.

(vi) *Where the proposed benefit would mandate coverage of an additional class of practitioners, the result of at least one professionally accepted, controlled trial comparing the medical results achieved by the additional class of practitioners and those practitioners already covered by benefits.*

This requirement is not relevant to the discussion of the mandates proposed under Senate Bill 1057.

(vii) *The results of any other relevant research.*

While it is clear that prevention efforts could significantly reduce the incidence of osteoporosis and related fractures, it is unclear as to whether bone density testing actually achieves this end.

From reviewing the relevant research, we suggest that (1) there does not seem to be sufficient proof that bone density testing actually improves preventive efforts or reduces the incidence of osteoporotic fractures, (2) there appears to be no universal definition of what constitutes osteoporosis in terms of bone density measurement, (3) there is no consensus within the medical community on who should undergo bone density testing and when, and (4) research does not seem to support the broad-based screening proposed under Senate Bill 1057.

We note, in particular, submissions which contend that the U.S. Preventive Services Task Force, the American College of Physicians, and the Canadian Task Force on the Periodic Health Examination do not recommend universal screening. In fact, the model legislation submitted by the National Osteoporosis Foundation does not advocate broad-based screening. A copy of the NOF model Act is attached at page 54.

Given the documentation received, we assert that perhaps increased educational efforts might be more appropriate than mandates in preventing osteoporosis.

(viii) *Evidence of the financial impact of the proposed legislation, including at least:*

(A) *The extent to which the proposed benefit would increase or decrease cost for treatment or service.*

While the overall figures presented are informative, submissions, in general, lacked specific data with regard to this issue. It was difficult to determine from this information “*the extent to which the proposed benefit would increase or decrease cost for treatment or service.*”

(B) *The extent to which similar mandated benefits in other states have affected charges, costs and payments for services.*

While the submitted information pertaining to similar mandated benefits in other states is informative from a policy perspective, it is not sufficient to understand the extent to which *charges, costs, and payment* for services have been affected by such mandates.

(C) *The extent to which the proposed benefit would increase the appropriate use of the treatment or service.*

We conclude that submitting entities did not provide sufficient evidence regarding “*The extent to which the proposed benefit would increase the appropriate use of the treatment or service*” mostly due to the subjective nature of the “appropriateness” debate surrounding bone density testing.

Further, the submission by Mercy Hospital suggests that knowing bone density results would produce appropriate lifestyle changes, but Council staff was unable to find documentation, and no supporters of the bill submitted documentation, that bone density testing actually results in these outcomes. Once again, however, it is clear that both

proponents and opponents agree that education and lifestyle changes are important components in preventing osteoporosis.

Council staff note, too, the assertion of the Insurance Federation that a huge demand for these tests might increase, rather than decrease, their price. Health care economics have shown this to often be the case and raise the question of whether this mandate would lead to many women having the test who would have chosen to undergo hormone replacement therapy and appropriate lifestyle habits *regardless* of test results.

(D) *The impact of the proposed benefit on administrative expenses of health care insurers.*

We were provided with little information regarding the impact of the proposed benefit on administrative expenses of health care insurers, and the information that was received was not specific. Both proponents and opponents appear to agree, however, that administrative expenses as a result of Senate Bill 1057 would be "minimal."

(E) *The impact of the proposed benefits on benefits costs of purchasers.*

While the Highmark submission provided informative figures regarding the proposed benefits costs, submissions, in general, lacked specific information with regard to how *purchasers* would be affected.

(F) *The impact of the proposed benefits on the total cost of health care within the Commonwealth.*

While *general* information regarding total cost was provided, the Committee concludes that neither supporters nor opponents of the bill provided sufficient, concrete information to the Council on which to base a cost estimate of the impact of the measure. In fact, much of the information received focused on mandates, in general, and was not specific to Senate Bill 1057. Further, no evidence of any potential cost *savings* was received.

Council Staff Analysis

Background

The Pennsylvania Health Care Cost Containment Council's current enabling legislation, Act 34 of 1993 (Section 9), provides that the Council review existing or proposed mandated health benefits when requested by the executive and legislative branches of government.

On September 2, 1997, Senator Edwin G. Holl, Chairman of the Senate Banking and Insurance Committee, requested that the Council review the provisions of Senate Bill 1057 (PN 1243 – Senator Costa), which would mandate insurance coverage for osteoporosis prevention and early detection. A copy of the bill is attached (Appendix D).

In accordance with Act 34, notification was published in the *Pennsylvania Bulletin* on September 20, 1997 requesting that interested parties submit documentation and information pertaining to the bill to the Council by November 19, 1997. Letters also were sent to 21 potentially interested individuals and organizations informing them of the pending review and inviting them to submit documentation pursuant to the notice. Following the 60-day comment period, a 30-day opportunity was provided for interested individuals and organizations to examine the responses received. The Pennsylvania Department of Health and the Insurance Department were notified and received a list of submissions. As provided under the Act, respondents were then given an opportunity (30 days) to submit a second round of documentation after examining responses received. No respondents submitted documentation a second time.

Attached (Appendix B) is a list with brief descriptions of the information received and by whom it was submitted.

Act 34 also provides for preliminary Council staff review of submitted materials to determine if documentation submitted is sufficient to proceed with the formal Mandated Benefits Review process outlined in the Act. This report presents the results of the Council's preliminary staff review and the conclusions of the Council's Mandated Benefits Review Committee regarding whether the material is sufficient to proceed with the formal review process and the recommendation of Senate Bill 1057.

Senate Bill 1057

Senate Bill 1057 (PN 1243, Senator Costa)—the proposed Osteoporosis Early Detection Act—would require insurers to provide coverage for bone mass measurement as a means of detection and treatment of osteoporosis for qualified individuals. An individual would qualify for benefits if they have a medical condition for which bone measurement testing is determined to be medically necessary by their attending physician, primary care physician, obstetrician, or gynecologist. The bill also specifies the following clinical indications for bone density testing: perimenopausal, postmenopausal, or estrogen-deficient status in women; long-term (> 3 months) corticosteroid therapy; fracture in absence of appropriate severe trauma; loss of height of 1.5 inches or more; hyperthyroidism; hyperparathyroidism; Cushing's syndrome; hypogonadism; prolactinoma; vertebral abnormalities on x-ray (such as compression fractures

or radiographic evidence of osteopenia); and diagnosed osteoporosis or osteopenia for evaluation of ongoing treatment.

Insurers would also be required to cover treatment for any individual whose bone mass measurement results in a diagnosis of osteoporosis.

As a state law, the measure would be preempted by the federal Employee Retirement Income Security Act of 1974 (ERISA) (PL 93-406), which precludes state laws from applying to the benefit plans of self-insured companies. It is hard to estimate the percentage of private payers that are preempted by ERISA, but estimates have ranged as high as 50% to 70% of all insureds.

Other Legislation—Federal and Other States

Council staff independently examined related legislation, both at the federal level and from other states.

Federal Legislation. Amendments to federal law regarding Medicare Coverage of Bone Mass Measurements were effective July 1, 1998 (42 USC 1395 §1861). The federal law defines “bone mass measurement” as “a radiologic or radioisotopic procedure or other procedure approved by the” FDA “performed on a qualified individual ... for the purpose of identifying bone mass or detecting bone loss or determining bone quality, and includes a physician’s interpretation of the results of the procedure” in the federal Act. (SB 1057 defines “bone mass measurement” specifically as “ procedure using dual energy x-ray absorptiometry, or other scientifically proven technology, which is accepted as the industry standard in the medical field, performed on an individual for the purpose of identifying bone mass or detecting bone loss.” SB 1057 does not specify coverage of interpretation of the test by physician or medical professional.)

A “qualified individual” under the federal Act includes “an estrogen-deficient woman at clinical risk for osteoporosis; an individual with vertebral abnormalities, an individual receiving long-term glucocorticoid steroid therapy; an individual with primary hyperparathyroidism, or an individual being monitored to assess the response to or efficacy of an approved osteoporosis drug therapy.”

Other States. According to information submitted by the National Osteoporosis Foundation, the following states passed legislation promoting or establishing osteoporosis education: Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Massachusetts, Mississippi, Missouri, New Hampshire, New Jersey, Ohio, Oklahoma (“encourages the health department to set up program), Rhode Island, South Carolina, Tennessee, Texas, West Virginia; and the following states have legislation regarding bone mass measurement: California, Florida, Maryland, Oklahoma, Tennessee, Texas.

Overview of Osteoporosis

In an effort to better understand this disease, Council staff conducted independent research, reviewed information included in the submissions received, and examined the Council’s own data. This section first discusses the prevalence, prevention, treatments, and risk factors associated with osteoporosis. Next, inpatient data from the Council’s 1995 database is displayed.

Throughout the life of a normal human, bone is in a constant state of change referred to as “remodeling”; bone is continuously broken down and resorbed into the blood stream and new bone formed. Peak bone mass is reached at age 20 to 30 (Dix Smith). Until about 35 years of age, the normal human body builds and stores bone efficiently. Then, as part of the normal aging process, bone begins to break down faster than new bone can be formed. Bone loss accelerates in women after menopause due to the cessation of estrogen production in the ovaries.

Osteoporosis occurs when the body fails to form enough new bone or when too much of the old bone is resorbed by the body, or both. It is a disease characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased susceptibility to fractures, particularly of the hip, spine, and wrist.

Hormone deficiency (estrogen in women, and androgen in men) is the leading cause of osteoporosis. Women over 60 are the most frequent sufferers due to the loss of ovarian function and hormone production that occurs around the time of menopause. Although there is no cure for osteoporosis, there are treatments available to help stop further bone loss and fractures. Osteoporosis can be effectively treated if it is detected before significant bone loss has occurred.

Osteoporosis is called a “silent disease” because bone loss often occurs without symptoms, causing people to be unaware that they have osteoporosis until their bones are weakened to the point that a sudden strain, bump, or fall causes a fracture or a vertebra to collapse. By the time an osteoporotic fracture occurs, the disease is in its advanced stages and damage is often profound.

For individuals with osteoporosis, “crush fractures” may occur during daily activities such as lifting, bending, getting up from a chair, coughing, or even aggressive hugging. Oftentimes, these crush fractures occur in the vertebrae and go undiagnosed but can cause pain and tenderness in the back and lead to a loss of height and spinal deformities such as stooped posture. Forty percent of all women will have at least one spinal fracture by the time they reach 80 years of age.

Hip fracture is the most serious and costly potential result of osteoporosis. Many hip fracture patients experience severe functional impairment following their fracture, and most never recover their pre-fracture level of functioning. Researchers have found that hip fracture is more likely to lead to functional impairment than other serious medical conditions, including heart attack, stroke, and cancer. Mortality rates are about 20 percent higher for individuals within one year of a hip fracture than individuals of the same age with no hip fracture.

Prevalence/Incidence

Osteoporosis is a major public health threat for 28 million Americans, 80 percent of whom are women. In the United States today, 10 million individuals have osteoporosis and 18 million more have low bone mass, placing them at high risk of developing the disease. The following statistics were provided by the National Osteoporosis Foundation (NOF):

- * One out of every two women and one in eight men will have an osteoporosis-related fracture in their lifetime.
- * By age 75, one third of all men will be affected by osteoporosis.
- * While osteoporosis is often thought of as an older person’s disease, it can strike at any age.

- * Osteoporosis is responsible for 1.5 million fractures annually, including: 300,000 hip fractures, 700,000 vertebral (spinal) fractures, 200,000 wrist fractures and more than 300,000 fractures at other sites.
- * The estimated national direct expenditures (to hospitals and nursing homes) for osteoporosis and associated fractures is \$14 billion a year, or \$38 million each day.

The occurrence of osteoporosis in both men and women is an important public health issue, and increasingly so as the “Baby Boom” population ages. The U.S. Census Bureau estimates there will be more than 1.5 billion individuals worldwide age 65 or over by the year 2050. The National Osteoporosis Foundation estimates that within 20 years, more than 41 million Americans will be affected by osteoporosis if current trends are not reversed.

The prevalence of osteoporosis is of real concern in Pennsylvania as the Commonwealth’s population becomes increasingly elderly. The Pennsylvania State Data Center estimates that Pennsylvania’s population age 65 and older increased by 4.1% from 1990 to 1994 -- with the largest increase occurring among those age 85 and older (26.3%) -- compared to 1.5% growth rate for the state population as a whole. According to the NOF, California, New York, Texas, and Pennsylvania top the list with the greatest number of women with osteoporosis. There were nearly 418,000 Pennsylvania women with osteoporosis in 1996.

While men generally have larger, stronger bones than women, and women can lose up to 20% of their bone mass in the five to seven years following menopause, making them more susceptible to osteoporosis, some two million American men also have osteoporosis today, and another three million are at risk for the disease (NOF).

According to the National Osteoporosis Foundation (NOF), each year, “men suffer 1/3 of all the hip fractures that occur, and 1/3 of these men will not survive more than a year following the fracture. In addition to hip fracture, men also experience painful and debilitating fractures of the spine, wrist, and other bones due to osteoporosis. Yet, despite the large number of men affected, osteoporosis in men remains underdiagnosed, underreported, and inadequately researched” (NOF Web Site).

According to the NOF, none of the medications that have been approved by the Food and Drug Administration for the treatment of osteoporosis in postmenopausal women have been approved for men. Treatments for osteoporosis are discussed later.

Prevention

Experts agree that there are several basic lifestyle factors that can prevent osteoporosis, including: ensuring adequate calcium intake with supplements when dietary intake is insufficient, increased physical activity, and cessation of smoking. Medical professionals agree that education in osteoporosis is an essential component of prevention. Particularly, women need to be educated about the benefits of calcium and vitamin D consumption, weight-bearing exercise, and the detriments of smoking and excessive alcohol consumption in the 20s and 30s—the prime bone mass forming years.

Public knowledge about osteoporosis is clearly lacking. According to the NOF, many adults get only half or less of their daily calcium requirement. The National Institutes of Health recommend that pre-menopausal adult women consume 1,000 mg of calcium each day and postmenopausal women 1,500 mg—an eight-ounce glass of whole or skim milk contains about 300 mg of calcium (NOF web site). Also, normal levels of vitamin D are necessary for the absorption of calcium.

Exercise also can be helpful in building and maintaining strong bones. Weight-bearing exercise is important in building and strengthening bones—this includes exercises that force you to work against weights or against gravity, such as walking or jogging.

Since estrogen helps protect against bone loss, physicians often prescribe estrogen replacement therapy (ERT) to women at menopause as a means of prevention, or as a treatment for osteoporosis.

According to the National Osteoporosis Foundation, there are three medications currently available to help stop further bone loss, increase bone density, and reduce the risk of fracture: estrogen is approved for both the prevention and treatment of osteoporosis; Alendronate, a bisphosphonate, is approved for prevention and treatment; and calcitonin is approved for treatment. Treatments under investigation include other bisphosphonates, sodium fluoride, vitamin D metabolites, and selective estrogen receptor modulators.

Estrogen

Women are at increased risk of osteoporosis after menopause, when the ovaries cease to produce estrogen. “Menopause normally takes place between the ages of 35 and 58. If it occurs before the age of 35 it is *premature menopause*; after 58 it is called *delayed menopause*.” About 25 percent of American women reach menopause by 47, half by the age of 50, and 75 percent by 52, and 95 percent by age 55 (Miller 688).

Studies have shown that taking estrogen replacement therapy (ERT) increases bone density and can reduce the risk of hip fracture by up to 50 percent if started at menopause (JAMA). In addition to preventing osteoporosis, many postmenopausal women take estrogen replacement therapy for its effects on alleviating some of the symptoms of menopause such as hot flashes and vaginal dryness, although estrogen combined with progesterone may cause the generally undesirable resumption of menstrual bleeding in some postmenopausal women. Research has also shown that long-term use of estrogen, for at least 10 years, reduces the risk of heart attack by 50% (Katalinic).

However, estrogen replacement therapy is not without risk. Some research has shown a link between estrogen replacement and increased risk of certain types of cancer, particularly cervical cancer and breast cancer. As a result, the current medical consensus is that ERT is not usually given to women who have breast cancer, or have a high risk of developing it. However, a growing number of physicians are prescribing ERT to women in these circumstances if they are experiencing severe post-menopausal symptoms, or are at high risk for developing heart disease or osteoporosis (University of Wisconsin).

Some research has indicated that the combination of the hormone progesterone with estrogen helps protect the uterus, and reduces some risk of cancer. Estrogen and progesterone therapy, combined, is referred to as Hormone Replacement Therapy (HRT). According to an article in the Harvard Women’s Health Watch, women who take unopposed estrogen replacement therapy, i.e. without progesterone, are at an increased risk for endometrial cancer. Progesterone causes the endometrial cells to slough off monthly and reduces the likelihood of the build-up of endometrium—and results in monthly bleeding for many women. Researchers estimate that up to 20 percent of menopausal American women use HRT because they believe the benefits outweigh the risks (Planned Parenthood). No one knows how many stay on the regimen.

Many women choose not to undergo HRT for many reasons, including cost, inconvenience, and health factors. Even among those women who do choose HRT, compliance rates are not very high. According to the Mayo Clinic Health Letter, synthetic estrogen

supplements vary in cost from \$20 to \$35 per month—or from \$240 to \$420 per year. Natural hormones cost a bit more—as much as \$45 per month for progesterone and \$24 per month for estrogen.

Research submitted by the Managed Care Association of Pennsylvania (MCAP) states, “Although the overall benefit of estrogen outweighs the risk for most women, long-term compliance with estrogen is poor. Studies have shown that most women take the medication only sporadically, and that many women prescribed estrogen will never fill their prescription. In one study of more than 2,000 new users, 59% had ceased filling their prescription at 2 years” (JCOM). This is particularly disconcerting because scientists know that the bone-saving benefits of estrogen replacement therapy last only as long as the therapy.

Reportedly, fear of cancer, especially breast cancer, is the main reason women give for stopping estrogen therapy. The Nurses’ Health Study found that the relative risk of breast cancer for women using HRT is small (JCOM). Many medical professionals agree that physicians need to better educate their patients and assure them that the possibility of increased risk for breast cancer is small. Many patients also are unaware that the risk of uterine cancer is removed when combination therapy (estrogen plus progesterone) is used. Again, it appears that better patient education is needed.

Other Treatments

In addition to estrogen therapies, other osteoporosis treatments have been approved by the Food and Drug Administration, including different forms of calcitonin and certain bisphosphonates.

Calcitonin is a hormone made by the thyroid gland that helps regulate calcium levels, primarily by inhibiting resorption of bone. Research has shown salmon calcitonin to be significantly more potent than human calcitonin, with a longer duration of action. It is therefore the preferred form of calcitonin for osteoporosis therapy. Injectable salmon calcitonin has been available for many years, but its use has been limited by the inconvenience of daily injections, frequent nausea and flushing post injections, occasional allergic reactions, antibody induced resistance, and high cost. Nasal spray calcitonin (Miacalcin Nasal) was recently approved in the United States and is generally indicated for the treatment of osteoporosis in females who are more than five years post-menopausal with low bone mass. Both forms of calcitonin also may have significant analgesic effects, making it a good choice for the patient with painful vertebral fracture.

Bisphosphonates are a class of drugs used to treat osteoporosis that interfere with bone resorption. Bisphosphonates are said to have minimal side effects and cause no known cancer risk. Alendronate, recently approved by the FDA, is one of the newer bisphosphonates, which also inhibits bone resorption. Didronel, an older bisphosphonate, has been available for bone metabolism manipulation for a number of years.

The National Osteoporosis Foundation estimates that treatment costs for osteoporosis range from \$50 to \$730 per year.

Many medical professionals agree that a single and rapid risk assessment of genetic, nutritional and lifestyle factors can be done to determine if it might be justified to tell a patient that her risk of osteoporosis may be higher than average and that she should consider a program of hormone replacement therapy (HRT), calcium and vitamin D supplementation and exercise. However, many also believe that individuals who have minimal risk factors could also be offered such a regimen on the basis that it is likely to diminish bone loss and prevent fractures in everyone.

Risk Factors

Researchers have identified the following primary risk factors for osteoporosis: being female, thin or small frame, advanced age, family history, abnormal cessation of menstruation, early menopause, low calcium intake, use of certain medications such as corticosteroids and anticonvulsants, low testosterone levels in men, an inactive lifestyle, cigarette smoking, and excessive use of alcohol.

However, experts agree that risk factors are not perfect predictors of osteoporosis. You may have several risk factors and still have strong bones, or have no risk factors and still develop osteoporosis. The National Osteoporosis Foundation contends that “a bone mass measurement is the only way to tell if you have osteoporosis” (NOF web site).

Bone Mass Measurement

Research regarding the efficacy and appropriate use of bone mass measurement is conflicting, as are the opinions on the subject of medical professionals and researchers alike. Proponents contend that Bone Mineral Density (BMD) is the single most valuable predictor of osteoporotic fractures.

Bone density tests measure bone density in the spine, hip, and/or wrist, the most common sites of osteoporotic fracture. Bone density measurements are compared either to the “age matched” or “young normal” norms. The “age matched” norm is used for a comparison of bone density to others of the same age, sex and size. The “young normal” standard is used to compare bone density to the estimated bone density of a healthy young adult of the same sex (NOF web site).

Proponents contend that a bone density test can:

- * detect osteoporosis before a fracture occurs;
- * predict the chance of fracturing in the future; and
- * determine the rate of bone loss and/or monitor the effects of treatment if the test is conducted at intervals of a year or more.

There are three types of bone density testing that are most commonly used for non-invasive assessment of bone mass:

- dual photon absorptiometry (DPA),
- dual energy x-ray absorptiometry (DEXA), and
- quantitative computed tomography (QCT).

The accepted industry standard for bone density measurement is dual energy x-ray absorptiometry, or DEXA. It is now established that a single accurate measurement of bone mass at any site has equal predictive value for subsequent fractures of all types.

The definition of a threshold bone density value for osteoporosis does not appear to be agreed upon. The World Health Organization (W.H.O.), however, has defined osteoporosis in terms of BMD, “as the presence of a fragility (atraumatic or minimally traumatic) fracture or by a BMD that is >2.5 standard deviations below normal sex and race matched young adults. Over 90% of patients with fragility fractures have BMD that are >2.5 S.D. below normal.”

The Office of Technology Assessment (OTA) estimates the actual cost of BMD screening at \$100 per patient. The National Osteoporosis Foundation found from a survey conducted of osteoporosis clinics that the average charge for a bone density test measuring the

hip and spine was \$215, including interpretation of the test results. An article in the *Harvard Women's Health Watch* estimates that a DEXA scan costs about \$150 to \$200 (January 1996).

Although it is largely agreed in the medical community that estrogen, taken alone or with progesterone, is the treatment and prevention of choice for osteoporosis, still in question, however, is whether all women should begin hormone replacement therapy (HRT) at menopause or whether menopausal women should undergo bone density screening and be treated only if the risk of fracture is detected. Council staff believe this to be the underlying issue in considering the merits of Senate Bill 1057.

The following section provides an overview of osteoporosis in the Council's 1995 inpatient database. This information was extracted from an issues brief prepared for the Governor's Office by Council staff.

It is important to note the data notes below when reviewing the tables and figures that follow.

Pennsylvania Health Care Cost Containment Council Data

1995 Inpatient data from the Pennsylvania Health Care Cost Containment Council show that there were 17,827 hospitalizations for individuals having osteoporosis, with charges totaling more than \$213 million. The average charge was about \$12,000. Nearly half of these patients were 80 years of age or older, and another 33% were between 70 and 79 years of age. Nearly 90% of the osteoporosis hospitalizations were women.

Of the osteoporosis cases, 7,338 were admitted with fractures, with charges totaling more than \$90 million. There were 1,552 hip fractures, 4,308 spinal fractures, 334 arm/wrist fractures, 489 leg/foot fractures, and 655 other fractures. Among these hospitalizations, 318 cases (4%) had multiple fractures.

Data Notes:

- (1) These figures were generated from the Pennsylvania Health Care Cost Containment Council's inpatient data for calendar year 1995. All osteoporotic admissions were considered regardless of principal diagnosis and/or principal procedure. The data reflect care received in the following facility types: acute care, rehabilitation, and psychiatric.
- (2) The charges are *unadjusted mean* averages. These charges are associated with the *entire* hospitalization not just treatment associated with osteoporosis and/or fractures, and they are *hospital* charges only (they do not include physician fees, outpatient fees, etc.). Understanding this limitation is especially important for osteoporosis patients because these individuals often have additional health conditions that would increase the charge/length of stay for the total hospitalization. Further, while charges are a standard way of reporting data, they do not reflect the actual *cost* of the treatment nor do they reflect the *payment* that the hospital may have actually received.
- (3) Cases were identified using ICD.9.CM codes (International Classification of Diseases, Ninth Revision, Clinical Modification). Definitions follow:
 - Osteoporosis codes (no fractures): 733.00-733.09
 - Fracture codes examined in conjunction with osteoporosis codes:
 - Hip fracture codes: 733.14, 820.0 – 820.9
 - Spinal fracture codes: 733.13, 805.0 - 806.9
 - Leg/foot fracture codes: 733.15, 733.16, 821.0 – 829.1
 - Arm/wrist fracture codes: 733.11, 733.12, 810.0 – 819.1
 - Other fracture codes (including pelvic fractures): 733.10, 733.19, 807.0 – 809.1
- (4) These counts reflect *hospitalizations*, not persons. For example, patients admitted to a hospital on two separate occasions in 1995 were counted twice in these data. Also, patients who underwent acute care treatment in one hospital and were transferred for physical rehabilitation to a separate hospital were counted twice in these data.

Figure 1: Osteoporosis Hospitalizations Including Fracture Site Cases, Length of Stay, and Hospital Charges

Fracture Site:	Cases		Total Days	Ave Stay	Total Charges	Ave Charge
	Number	Percent				
Hip	1,552	8.7%	15,617	10.1	\$24,884,000	\$16,034
Spine	4,308	24.2%	37,097	8.6	\$48,957,500	\$11,367
Leg/Foot	489	2.7%	4,415	9.0	\$6,506,200	\$13,387
Arm/Wrist	334	1.9%	2,385	7.1	\$3,350,500	\$10,032
Other Site	655	3.7%	5,462	8.3	\$6,699,900	\$10,292
No Fractures	10,489	58.8%	81,799	7.8	\$122,843,300	\$11,719
All Cases	17,827	100.0%	146,775	8.2	\$213,241,500	\$11,972

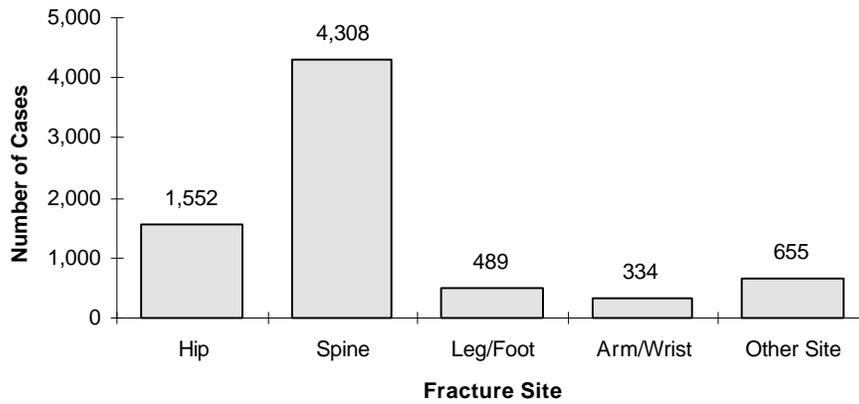
Figure 2: Osteoporosis Hospitalizations by Facility Type Cases, Length of Stay, and Hospital Charges

Facility Type:	Cases		Total Days	Ave Stay	Total Charges	Ave Charge
	Number	Percent				
General Acute Care	16,815	94.3%	128,101	7.6	\$195,162,200	\$11,608
Medical / Surgical Unit	16,126	90.4%	119,229	7.4	\$185,200,700	\$11,486
Rehabilitation Unit	689	3.9%	8,872	12.9	\$9,961,500	\$14,458
Rehabilitation Facility	944	5.3%	16,597	17.6	\$16,465,500	\$17,686
Other*	68	0.4%	2,077	30.5	\$1,613,800	\$23,070
All Facilities	17,827	100.0%	146,775	8.2	\$213,241,500	\$11,972

Source: PHC4, 1995 Inpatient Database

*Note: Other includes psychiatric, drug and alcohol, and state-owned psychiatric facilities.

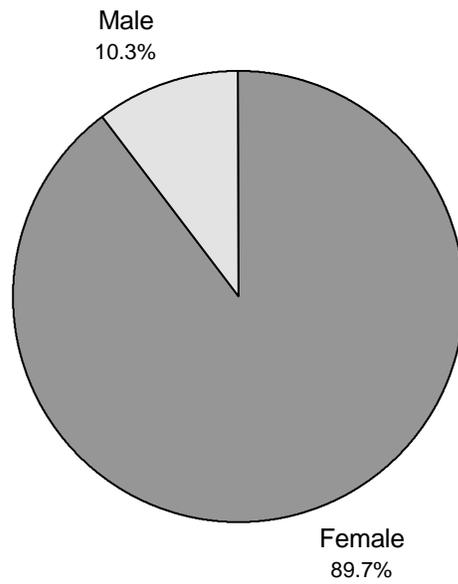
Figure 3: Osteoporotic Fractures by Site



<u>Fracture Site:</u>	<u>Cases</u>	
	<u>Number</u>	<u>Percent</u>
Hip	1,552	21.1%
Spine	4,308	58.7%
Leg/Foot	489	6.7%
Arm/Wrist	334	4.6%
Other	655	8.9%
All Fractures:	7,338	100.0%

Source: PHC4, 1995 Inpatient Database

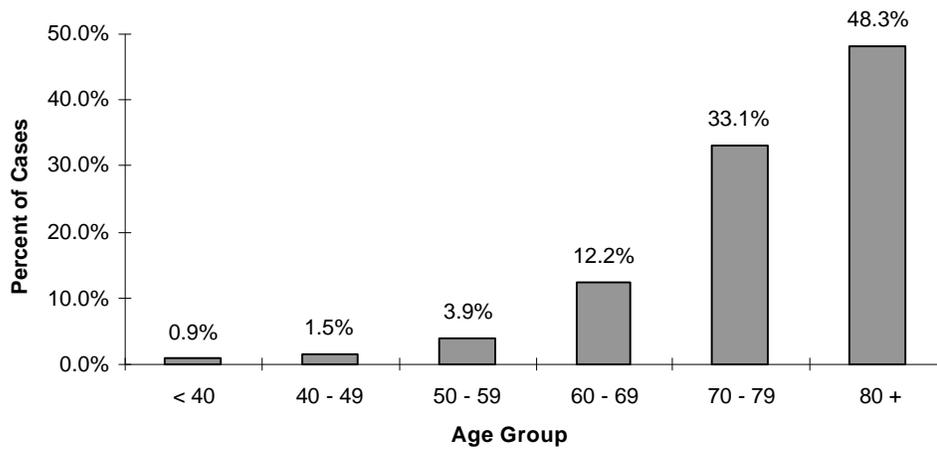
Figure 4: Osteoporosis Hospitalizations by Sex



<u>Patient Sex:</u>	<u>Cases</u>	
	<u>Number</u>	<u>Percent</u>
Female	15,983	89.7%
Male	1,844	10.3%
All Cases	17,827	100.0%

Source: PHC4, 1995 Inpatient Database

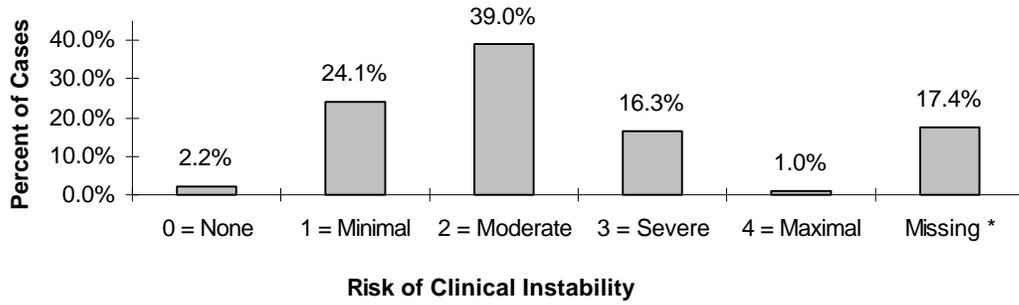
Figure 5: Osteoporosis Hospitalizations by Age Group



<u>Age Group:</u>	Cases	
	<u>Number</u>	<u>Percent</u>
Less than 40 years.....	154	0.9%
40 - 49 years.....	273	1.5%
50 - 59 years.....	699	3.9%
60 - 69 years.....	2,183	12.2%
70 - 79 years.....	5,903	33.1%
80 + years.....	8,615	48.3%
All Cases	17,827	100.0%

Source: PHC4, 1995 Inpatient Database

Figure 6: Severity of Illness of Osteoporosis Cases

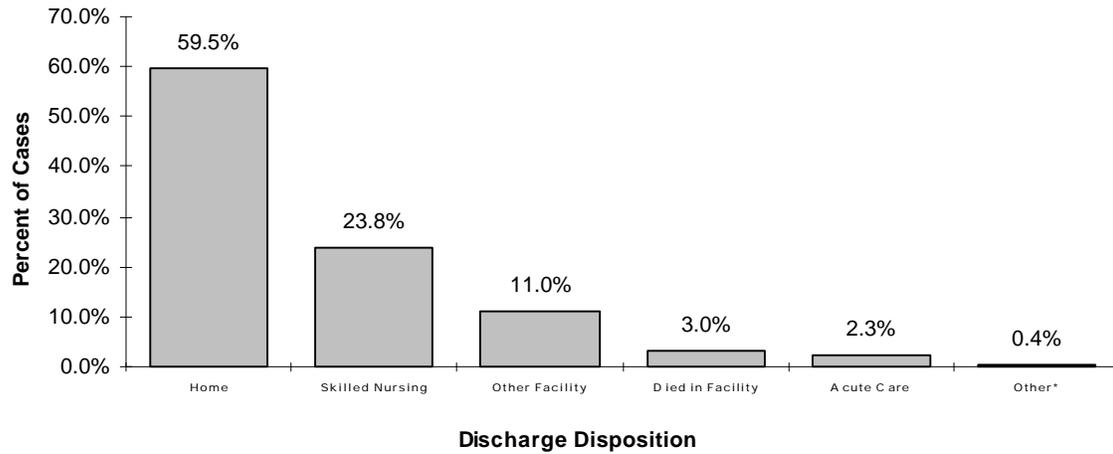


<u>Severity:</u>	<u>Cases</u>	
	<u>Number</u>	<u>Percent</u>
0 (No Risk)	393	2.2%
1 (Minimal Risk)	4,291	24.1%
2 (Moderate Risk)	6,959	39.0%
3 (Severe Risk)	2,905	16.3%
4 (Maximal Risk)	181	1.0%
Missing / NA	3,098	17.4%
All Cases	17,827	100.0%

Source: PHC4, 1995 Inpatient Database

***Notes:** 3,098 "Missing" cases also include non-acute care hospital admissions. Atlas™ Severity of Illness System was used to classify clinical instability in acute care hospitalizations.

Figure 7: Discharge Disposition of Osteoporosis Hospitalizations



<u>Discharge Disposition:</u>	<u>Cases</u>	
	<u>Number</u>	<u>Percent</u>
Home	10,602	59.5%
Skilled Nursing.....	4,251	23.8%
Other Facility (e.g., physical rehab or psychiatric).....	1,963	11.0%
Died in Facility	529	3.0%
Acute Care	408	2.3%
Other*	74	0.4%
All Cases	17,827	100.0%

Source: PHC4, 1995 Inpatient Database

*Note: Other includes unknown/missing cases, and those discharged against medical advice.

STAFF ANALYSIS OF ACT 34 REQUIREMENTS

Act 34 provides that the documentation submitted to the Council by supporters and opponents of a proposed mandated benefit should address eight specific areas. This section provides a summary of the documentation submitted to the Council by supporters and opponents of Senate Bill 1057 for each of these eight categories. In reviewing these eight points, Council staff performs a preliminary review to determine whether the information received is sufficient to warrant the formal Mandated Benefits Review process outlined in the Act. Following are Council staff findings pertaining to the documentation received for each area:

Summary of the Responses to the Eight Categories Required by Act 34

In general, supporters of Senate Bill 1057 contend that the bone mineral density testing benefits proposed would help eradicate osteoporosis by improving early identification efforts, improving compliance with treatment regimens, and facilitating greater public awareness of osteoporosis.

In general, opponents of mandated benefits such as those proposed under Senate Bill 1057 contend that legislative intrusion into the health care marketplace via specific mandates on services artificially inflates costs, and manipulates the market to limit purchasers' ability to design benefit packages that suit the needs and demands of insureds.

Typically, opponents of mandates such as those proposed under Senate Bill 1057 include insurers and purchasers of health care coverage. For example, the Managed Care Association of Pennsylvania states in their submission that, "To date, the Commonwealth has imposed in excess of 20 mandated benefits on the health insurance industry/purchaser community. The Managed Care Association does not generally support legislative mandates and views such proposals as unwarranted interference in the practice of medicine. Further, mandated benefits increase the cost of health insurance and impede HMOs in their ability to structure benefits which are responsive to the needs and demands of employers and other purchasers."

In addition, Highmark Blue Cross Blue Shield included in their submission a study from the National Center for Policy Analysis that analyzes the cost of health insurance mandates. The study cites a 1990 literature survey by a National Bureau of Economic Research economist that found "the cost of mandated benefits is usually borne by employees in the form of reduced wages, reduced work hours or lost employment." The study also goes on to note that, "While mandated benefits mean that people with health insurance have more health care options, they also mean that fewer people are insured. When employers who canceled their employees' health insurance policies have been polled on why they did so, the majority claimed that it was because the price was too high."

Detractors of the specific mandate proposed under Senate Bill 1057 assert that scientific research does not support the use of bone mineral density testing as a general screening measure. Opponents also contend that there is no evidence that bone mineral density testing improves treatment compliance, and that the best way to

eradicate osteoporosis is through education in preventive lifestyle changes such as increased calcium and vitamin D consumption, maintaining a healthy lifestyle including weight-bearing exercise, and the use of hormone replacement therapy in most postmenopausal women. Critics also cite the lack of consensus among medical professionals as to exactly at what bone mineral density level an individual would have osteoporosis.

Some critics of the measure also contend that the language of the bill which includes perimenopausal women among those for whom testing would be covered as too broad, and that there are no limits on testing frequency or costs covered. The Insurance Federation of Pennsylvania states in their submission that, "bone density tests costing \$150 to \$250 for each body site are proposed to be made available virtually on demand and without limit to a large cross section of the public. This bill makes these tests available to any perimenopausal or post menopausal woman."

Some opponents of the measure also contend that bone mineral density testing is already often covered when it is truly warranted, and not available as a universal screening tool for good reasons--such as to maintain the affordability of health insurance in Pennsylvania by covering accepted medical treatments of proven efficacy, while safeguarding subscribers' health and premium dollars from services that are ineffective, cost inefficient, or potentially dangerous.

Specific Responses to the Eight Categories Required by Act 34

(i) The extent to which the proposed benefit and the services it would provide are needed by, available to and utilized by the population of the Commonwealth.

Proponents of the mandates under SB 1057 cite statistics on the prevalence and incidence of osteoporosis and related fractures in Pennsylvania and nationwide to illustrate the need for the benefit. For example, according to the submission of the Magee-Womens Hospital Osteoporosis Prevention & Treatment Center, "Osteoporosis is responsible for about 1.3 million broken bones in the US each year, and costs Americans \$10 billion per year (congestive heart failure costs \$7.5 billion/year; asthma costs \$6.2 billion/year)." The Magee submission also includes estimates that:

- "Between 1995 and 2015, 270,000 Pennsylvania women age 45 and over are expected to suffer hip fractures
- Pennsylvania women age 45 and over will suffer 58,457 hip, spine, and wrist fractures in the year 2015
- The cost of these fractures will rise more than 16% by 2015
- The annual cost to Pennsylvania's health care system will rise from \$290 million in 1995 to \$907 million in 2015."

The Magee submission also contains research on the cost of hip fractures in the United States, which estimates the annual combined direct and indirect costs of hip fractures to be in excess of \$8 billion and the "cost of fractures in the United States [as a whole] may be as much as \$20 billion per year" (Melton).

Information submitted by the Mercy Hospital of Pittsburgh states, “A women’s risk of hip fracture is equivalent to her combined risk of developing breast, uterine and ovarian cancer. The lifetime risk for white men of an osteoporotic fracture at age 50 and above is 13%.”

Research was also submitted by proponents on the effect of hip fracture on quality of life and functionality showing that, “10% of women who sustain a hip fracture become functionally dependent in the activities of daily living, taking pre-fracture functional status into account, and that 19% require long-term nursing home care because of the fracture. ... At least 60,000 nursing home admissions are attributed to hip fractures each year in the United States, along with over seven million restricted activity days (62.5 days per episode) among non-institutionalized individuals. As many as 8% of all nursing home residents have had a hip fracture” (Melton).

The National Osteoporosis Foundation (NOF) states in their submission that, “In 1996, it was estimated that 417,940 women and 105,176 men age 50 and over in Pennsylvania had osteoporosis. An additional 793,887 women and 157,764 men had low bone mass, putting them at risk for the disease. By the year 2015, assuming no additional steps are taken to prevent, diagnose, or treat the disease, 520,654 women and 118,908 men age 50 and over will have the disease. An additional 993,486 women and 178,362 men will suffer from low bone mass. ... Each year in the United States, this disease leads to a million and a half fractures, mostly of the hip, spine and wrist, although any bone can be affected. Ninety percent of hip and spine fractures in elderly white women can be attributed to osteoporosis. Hip fractures, which occur about twice as often in women as men, are more serious than most people realize: 12 to 20% of hip fracture patients will die in the year after fracture, usually from complications like pneumonia or blood clots in the lung, which are related to the fracture or to the surgery to repair the fracture. More than half of those who survive will not be able to walk independently, and a quarter will need long-term nursing home care. In 1995, \$13.8 billion in health care costs were attributed to osteoporosis in the United States.”

Also according to the NOF, “California, New York, Texas, and Pennsylvania top the list with the greatest number of women with osteoporosis” (1996 and 2015 Osteoporosis Prevalence Figures State-by-State Report).”

The Mercy submission also states that, “By the year 2015 it is estimated that 1,811,410 Pennsylvanians (or 13% of the total population), 1,514,140 women and 297,270 men will have osteoporosis or low bone mass and the potential for increased fracture risk. Within that time frame, it is estimated also that about 55,600 women age 50 and over will die within one year of having a hip fracture. Of these deaths, about 34,300 can be directly attributed to hip fracture.”

Included in the Mercy Hospital of Pittsburgh submission, a letter from John D. Brungo, MD, Chairman, Department of Medicine, states that “Bone mass correlates directly with fracture risk. The diagnostic process in osteoporosis focuses on evaluating the type and degree of bone loss. To avoid the potentially devastating effects of osteoporosis, it is both clinically warranted and cost effective to assess bone density in patients **at high risk** especially before any fractures or deformities occur” [emphasis added]. Opponents of the measure contend, however, that the bill would not distinguish those patients “at high risk.” Opponent submission are discussed below.

Among the opponents of the measure, Highmark states in their submission that, “It is reasonable to assume that some additional women will be tested when payment for the service is made available by insurers. The medical literature does suggest that bone density testing is a useful method in predicting bone loss and an early indication of osteoporosis. However, it is not necessarily useful as a screening tool for all women. Certain risk factors can be taken into consideration before bone density testing is recommended. There are three types of bone density testing that are most commonly used and are determined to be most effective:

(1) Dual Photon Absorptiometry (DPA) – a modification of the single-energy technique using a radioisotope that emits photons at two different energy levels. This method measures the total integrated mineral in the path of the beam.

(2) Quantitative Computed Tomography (QCT) – may be used to measure cancellous bone, cortical bone, or an integrated sum of both. The method can identify the absolute mineral content of a specific volume of bone.

(3) Dual Energy X-ray Absorptiometry (DEXA) – a two-dimensional projection similar to DPA except that it uses an x-ray tube for its photon source rather than a radioisotope. DEXA is most commonly used to measure bone mineral of the hip and spine, but measurements may also be taken of the forearm, calcaneus or the total body.”

Another opponent of the measure, the Insurance Federation of Pennsylvania (IFP), contends in their submission that, “Even the National Osteoporosis Foundation does not recommend a densitometry screening for all perimenopausal and postmenopausal women.” The IFP included in their submission a document entitled, “Recommended use of Bone Densitometry Measurements,” which was submitted to the Health Care Financing Administration (HCFA) by the Scientific Advisory Board of the National Osteoporosis Foundation and identifies indications for bone mass measurement, as justified by current research. The clinical indications recommended include: “estrogen deficiency in menopausal women indicates the need for measuring low bone mass to help physicians and patients make decisions about hormone replacement therapy. Not all menopausal women are included in this recommendation. It should be understood that this recommendation is not for a general screening, but for helping women with specific problems. [emphasis added]; vertebral anomalies and radiographic osteopenia ...; long-term glucocorticoid therapy is an indication for bone mass measurement so that identification and adjustment of therapy can be efficiently assessed...; primary asymptomatic hyperparathyroidism is another condition that indicates the use of bone mass measurement; and potential indications include assessment of efficacy of treatment.”

The IFP submission also states that “most health policies today pay for this testing when it is indicated for a specific purpose, i.e., to design a proper health maintenance program or to diagnose further types of conditions for treatment and therapy.” The IFP also contends that “One of the problems with such a mandate is that coverage will increase the use for many reasons, some of questionable efficacy. Unfettered access to the procedure, not a cheap one, encourages its use, repeating one of the errors of pre-managed care days. ... There is no need to have the benefit that broadly available because it is then particularly susceptible to abuse and waste.”

We found that many Pennsylvanians have access to bone density testing through Medicare coverage under certain medical restrictions, and that it appears that insurers often cover the service when deemed medically appropriate. Council staff conclude that there is no consensus in the medical community on the efficacy of broad-based bone mineral density testing, as would be mandated under Senate Bill 1057, or when such testing is warranted for certain clinical indications. Therefore, the need for the benefit is not clear.

We recognize the problems caused to Pennsylvanians by osteoporosis and the need to prevent the disease and subsequent related fractures. Nevertheless, Council staff find it to be significant that the National Osteoporosis Foundation stated expressly that they do not recommend a general screening of all menopausal women, as would be the case under Senate Bill 1057.

While the general figures on osteoporosis prevalence submitted by the proponents are informative, Council staff suggest that it is not possible to estimate the increase in testing utilization that most likely would occur as a consequence of implementing Senate Bill 1057. Also, if proponents of the measure are correct in their contention that increased insurance coverage of bone mineral density testing would increase preventive and treatment measures for osteoporosis, the increased costs of the treatment of osteoporosis and use of hormone replacement therapy would be a likely result. However, it is unknown to what extent future savings from avoided fractures and the early identification of osteoporosis would be.

(ii) The extent to which insurance coverage for the proposed benefit already exists, or if no such coverage exists, the extent to which this lack of coverage results in inadequate health care or financial hardship for the population of the Commonwealth.

The National Osteoporosis Foundation submission states that, “An informal survey of providers in Pennsylvania was conducted to ask for feedback regarding the current coverage and reimbursement practices of health plans operating in the state of Pennsylvania when it comes to the prevention, diagnosis and treatment of osteoporosis. An overall dissatisfaction was expressed by every respondent regarding the rationing of bone density tests by health care plans. This rationing in most cases was so extreme that medically necessary patient care was compromised. The following represents some of the barriers imposed by health plans.”

“Health Plans Disallowing Coverage for Estrogen Deficient Women at High-Risk for Osteoporosis ... Health care costs of osteoporosis to Pennsylvania’s health care system were \$290 million in 1995 and are projected to be \$907 million in 2015. ... Some health care plans in Pennsylvania have adopted Pennsylvania Medicare’s policy to exclude estrogen deficient high-risk women from coverage. This has resulted in providers withholding the test for these women unless the enrollee can pay out-of-pocket. For many people this is not possible. For one osteoporosis clinic in an area of Pennsylvania with a very low median income, this has results in bone density tests not being offered or only for people with Cushings syndrome, hyperparathyroidism, hypogonadism, prolactinoma, long

term steroid therapy, vertebral abnormalities on x-ray (compression fractures or radiographic osteopenia), fractures of the hip, wrist, or spine in the absence of severe trauma, documented loss of height greater than 1.5 inches, and to monitor the response to ongoing restorative treatment for patients with documented osteoporosis. This is a very restrictive policy, which covers only a small group of individuals. The bottom line is that for many people covered under these health plans, fractures must occur before a bone density test will be allowed. This is a travesty, as bone mass measurements predict fracture risk and allow for treatment to begin well before fractures occur. Half of all Medicare carriers currently do and half do not allow bone mass measurements for estrogen deficient high-risk women. It is because of these discrepancies that as of July 1, 1998 all Medicare carriers will be required by law to cover bone density tests for several groups of individuals, including estrogen deficient high-risk women.”

“Coverage Criteria Deemed Proprietary. Some health plans are unwilling to give providers or enrollees criteria (written or verbal) under which a bone density exam would be covered. Withholding this type of information makes it extremely difficult for providers to code appropriately and for patients to receive the timely care they need. Also, if the physician believes the bone density test is necessary, both the patient and the provider must know if the test is covered and who will ultimately pay for the test.”

According to the Mercy Hospital of Pittsburgh, “The current availability of health insurance benefits to include bone mass measurement and treatment for osteoporosis for a qualified individual is very limited at best. Although Medicare Part B will provide payment for a bone mass measurement under certain limited criteria, this test would be available to only a very small percentage of those individuals identified above. Many people do not carry Medicare Part B, and do not have any health care/pharmaceutical benefits, others have insurance that doesn’t cover this test or the purchase of medications. Physicians caring for these individuals would not order the test because of the financial restrictions placed upon them by managed care coverage and some individuals have no general medical physician.”

The Mercy submission also states, “Currently, reimbursement for the bone mass measurement, DEXA, is variable and usually incomplete. Medicare Part B will provide payment if the test is ordered by a physician and the individual for whom it is ordered meets some very restrictive criteria. Reimbursement by other insurers is sketchy and inconsistent. Insurance companies often will not clearly state if they will cover a bone mass measurement until a claim is submitted, thus only retrospective data provide the answer for a given carrier. This has led physicians to screen only after fracture when morbidity has already occurred.”

Mercy goes on to state, “The Medicare Bone Mass Measurement Coverage Standardization Act was signed into law in August, 1997, to become effective July 1, 1998. This will permit individuals at high risk for osteoporosis to have a bone mass measurement test and to receive treatment. Passage of this legislation is indicative of the recognition by Congress and the Administration that osteoporosis is a major public health problem which can and must be overcome. Similar legislation needs to be passed at the State level to provide adequate coverage for all Pennsylvania residents.”

Highmark Blue Cross Blue Shield states in their submission that they provided coverage in 1996 for 4,444 bone density tests. "Included in this total are Dual Photon Absorptiometry (DPA), Quantitative Computed Tomography (QCT) and Dual Energy X-ray Absorptiometry (DEXA)." According to Highmark, "Of the eleven clinical indications included in Senate Bill 1057, Highmark Blue Cross Blue Shield provides payment for bone density testing for the following ten:

- (1) long-term (longer than three months) corticosteroid therapy;
- (2) fracture in the absence of appropriate severe trauma;
- (3) loss of height of one and one half inches or more;
- (4) Hyperthyroidism;
- (5) Hyperparathyroidism;
- (6) Cushing's Syndrome;
- (7) Hypogonadism;
- (8) Prolactinoma;
- (9) Vertebral abnormalities on X-ray (such as compression fractures or radiographic evidence of osteopenia); and
- (10) diagnosed osteoporosis or osteopenia for evaluation of ongoing treatment."

Highmark contends in their submission that, "mandating coverage for bone density testing for asymptomatic patients as in the first clinical indication mandating coverage for perimenopausal, postmenopausal and estrogen-deficient women, will not assure that osteoporosis will be eradicated."

Highmark also included information on Medicare coverage of bone mineral density testing under certain conditions.

The Insurance Federation of Pennsylvania contends that, "Insurers believe that osteoporosis and bone density testing are covered to an appropriate degree in present health insurance available in the Commonwealth." "Lack of a screening program cannot be deemed to be creating a hardship where the same services are covered in those instances where a physician notes a medical necessity for these procedures. Moreover, as the authorities above point out, the usefulness of such screening is still open to question. These questions are very serious. The Osteoporosis Coalition of New Jersey states in [their practice guidelines] 'There are no studies, however, determining how well perimenopausal bone density predicts long-term risk of fracture.' The same source casts considerable doubt on the medical efficacy of this mandate by noting, 'The indications for bone density testing are still somewhat controversial both for an initial determination as well as need/frequency of follow-up testing.'"

The Managed Care Association states in their submission that, "Treatment for osteoporosis is a covered benefit under the majority of health insurance benefit plans in the Commonwealth. In terms of members of the Managed Care Association specifically, our member HMOs practice and promote preventive medicine. If a patient has risk factors associated with osteoporosis, the treating physician would provide the patient with the information necessary to take steps to counter further bone weakening. Prevention may include calcium supplements, increased physical activity, smoking cessation or, in some cases, hormone replacement therapy. If medically necessary, a physician may also request a bone mass measurement or other screening measurement to assess fracture risk."

Again, Council staff found that many Pennsylvanians have access to bone density testing through Medicare coverage under certain medical restrictions, and that it appears that insurers often cover the service when deemed medically appropriate.

With regard to this category, Council staff suggest that other solutions, rather than mandating benefits, might be appropriate. For example, in the submission from Mercy Hospital of Pittsburgh, it is claimed that, "Insurance companies often will not clearly state if they will cover a bone mass measurement until a claim is submitted, thus only retrospective data provide the answer for a given carrier. This has led physicians to screen only after fracture when morbidity has already occurred." Perhaps clearer communication guidelines are in order rather than mandates.

Overall, we found that neither supporters nor opponents of the bill submitted sufficient, *specific* information regarding Issue ii. For example, reference to an informal survey discussed by the National Osteoporosis Foundation lacked *specific* information to help staff determine the extent to which lack of coverage results in inadequate health care or financial hardship. Similarly, while opponents provided some general information, it was not sufficiently specific to understand the true "picture" of this issue for the "population of the Commonwealth."

(iii) *The demand for the proposed benefit from the public and the source and extent of opposition to mandating the benefit.*

According to the National Osteoporosis Foundation, "One out of every two women and one in eight men over the age of 50 will have an osteoporosis-related fracture in their lifetime. The earlier osteoporosis is detected the less expensive the treatment (drug therapy, exercise, diet) and the later osteoporosis is detected, i.e. at the time of fracture, the more costly the treatment such as hospitalization for the acute systems and nursing home care for the rehabilitation. The average health care cost of a hip fracture today is approximately \$33,000. From a survey we conducted of osteoporosis clinics, we found the average charge for a bone density test (which measured the hip and spine and included an interpretation of the test results) was \$215. Treatment costs for the disease range from \$50 to \$730 per year. ... Legislation mandating health plan coverage for bone mass measurement as it will be implemented for Medicare beneficiaries will remove the barrier to this diagnostic test and ensure that people receive the care they need to prevent fractures. In this way, the costs of fractures can be avoided, as well as the dramatic toll this disease takes on the quality of life."

The Mercy Hospital of Pittsburgh contends that, "Bone mineral density (BMD) is the unequivocal major predictor of fracture risk. ... Using the standard risk factors alone, it is not possible to predict the actual likelihood for osteoporosis in any individual. The relationship between bone mass and fracture risk is more powerful than that between serum cholesterol concentration and coronary artery disease."

According to the Highmark submission, however, "The demand for coverage of bone density testing and the treatment of osteoporosis is being driven by the provider community. Those already diagnosed with osteoporosis currently have coverage for bone density testing and treatment of the disease. Physicians contend that screening of

the general population is a cost-effective way to locate women with the disease. However, although a bone mass measurement is completed, someone at a relatively young age could still contract the disease a number of years in the future. Unless a test is completed every year or every so many years on an asymptomatic woman, it is difficult to predict if the disease will appear, has appeared or is progressing.”

Highmark goes on to state, “Insurers and employers who pay health insurance premiums are generally opposed to mandated benefits because they have a tendency to increase health insurance costs. A recent study conducted by the U.S. Department of Health and Human Services’ Agency for Health Care Policy and Research indicates that even when employers offer health insurance to their employees, an increasing number of employees decline the coverage. ... Between 1987 and 1996, the number of workers declining coverage jumped by 140 percent. One of the reasons given is that state mandates increase insurance costs. ... Another study conducted by Milliman and Robertson for the National Center for Policy Analysis estimates that the cost of 12 of the most common mandates can increase the cost of health insurance by as much as 30 percent. ... This represents an increase in costs of between \$525 to \$1,050 [*based on a standard family policy without mandates costing \$3,500 per year*]. Although bone density testing would not be one of the 12 most common mandates, it would further increase costs for employers and ultimately employees. The Pennsylvania General Assembly has already enacted six of the 12 most common mandates.”

“The Federal Employee Retirement Income Security Act (ERISA) of 1974 regulates health benefits and does not require an employer to offer a specific level of benefits. Therefore, employers that self-fund or self-insure their own programs are exempt from all state insurance laws. The Insurance Commissioner of the Commonwealth of Pennsylvania, or any other state, has not jurisdiction or regulatory oversight over self-insured employers who in turn can essentially craft their own benefit package to include whatever services they wish to cover. The growing number of self-insured plans places large segments of the “insured” population in ERISA-exempt health benefit plans. According to Pennsylvania Insurance Department data, an estimated 50 percent of the employer group market is self-insured.”

According to the Insurance Federation of Pennsylvania, “Insurers oppose the mandated screening benefit because it will be extremely costly, its benefits to the public health have not been demonstrated and it would be far more effective for government to inform citizens about the causes and cure for osteoporosis so that they can act on their own.” The IFP submission goes on to state that, “Moreover, insurers oppose mandates generally as intrusions into the marketplace which should not be enacted unless public health considerations demand it. That is far from the situation here, where even national organizations devoted to combating this condition are unable to recommend the benefits of the kind of testing program prescribed in the bill.”

The Managed Care Association contends that, “The demand for the benefit ... stems in part from a recognition of the prevalence of osteoporosis and the potential cost effectiveness of early intervention/prevention efforts. According to recent statistics, osteoporosis affects approximately 25 million Americans—the vast majority of whom are women—and is four times more prevalent than breast cancer. The demand for a specific benefit level for a specific disease, however, must be carefully balanced with the subsequent costs to imposing a legislative mandate. ... According to an October 31, 1997 study by the Employee Benefits Research Institute, employer-sponsored health

care coverage continues to decline and now stands at an estimated 64 percent nationally, a 6 percent decrease from 1988 to 1995. It has been demonstrated that mandated benefits result in employers imposing greater cost-sharing requirements on employees, reducing the amount of coverage, eliminating health insurance benefits altogether, or, if feasible, self-insuring to avoid all mandated benefits. ... Senate Bill 1057 would mandate health insurance coverage for **all costs** associated with the diagnosis and treatment of osteoporosis. While the bill clearly mandates health insurance coverage for the detection of osteoporosis through bone mass measurements, the bill does not define the frequency or duration of treatment following diagnosis. This clearly represents an open-ended benefit, which could have significant cost impacts. In addition ... the medical appropriateness of bone mass testing for osteoporosis patients is disputed by a number of organizations and scientific studies.”

The Managed Care Association further contends that “...the bill’s definition of ‘clinical indications’ for ‘qualified individuals’ should be clarified. Contrary to what is stated in Senate Bill 1057, perimenopausal, postmenopausal or estrogen-deficient status in women are not, in and of themselves, indicators for bone mass measurement as defined by the medical community standard of practice in most expert opinions. In fact, nearly all women in this category should be offered appropriate hormone replacement therapy regardless of their bone mass. ... MCAP again notes the open-ended and potentially costly nature of the language in the bill. As an illustrative example of specific suggested limits, follow-up bone measurement tests sooner than one year after the initial test study cannot be justified. For patients receiving hormone replacement therapy, repeat measure bone density exams should occur at intervals of 2 to 4 years, again at the discretion of the physician and based on medical necessity.”

The Managed Care Association also states that, “Unlike other legislative mandates enacted recently in Pennsylvania (maternity, mastectomy), osteoporosis detection and treatment protocol is not definitive. ... [T]here remains widespread disagreement as to the viability of bone mass testing. As proposed therefore, Senate Bill 1057 represents a disease-specific mandate for a condition for which treatment modes continue to evolve.”

Although it is clear from where the demand for the benefit arises, the Council did not receive sufficient information on which to conclude the *extent of that demand*. Likewise, opposition to the benefit was found to be from some payers of health care, although the Council did not receive sufficient information to come to conclusions regarding *the extent of that opposition*.

One particularly interesting point was made by the Managed Care Association in suggesting that osteoporosis is a “condition for which treatment modes continue to evolve.” Through independent research, Council staff note that bone density *measurement* techniques continue to evolve as well and cite the recent approval of a test that estimates bone density using ultrasound (Neergaard).

(iv) All relevant findings bearing on the social impact of the lack of the proposed benefit.

According to the National Osteoporosis Foundation, “Quality of life is greatly impaired in persons with severe osteoporosis, not only because of the debilitating pain and deformity, but also because of limited ability to move and be active for the fear of breaking more bones. When several vertebrae are fractured, the spinal column becomes shorter or compressed, resulting in a loss of height and a forward curvature of the spine called kyphosis, sometimes so severe that the person is unable to look up and is condemned to walking for the rest of their life stooped over looking at the ground. Depression is a common result among severe cases of osteoporosis.”

In addition, the Mercy Hospital of Pittsburgh submission states, “The number of restricted activity days annually as a result of an osteoporotic fracture is a significant social impact of this disease; there are estimated to be greater than 7 million restricted activity days for hip fractures, greater than 5 million for vertebral fractures and 6 million for forearm fractures.” “The human costs of the disease are immense but difficult to measure. Quality of life is affected following a fracture due to fears about additional fractures, limited mobility, and coping with deformity. Other complications of fracture include acute and chronic pain, loss of exercise tolerance and ultimately generalized disability, loss of self-esteem and body image. The most important causes of fractures in osteoporosis are an increased tendency to fall, decreased resistance to minimal trauma, and low bone mass.”

According to Highmark, “More than 200,000 hip fractures occur each year in the United States and about one patient in five dies from complications. (Smith, 1997) The cost of hip fractures in the United States has been estimated at \$8.7 billion per year. These are large numbers, but screening the general population will not necessarily make them decrease. The most effective way to prevent osteoporosis is to follow certain dietary and health recommendations. Mandating this benefit does not mean that the incidence of the disease or of fractures will decrease. Nor does it mean that women will actually seek out testing.”

The Insurance Federation of Pennsylvania submission states, “Since insurers in the Commonwealth provide the same services, at least when indicated in individual cases, there appears to be no impact owing its origin to a lack of a broad based screening mandate. Indeed, the cost considerations, including possible overutilization, and minimization of health insurance premium levels represented by not having the benefit which this bill requires are beneficial for the Commonwealth, its businesses and its citizens.”

The Managed Care Association submission states, “The Association contends and medical research supports that bone mass measurement may not be the most appropriate method for diagnosing osteoporosis. Developed within the last decade, bone density screening is a relatively new medical technique, the efficacy of which continues to be debated.” MCAP further states, “Neither the U.S. Preventive Services Task Force nor the Canadian Task Force on the Periodic Health Examination endorse routine bone mineral density screening. Instead, these organizations recommend that physicians counsel all peri and postmenopausal women about hormone replacement therapy. Hormone replacement therapy is usually the therapy of choice for treating osteoporosis in postmenopausal women.” Examples of studies that do not support use

of bone mass measurement as an appropriate indicator were enclosed with the submission.

While Council staff recognize the social implications of osteoporosis and are sympathetic to the plight of those with this disease, perhaps solutions other than mandates would be more appropriate. The above references argue for more education regarding osteoporosis prevention and treatment.

The social impact of osteoporosis is clear, however, we contend that we did not receive information regarding “*the social impact of the lack of the proposed benefit,*” as required under Act 34. Council staff assert that the social impact of the lack of the benefit can not be proven because the proposed benefit is of unproven efficacy and, therefore, uncertain value.

(v) *Where the proposed benefit would mandate coverage of a particular therapy, the results of at least one professionally accepted, controlled trial comparing the medical consequences of the proposed therapy, alternative therapies and no therapy.*

The Mercy submission states, “Quantification of bone density helps establish the severity of bone loss and serves as a baseline for evaluating the success of therapy. Most noninvasive measurements of bone density provide site-specific information about the quantity of bone at the time of the examination. However these measurements do not assess either the current or past rate of bone remodeling.” “Quantitative measurement of bone density provides information about the remaining assets in the bone mineral bank but no information about past or present deposits or withdrawals. Sequential measurements of bone density are necessary to assess the rate of bone loss in an individual patient.” “Bone mass measurement should be performed in the following settings: for risk assessment in perimenopausal or postmenopausal women who are concerned about osteoporosis and willing to accept available interventions; in women with x-ray findings that suggest the presence of osteoporosis; in women undergoing treatment for osteoporosis; and as a tool for monitoring the therapeutic response. The only effective way to monitor therapy objectively is by comparison with a baseline bone mass measurement.”

According to the Highmark submission, “In doing a literature search, it was difficult to find any medical trials that did not include bone density testing for all participants in the study. However, several articles are included with this submission that have studied bone density testing in relation to the diagnosis and treatment of osteoporosis.”

Research articles are summarized as follows: Raisz recommends that “risk assessment be used to develop a cost-effective prevention program and to guide therapy approaches;” Sampietro-Colom “concluded that there is no scientific evidence to support screening of the general population or menopausal women for the prevention of future bone fractures;” Kroger studied “a sample of 1,600 perimenopausal women aged 48-59 years of age to study the effect of menopause on bone density. Menopause was found to have a major impact on bone density, with physical activity being another risk factor. This study did find, however, that risk factor evaluation is not a sufficient

substitute for bone density testing.” Marshall studied the “different types and amounts of technology used for bone density testing and the treatment of osteoporosis in Sweden and Australia. These countries have very different approaches to the amount of technology necessary and how to screen for diseases such as osteoporosis. This article explains the health policies of the two countries related to bone density testing.”

The Insurance Federation of Pennsylvania contends in their submission that “there is no proof, much less reasonable expectation that widespread screening would ... reduce the total costs of health care in the Commonwealth.” The submission goes on to state that “one can only hypothecate the degree of utilization, etc., logic dictates that forcing the coverage of unfettered and at will densitometry testing for all women approaching or through menopause is a major financial step.” The IFP contends in their submission that bone density testing should not be a mandated therapy.

Given the contradictory findings suggested in the documentation received, Council staff believe that further research focusing on controlled trials with regard to bone mass measurement might shed more conclusive light on this issue. Without more consistent, conclusive findings, Council staff suggest that the information submitted is not sufficient, nor specific enough, for full review of this category.

(vi) Where the proposed benefit would mandate coverage of an additional class of practitioners, the result of at least one professionally accepted, controlled trial comparing the medical results achieved by the additional class of practitioners and those practitioners already covered by benefits.

This requirement is not relevant to the discussion of the mandates proposed under Senate Bill 1057.

(vii) The results of any other relevant research.

The Mercy Hospital submission states, “In the past, patients at highest risk have not been screened or screened late in part due to few treatment options being available. There are now a number of published trials indicating that estrogen (+/- progestin) can increase bone density and reduce fracture risk. ... Calcium and Vitamin D supplementation have been demonstrated in equally reliable study formats to increase bone density. Treatment to restore bone strength in women with established disease may also reduce the risk of fractures.” The Mercy submission also contends that, “Mammogram benefits have resulted in earlier breast cancer detection in women over 50 and have contributed to improved survival. Many of the same results could be achieved for osteoporosis.”

The Managed Care Association states in their submission, “medical research supports that bone mass measurement may not be the most appropriate method for diagnosing osteoporosis. Developed within the last decade, bone density screening is a relatively new medical technique, the efficacy of which continues to be debated.” MCAP goes on to state, as have other opponents that, “Neither the U.S. Preventive Services Task Force nor the Canadian Task Force on the Periodic Health Examination endorse

routine bone mineral density screening. Instead, these organizations recommend that physicians counsel all peri and postmenopausal women about hormone replacement therapy. Hormone replacement therapy is usually the therapy of choice for treating osteoporosis in postmenopausal women.”

In addition, the Highmark Blue Cross Blue Shield submission included in the April 1996 report entitled, *Employer Health Care Costs - A Comparative Study of its Role in Pennsylvania's Business Climate* by the Pennsylvania Economy League for the Pennsylvania Coalition for Quality Health Care. The report states the following:

PEL found that state laws which affect the structure of managed care delivery systems, mandate benefits, and require certain procedural requirements reduce the competitiveness now being generated in the [health care] market place and increase costs significantly. Health care continues to be a significant cost for employers in Pennsylvania and other states. However, according to a national survey, these costs are comparatively low for Pennsylvania employers. ... (Page i).

Certain mandated benefits increase the quality of health care for patients while at the same time lower long term costs for the entire system. However, most mandated benefits have the effect of imposing additional and medically unnecessary cost into the system [and] ... the added costs are passed along to the purchaser, which in most cases is the employer or government (Page 38). ...

A new challenge for emerging health care delivery systems is unnecessary regulation which can distort beneficial market forces. Several other states have adopted pieces of these proposals in varying forms and scope of application. These proposals, if enacted in Pennsylvania, would restrict the market forces which finally have driven sensibility into the market place. Most importantly, as these changes limit competition among providers, gains in cost control will erode. Similarly, employers would have less incentive to consider quality in purchasing decisions with cost considerations. The bottom line: reducing competition and mandating additional costly provisions will generate increased cost without commensurate increase in service and quality. These costs will be borne first by the payers: employers, government and individuals. All will experience higher premiums for similar coverage than if these laws were not passed (Page 47).

The unlevelled playing field forces small businesses, the larger growth sector in our economy, to pay higher costs and eventually insure fewer employees. An objective of most public policy is to reduce the number of uninsured, not increase it. Since all payers pay some portion of the cost of uninsured either through cost shifting within the system or through additional taxes, employers and government will pay higher premiums. Currently, costs for health care services for employers in Pennsylvania are below the national average and are among the lowest in the 13 state group of states competing with Pennsylvania despite Pennsylvania's high ranking for total health care expenditures. ... From a business perspective, added costs through legislative regulation will erode Pennsylvania's comparative position in competition for retaining existing employment and attracting new jobs. ... Increased health care costs could represent one more negative factor to be included in Pennsylvania's business climate package that many people already feel is noncompetitive in many aspects (Page 47).

Highmark Blue Cross Blue Shield also cites the *Record of the Society of Actuaries* (Volume 16, Number 1), as stating the following regarding mandated benefits in general: "1. State-mandated benefits cause increases in premiums that may cause more employers to drop their health coverage. A recent study indicated that each new mandated benefit in a state increased by 1.5% the likelihood that a small firm could not offer coverage. 2. State-mandated benefits cause large employers to self-insure. 3. State-mandated benefits disproportionately benefit specific providers. 4. State-mandated benefits increase administrative costs of both insurers and employers, especially multi-state employers. 5. State-mandated benefits further escalate the cost of health insurance."

Highmark Blue Cross Blue Shield included in their submission a research article on the cost-effectiveness of osteoporosis screening (Dix Smith). The researchers noted that, "The evidence is clear: Estrogen replacement prevents the rapid bone loss normally seen after menopause. Still in question, however, is whether women should begin hormone replacement therapy (HRT) at menopause or whether menopausal women should undergo bone density screening and be treated only if the risk of fracture is detected." The research goes on to summarize relevant research and notes that, "One cost-effectiveness analysis compared screening pre-menopausal women and treating those at high risk with HRT for 15 years with unselective, universal HRT treatment. The cost per year of life gained was \$11,700 for selective therapy vs. \$22,100 for universal therapy. If screening cost less than \$84 per person, then the savings from hip fractures prevented would exceed the cost of screening and treatment, the researchers found. Universal treatment (without screening) would prevent additional fatal fractures, the research suggests, but would also expose many more women to HRT's adverse effects, ending up costing an additional \$349,000 per year of life gained" (Dix Smith).

The article also summarizes another study that found that "universal hormone therapy is likely to prevent more fractures than selective therapy, at a similar or lower average cost per fracture averted. If bone density screening increases compliance, however, or the more costly types of therapy ... are used, then screening followed by therapy for high-risk patients is more cost effective." "Overall, screening for low bone mass at menopause and targeting hormone replacement therapy to women at greatest

risk is a reasonably cost-effective use of resources.” Finally, the researchers conclude that, “explicit guidelines cannot be set until further data on the link between hip bone mass measurements and hip fracture risk are available” (Dix Smith).

Council staff contend that, while it is clear that prevention and early detection of osteoporosis *could* significantly reduce the incidence of osteoporosis and related fractures, it is unclear as to whether bone density testing actually achieves this end.

From reviewing the relevant research, Council staff suggest that (1) there appears to be no universal definition of what constitutes osteoporosis in terms of bone density measurement; (2) there is no consensus within the medical community on who should undergo bone density testing and when; (3) research does not seem to support the broad-based screening proposed under Senate Bill 1057; and (4) there does not seem to be sufficient proof that bone density testing actually improves preventive efforts or reduces the incidence of osteoporotic fractures.

Council staff note, in particular, submissions which contend that the U.S. Preventive Services Task Force, the American College of Physicians, and the Canadian Task Force on the Periodic Health Examination do not recommend universal screening. In fact, the model legislation submitted by the National Osteoporosis Foundation does not advocate such broad-based screening as Senate Bill 1057, which includes perimenopausal women among those who would be eligible for coverage. (See Appendix C.)

Given the documentation received, Council staff suggest that perhaps increased educational efforts might be more appropriate than mandates in preventing osteoporosis.

(viii) Evidence of the financial impact of the proposed legislation, including at least:

(A) The extent to which the proposed benefit would increase or decrease cost for treatment or service.

The Mercy Hospital submission states that, “Currently, the direct and indirect costs of osteoporosis exceed \$18 billion annually (hospitals and nursing homes). Each hip fracture represents \$32,428 in total medical costs. Annual physician office visits as a result of fractures include 122,000 for hip fractures, 161,000 for vertebral fractures, and 422,000 for forearm fractures.” “Based on the Pennsylvania Burden of Illness Model, over the next twenty years, the total cost of hip, wrist, and vertebral fractures will be about \$11.7 billion in PA. During the same twenty year period, PA residents will experience almost 270,000 hip fractures. ... As Pennsylvania’s population ages, the incidence of all fractures will rise by more than 16%. The annual cost for these fractures will increase from \$290 million in 1995 to \$907 million in 2015.” “Because of the disparity in costs among the different types of fractures, about 97% of the costs reflected in the model can be attributed to hip fractures. However, hip fractures account for only 24% of total fractures projected to occur in the twenty year period included in the model.”

According to the Highmark submission, "As the number of women seeking bone density screening increases, the cost of providing this service will increase. As with all mandated benefits, utilization and costs increase when the particular procedure or provider is covered by insurance. According to the Pennsylvania Vital Statistics Annual Report 1995, there are 1,334,863 women in Pennsylvania between the ages of 45 and 64. The first clinical indication in Senate Bill 1057 would allow bone density testing for perimenopausal, postmenopausal and estrogen deficient women. Women aged 45 to 64 in our health plans would be considered eligible according to this indication. Although some of the women may also fall under another clinical indication or have already been diagnosed with the disease, in large part these women would be newly eligible for the testing. Based on information from Highmark Blue Cross Blue Shield's current health care contracts, our actuaries estimate that the cost increase of this benefit for those falling under the first clinical indication would be \$9.87 million annually, which reflects a utilization rate of approximately 50% of eligible members. Other assumptions taken into consideration include:

- Total eligible population base of 293,764 women (represents women aged 45-64 residing in the 29 County-area of Western Pennsylvania, or 22% of Pennsylvania women in this age group);
- The average Highmark Blue Cross Blue Shield allowance per procedure is \$70;
- Average utilization will increase by approximately six times the current level;
- 15% of members are eligible, 2% of which currently use the benefit; We expect this number to increase as the eligible population continues to age;
- No cost sharing for the member;
- Does not vary by product;
- Traditional costs are hospital and physician combined; and
- One visit per year, if used."

"Assuming if the remaining 240,275 women aged 45 – 64 covered by Highmark Inc., who reside in the 38-county area of Central, Northeastern and Southeastern Pennsylvania, were to utilize this benefit at a rate of 50%, we could experience an additional increase in claims expense of approximately \$8.4 million annually. This would result in a total annual increase of \$18.3 million."

The Insurance Federation of Pennsylvania contends that, "Assuming a retirement age of 65 and a work experience that begins around age 20, it is clear that large employers could wind up with nearly half of their female workforce impacted by this requirement. It is not easy to gauge the incremental cost, however, because in the vast majority of cases existing insurance already provides the costs of at least some of these tests and resultant treatment on an individually indicated basis."

The IFP further contends that, "Notwithstanding the lack of specificity, it is clear that this mandate certainly has the potential to add significant costs to the health care of individuals and large and small employers. Considering that the tests proposed are of unproven effectiveness in achieving the results in combating osteoporosis which proponents of the bill hope for them, it is impossible for these proponents to affirmatively document that the costs are either minimal or cost justified. With a proposal which represents so great an intrusion into the health insurance of the Commonwealth, this is reason alone to report negatively on the legislation."

The overall figures presented are informative, but with the exception of Highmark, submissions, in general, lacked specific data with regard to this issue. It was difficult to determine from this information “*the extent to which the proposed benefit would increase or decrease cost for treatment or service.*”

(B) The extent to which similar mandated benefits in other states have affected charges, costs and payments for services.

According to the National Osteoporosis Foundation, “Several of the state legislators responsible for passing legislation which mandates insurers to cover and reimburse bone density tests for specific groups of individuals ... indicated that it was determined there would be no fiscal impact on the state. In addition, it was noted that this was not a bill which mandated screening. Screening is defined as providing bone mass measurement to all people at a specific age, regardless of risk factors. We do not support screening across the board. Instead, our model bill stipulates bone mass shall be measured for five groups of individuals, including estrogen deficient high-risk women. The Congressional Budget Office (CBO) was asked to estimate the cost to Medicare of the bone mass measurement legislation before it was passed... CBO considered the fact that according to our figures, 1.92% of eligible women in Medicare plans that offered bone density coverage for hyperparathyroidism, long-term glucocorticoid treatment, vertebral abnormalities, and monitoring of treatments actually had the test done. When eligible women in Medicare plans that covered bone density tests for estrogen deficient high-risk women, hyperparathyroidism, long-term glucocorticoid treatment, vertebral abnormalities, and monitoring of treatments were considered, 2.65% of these women had the test done. The estimates were based on the total number of bone mass measurement tests performed on Medicare beneficiaries in 1996 as compared to the total number of women age 65 and over.” (See Appendix C.)

According to Highmark, the following states currently have laws related to bone density testing:

California	Insurers may cover bone density testing. There is no requirement that they must cover the tests.
Florida	Insurers must cover bone density tests.
Maryland	Insurers must cover bone density tests for the following indications: (a) an estrogen deficient woman at clinical risk for osteoporosis; (b) an individual with vertebral abnormalities; (c) an individual receiving long-term glucocorticoid steroid therapy; (d) an individual with primary hyperparathyroidism; and, (e) an individual being monitored to assess the response to or efficacy of an approved osteoporosis drug therapy.
Oklahoma	Precludes health plans from denying coverage for bone mass measurements for women 40 years or older if the physician believes it medically necessary.
Tennessee	Provides for payment of bone mass measurement if the physician determines the test is medically necessary.
Texas	Provides for payment of bone mass measurement if the physician determines the test is medically necessary.

Council staff suggest, that while the submitted information pertaining to similar mandated benefits in other states is informative from a policy perspective, it is not sufficient to understand the extent to which *charges, costs, and payment* for services have been affected by such mandates.

(C) The extent to which the proposed benefit would increase the appropriate use of the treatment or service.

Central to consideration of this particular area which documentation should address is the understanding that what constitutes “appropriate” use of bone mineral density testing depends on who is defining appropriateness. Some critics of the bill contend that it would result in an inappropriate increase in the exposure of insureds to unproven tests. Some supporters of the measure argue, however, that bone density is the only clear measure on which to base the diagnosis of osteoporosis.

The Mercy Hospital submission states, “The diagnostic process in osteoporosis focuses on evaluating the type and degree of bone loss. To avoid the potentially devastating effects of osteoporosis, it is both clinically warranted and cost effective to assess bone density in patients at high risk especially before any fractures or deformities occur. Quantification of bone density helps establish the severity of bone loss and serves as a baseline for evaluating the success of therapy” (emphasis added).

The Mercy submission also states, “I believe that if this benefit were generally available, it would significantly increase patient requests and physician prescriptions for bone mass measurement. Once the bone density results are known, I believe more patients would make appropriate lifestyle changes such as exercising, eating milk products, taking calcium/vitamin D, and providing positive influences on their children to develop healthy habits at an early age. These informed consumers also would be more likely to start medical treatment, if appropriate, and maintain the required healthy behaviors.”

Opponents have expressed concern that mandated insurance coverage of bone mass testing would lead to over-utilization and increased prices. The Insurance Federation asserts in their submission that, “the law of supply and demand ... dictates that creating a huge demand for these tests is likely to increase, rather than decrease, the price of them.”

Highmark contends that, “Utilization of bone density testing will increase, but only for those with insurance coverage to which the mandate applies. Those lacking adequate insurance coverage will not be able to obtain payment for this service for any of the eleven clinical indications. That means that there will always be a population for whom the testing will not be available to because they have no insurance coverage and cannot pay for the service. Educating women on the risk factors and the need to change their lifestyle to include more calcium, increase exercise and stop smoking is just as important as receiving the bone density test.”

Council staff find that submitting entities were unable to provide sufficient evidence regarding “*the extent to which the proposed benefit would increase the appropriate use of the treatment or service*” mostly due to the subjective nature of the “appropriateness” debate surrounding bone density testing.

Council staff note the submission by Mercy Hospital which suggests that knowing bone density results would produce appropriate lifestyle changes. While Council staff was unable to find documentation, and no supporters of the bill submitted documentation, that bone density testing actually results in these outcomes. Once again, however, it is clear that both proponents and opponents agree that education and lifestyle changes are important components in preventing osteoporosis.

Council staff note, too, the assertion of the Insurance Federation that a huge demand for these tests might increase, rather than decrease, their price. Health care economics have shown this to often be the case and raise the question of whether this mandate would lead to many women having the test who would have chosen to undergo hormone replacement therapy and appropriate lifestyle habits regardless of test results.

(D) The impact of the proposed benefit on administrative expenses of health care insurers

The Mercy submission states, "The development of scientifically valid screening devices and standards of care for women and men to determine relative need for bone mass measurements would minimize administrative intervention."

"Highmark Blue Cross Blue Shield actuaries estimate that the increase in administrative expenses as a result of Senate Bill 1057 will be minimal. The financial exposure of other health insurers in Pennsylvania should be comparable."

Given the minimal information provided above, Council staff find that neither supporters nor opponents of the bill provided the Council with sufficient information which could be used to estimate the precise impact of the proposed benefit on administrative expenses of health care insurers.

(E) The impact of the proposed benefits on benefits costs of purchasers.

Mercy Hospital of Pittsburgh contends in their submission that "the impact on NOT providing these benefits would have a far greater effect on the benefits costs of purchasers."

Highmark contends that, "Whenever a benefit is added to an insurance product, the cost will increase due to increased utilization. These costs are often then passed onto customers primarily, employers and labor groups. Because Highmark Blue Cross Blue Shield allows large employers the ability to custom tailor their benefit packages, mandated benefits increase their costs and preclude the employer from selecting those benefits which their employees want and need.

As previously stated, Highmark Blue Cross Blue Shield actuaries estimate that Senate Bill 1057 will increase costs by \$9.87 million annually. This amount was calculated using 293,764 women, the total number of Highmark Blue Cross Blue Shield female subscribers between the ages of 45-64 in their 29-county service area.

Also, assuming if the remaining 240,275 women aged 45 to 64 covered by Highmark Inc., who reside in the 38-county area of Central, Northeastern and Southeastern Pennsylvania, were to utilize this benefit at a rate of 50%, they could experience an additional increase in claims expense of approximately \$8.4 million annually. This would result in a total annual increase of \$18.3 million.”

While the Highmark submission provided informative figures regarding the proposed benefits costs, submissions, in general, lacked specific information with regard to how *purchasers* would be affected.

(F) The impact of the proposed benefits on the total cost of health care within the Commonwealth.

According to the National Osteoporosis Foundation, “In 1995 the estimated health care expenditures attributable to osteoporotic fractures exceeded \$13 billion in the United States alone. This figure is expected to exceed \$60 billion by the year 2030. As the population ages, the number of people with osteoporosis will continue to increase dramatically as the baby boomers age. Equal and affordable access to bone density tests will allow early detection and treatment for osteoporosis. As mentioned previously, the average charge for a bone density test is \$215. Treatment costs range from \$50 to \$730 per year. These costs pale in comparison to the many thousands of dollars in health care costs attributed to osteoporosis for surgery, hospitalization, nursing home care and home care for a year if this disease is not treated in the early stages.”

The Mercy Hospital submission states that, “The cost of screening is finite, but I believe nominal in the LONG TERM. As long as managed care continues to look at returns only in the short term, preventative strategies will not be valued. There is no question, however, that preventative interventions are better for people as opposed to those institutions that limit their focus to financial returns.”

According to the Highmark submission, “the adoption of new mandated benefits and/or provider groups generally does not benefit the group for which it was originally intended—millions of other lives are impacted in ways in which those individuals proposing the coverage may not have considered.” The Highmark submission further notes that “The **‘Record of the Society of Actuaries, Volume 16, Number 1’** states the following regarding mandated benefits:

- “State-mandated benefits cause increases in premiums that may cause more employers to drop their health coverage. A recent study indicated that each new mandated benefit in a state increased by 1.5% the likelihood that a small firm could not offer coverage.
- State-mandated benefits cause large employers to self-insure.
- State-mandated benefits disproportionately benefit specific providers.
- State-mandated benefits increase administrated cost of both insurers and employers, especially multi-state employers.
- State-mandated benefits further escalate the cost of health insurance.”

The Highmark submission also notes that, “earlier this year, the Blue Cross Blue Shield Association (BCBSA) prepared an analysis of activity on mandated benefits in the

state legislature. More than twice as many new mandates were enacted in 1996 compared to 1994, according to the BCBSA. It is interesting to note that the mandates offered today have changed in that they impose specific clinical treatment policies in an effort to protect consumers against perceived managed care abuses unlike traditional mandates that simply expanded the type of service covered.”

“Most businesses and insurers oppose any form of mandated benefits because they force these groups to pay for unwanted benefits. As a result, many businesses are turning to self-insurance to control their health insurance costs and to avoid any mandates that are passed by state legislatures. According to recent testimony offered by Acting Insurance Commissioner Diane Koken before the House Insurance Committee, she indicated that in the Commonwealth the self-insureds account for approximately 50 percent of the insured population. No state legislative mandate will affect these insureds.”

“Small employers generally do not have the luxury of turning to self-insurance. They can barely afford to provide the “basics” when it comes to health insurance. When faced with the addition of mandated benefits, some must choose between requiring their employees to share in the cost or eliminating health insurance coverage altogether. To make this point, we direct your attention to an article from the Washington Post, (November 13, 1997) which summarized a recent government report. The report concluded that while the number of American workers who are offered health insurance at work has continued to increase, rising premiums and out-of-pocket payments have prompted an increasing number of workers to pass up coverage, particularly the young and less affluent.”

Highmark goes on to state that, “Another point to be made about limiting the number of mandated benefits is the fact that the Commonwealth of Pennsylvania, when compared with surrounding states, stacks up well in the relative cost of health care. According to a recent study conducted by the Pennsylvania Economy League for the Pennsylvania Coalition for Quality Health Care, the ‘costs of health care is comparatively low for Pennsylvania employers.’ The study goes further by stating ‘Added costs through legislative regulation will erode Pennsylvania’s comparative position in competition for new jobs and retaining existing employment. Increased health care costs could turn one of Pennsylvania’s competitive advantages into one more negative factor in Pennsylvania’s business climate, a climate many people already feel is noncompetitive in many aspects.’ Mandated benefits such as contained in Senate Bill 1057 add to this dilemma.”

The Managed Care Association states in their submission that, “Bone mineral density screening can cost up to \$200 per screening and is not a guarantee to diagnosis. Because Senate Bill 1057 places no limit on either frequency of testing or duration or level of ongoing treatment, actual cost to the insurer/purchaser community are likely to be much higher than the cost of screening.” Also, “the Association contends that early prevention and patient-centered assessment and treatment – not legislative mandates – will provide the greatest impact to lowering costs related to osteoporosis later in life. Decisions regarding bone mass measurement and ongoing treatment for osteoporosis should be made by physicians on an individual, case-by-case basis. Health insurers should not be mandated to provide open-ended coverage for a specific, unproven mode of treatment for a specific condition.”

While *general* information regarding total cost was provided, the Committee concludes that neither supporters nor opponents of the bill provided sufficient, concrete information to the Council on which to base a cost estimate of the impact of the measure. In fact, much of the information received focused on mandates, in general, and was not specific to Senate Bill 1057. Further, no evidence of any potential cost *savings* was received. Since this information was not available to the Council, staff had to use some very broad, rudimentary assumptions to estimate the potential cost of the benefit.

COUNCIL COST ESTIMATES

Highmark Blue Cross Blue Shield estimates in their submission that, "According to the Pennsylvania Vital Statistics Annual Report 1995, 1.3 million women residing in the Commonwealth between the ages of 45-64 would be eligible for osteoporosis-related testing under Senate Bill 1057."

Independent research by Council staff have found the definition of "peri-menopause" in medical literature to be the time just before menopause, when the menstrual cycle is irregular and the length of the cycle varies from month to month. Additional research has found the following in a medical dictionary, "Menopause normally takes place between the ages of 35 and 58. If it occurs before the age of 35 it is *premature menopause*; after 58 it is called *delayed menopause*" (Miller 688). About 25 percent of American women reach menopause by 47, half by the age of 50, and 75 percent by 52, and 95 percent by age 55 (Miller 688).

The Office of Technology Assessment (OTA) estimates the actual cost of BMD screening at \$100 per patient. An article in the *Harvard Women's Health Watch* estimates that a DEXA scan costs about \$150 to \$200 (January 1996). The National Osteoporosis Foundation found from a survey conducted of osteoporosis clinics that the average charge for a bone density test measuring the hip and spine was \$215, including interpretation of the test results. Since Senate Bill 1057 does not specify whether benefits would be required to cover interpretation of test results and how many sites would be measured, Council staff chose to use the \$215 estimate of the NOF as a good ball park figure.

According to State Data Center statistics, there were an estimated 2.3 million women between the ages of 35 and 64 in Pennsylvania in 1996, and more than 1.1 million women 65 years of age and over--totaling more than 3.4 million women 35 years of age and over.

To estimate the potential pool of Pennsylvanians eligible for the benefits mandated under Senate Bill 1057, we applied several broad assumptions to find the following components of the eligible population:

- The female Medicare managed care population;
- The female Medicaid managed care population; and
- The non-ERISA exempt female population 35-64 years of age.

Council staff believe that Pennsylvanians receiving managed care services under Medicare would be affected by the bill. According to the Health Care Financing Administration, there were more than 2.1 million Medicare beneficiaries as of December 1997, and about 22 percent (467,000) of these individuals received Medicare managed care services (HCFA Web Site). State Data Center statistics show that more than 60 percent of individuals age 65 and over are female, which would lead to the gross estimation that more than **280,000 female Medicare beneficiaries who receive managed care services would be eligible for benefits under Senate Bill 1057**. Council staff caution that this estimate could be quite low since we know that the proportion of women in the population increases significantly with age (reaching more than 71 percent female for Pennsylvanians 85 and over).

Officials from the state's Department of Public Welfare estimate that there were 196,885 female Medicaid beneficiaries between 35 and 64 years of age as of the end of February, 1998 (Mancuso). According to estimates in the Governor's 1998-99 budget document, approximately 59 percent of Medicaid beneficiaries will be receiving managed care services. Applying this estimate to the female Medicaid beneficiaries 35 to 64 years old, we estimate there to be **about 115,500 Medicaid beneficiaries enrolled in managed care plans** who would be eligible for benefits under Senate Bill 1057.

We also note that nearly 100 percent of these Medicaid enrollees would eventually be eligible for benefits under Senate Bill 1057, since it is the Department of Public Welfare's stated intention to move the entire Medical Assistance Program to managed care in coming years.

To estimate the number of women ages 35 to 64 who would be eligible for benefits under Senate Bill 1057, Council staff also needed to find the proportion of the privately insured women who receive benefits under ERISA-exempt plans. If enacted, Senate Bill 1057 would be preempted by the federal Employee Retirement Income Security Act of 1974 (ERISA) (PL 93-406), which precludes state laws from applying to the benefit plans of self-insured companies. It is hard to estimate the percentage of private payers that are preempted by ERISA, but estimates have ranged as high as 50% to 70% of insureds.

According to the Department of Health 1996 statewide survey of health care coverage, about 85 percent of all insured women between 35 and 64 years of age (nearly 1.8 million) have employer-provided coverage.

If the 50% ERISA coverage estimate is chosen, more than **880,000** additional women would be eligible for benefits under Senate Bill 1057. If the 70 percent estimate is applied, more than 1.2 million women could be exempt—leaving about **530,000 women** eligible.

We estimate the potential pool of women who would be eligible for benefits under Senate Bill 1057 to be the sum of the following:

- + **280,000** Medicare managed care women
- + **115,500** women enrolled in Pennsylvania's Medicaid managed care plans
- + **530,000 to 880,000** non-ERISA exempt women

= 925,000 to 1.3 million women

Using the National Osteoporosis Foundation estimate that bone mineral density testing and corresponding test interpretation costs approximately \$215 dollars per patient, we estimate that the potential costs of Senate Bill 1057 could range from **\$199 million to \$275 million annually.**

As previously noted, the Council received no information from either proponents or opponents of the bill estimating the potential cost savings of the measure. While it is likely that any significant increase in prevention and early detection of osteoporosis would result in saved health care dollars from fractures, the degree to which the long-term savings would outweigh the cost is indeterminable. If only 50% of the eligible population would undergo bone density testing in any year, the cost for the test and interpretation could reach as high as from \$99 million to \$137 million per year.

Since scientific evidence does not seem to support a direct link between bone mineral density testing and a reduction of osteoporotic fractures or even increased compliance with hormone replacement therapy, we were unable to come up with any independent estimates of potential health care cost savings of the measure.

In addition to fiscal considerations, we raise the following policy issues for consideration in the discussion of Senate Bill 1057.

OTHER POLICY CONSIDERATIONS

Council staff have identified the following policy considerations to be of concern in the analysis of Senate Bill 1057:

- There appears to be no universal definition of what constitutes osteoporosis in terms of bone density measurement;
- Research does not seem to support the broad-based screening proposed under Senate Bill 1057; and
- There does not appear to be sufficient proof that coverage of bone density testing actually improves preventive efforts or reduces the incidence of osteoporotic fractures.

Insurance Commissioner Koken stated in her testimony before the House Insurance Committee on House Bill 1137, which would mandate mental health parity, that “While the Department believes that the services provided under mandated benefits may be important, we are concerned that this trend toward increasing mandated benefits has a negative impact on the consumers and purchasers of health insurance.” The Department’s concerns about employer mandates listed in the written testimony include the following:

- “they create an uneven competition between fully insured and self-insured employers and between Pennsylvania’s employers and employers in other states;
- they have a disproportionate effect on small employers and individuals purchasing health insurance;

- they reduce employer and consumer flexibility in choosing the most appropriate and affordable benefits;
- they increase the overall cost of health insurance; and
- they can lead to the loss of insurance coverage for Pennsylvanians, thereby increasing the overall uninsured rate in the Commonwealth” (Koken).

Commissioner Koken’s testimony has been reinforced by much research on the health care marketplace. Numerous studies have shown legislative mandates to be a significant contributing factor to rising health care costs, and the Council contends that it is important to use extreme caution in enacting such measures and it reserves the recommendation of such measures to those which are of proven efficacy and cost-effectiveness. The Council does not find that to be the case with Senate Bill 1057.

While the Council recognizes the importance of preventing osteoporosis and the burden this disease places on Pennsylvanians and the health care industry, we did not receive, nor could we find, evidence that bone mineral density testing is of proven efficacy or cost-effective, either in terms of dollars or quality of life.

Council staff research has found there to be no universal level of bone mineral density at which osteoporosis is defined. “There is no universal threshold value for defining osteoporosis and whom to treat. These values have a dramatic influence on those considered to be osteoporotic in a population, and the number of women who would be treated. For example, about 14% of the Swedish population between 40 and 89 years has a bone density value less than 2.5 standard deviations below the healthy adult population mean and about 52% have a bone density value less than 1 standard deviation below the healthy adult population mean” (Marshall).

In addition, Council staff were unable to find research that supports the broad-based screening called for under Senate Bill 1057, which includes perimenopausal status as a qualifying clinical indication for coverage of bone density testing. Even the model legislation of the National Osteoporosis Foundation, the “Osteoporosis Bone Mass Measurement Coverage Act,” does not include perimenopausal women among those qualified for coverage. This model Act would define “qualified individual” as: “an estrogen-deficient woman at clinical risk of osteoporosis and who is considering treatment; an individual with vertebral abnormalities; an individual receiving long-term glucocorticoid (steroid) therapy; an individual with primary hyperparathyroidism; or an individual being monitored to assess the response to or efficacy of approved osteoporosis drug therapies.” (See Appendix C.)

As previously noted, independent research by Council staff have found the definition of “peri-menopause” in medical literature to be the time just before menopause, when the menstrual cycle is irregular and the length of the cycle varies from month to month. Additional research has found the following, “Menopause normally takes place between the ages of 35 and 58. If it occurs before the age of 35 it is *premature menopause*; after 58 it is called *delayed menopause*” (Miller 688). About 25 percent of American women reach menopause by 47, half by the age of 50, and 75 percent by 52, and 95 percent by age 55 (Miller 688).

As discussed in the previous section, adjusting this number for the proportion of Pennsylvanians who are uninsured, those whose health plans are exempt under ERISA, and the proportion of women whose benefits are from non-managed care Medicaid or

Medicare plans, Council staff assert that the potential pool of Pennsylvanians who could be eligible for benefits mandated under Senate Bill 1057 could reach as much as \$199 to \$275 million. In addition, these women could be eligible for the benefit on an unlimited basis, as the bill does not specify that the test must be covered annually, biannually, etc.

Council staff also found research to show that, “Unfortunately, there are not studies to indicate whether one can predict later fracture incidence by bone mass measurements at the menopause. This critical question needs to be resolved before we can evaluate long-term therapeutic options. Moreover, bone mass measurements at the menopause may not tell us what is likely to happen to the patient over the next few years with or without treatment” (Raisz). We have concern that coverage of this test at an early age may lead women with early normal results to disregard important preventive efforts due to a false sense of security.

Some medical professionals also contend that, “Bone density, although important, is only one of many risk factors for fractures. The relative benefits of a high risk approach to prevention of osteoporosis through a BDM screening programme and subsequent treatment versus a population-based approach to increase the average bone density of the entire population through primary prevention activities such as exercise, reduced smoking, fall prevention strategies and dietary changes should also be evaluated in the health policy context” (Marshall).

It was also found that while the efficacy of routine bone density screening in asymptomatic individuals remains a controversial issue, neither the US Preventive Services Task Force or the Canadian Task Force on the Periodic Health Examination endorses routine BMD screening. These expert panels chose instead to recommend that clinicians counsel all peri- and post-menopausal women about the potential benefits and risks of hormone replacement therapy (Atkins). We find this to be significant.

“If there is any point, and there are certainly few, on which clinicians in this field can agree, it is that the most effective way to deal with osteoporosis is to prevent it” (Raisz). Since there appears to be little evidence that bone density testing improves osteoporosis prevention, Council staff raise the question as to whether prevention would not be more cost-effectively attained by improved education efforts.

Information submitted by the Magee-Womens Hospital Osteoporosis Prevention & Treatment Center emphasizes this need: a 1991 survey of American women found that 30% did not associate osteoporosis with disabling hip fractures, and 90% did not know death was a potential outcome. In addition, 60 percent of these women could not identify potential osteoporosis risk factors and nearly half saw no need to discuss the problem with their doctor.

Compliance with prescribed treatment is also a problem in osteoporosis prevention that can be addressed by patient education and counseling. “Estimates of [treatment] compliance for 10 years suggest that only 30% of women will still be taking therapy. There is also evidence that when HRT is discontinued, bone loss subsequently occurs at an accelerated early post menopausal rate, and after some years (3-6 years) the relative risk for fracture returns to the baseline. Finally, there is evidence that estrogen should be initiated early in the menopause and continued indefinitely for

protection against fractures. This means at least 20-30 years of use with high compliance” (Marshall).

The Pennsylvania Health Care Cost Containment Council finds that the cost of Senate Bill 1057 could reach as high as \$199 to \$275 million annually, and while it is likely that any significant increase in prevention and early detection of osteoporosis would result in saved health care dollars, the degree to which the long-term savings from prevention would outweigh the cost is indeterminable as no information was provided to the Council to show any projected cost savings of the measure.

The following section provides the conclusions of the Council’s Mandated Benefits Review Committee regarding the review of the benefits proposed under Senate Bill 1334.

Conclusions

While sympathetic to the plight of the Pennsylvanians and their family members whose lives have been affected by osteoporosis, Council staff suggest that the Mandated Benefits Review Committee not recommend passage of Senate Bill 1057 in its current form.

We conclude that, in as much as neither proponents nor opponents have submitted sufficient documentation pursuant to Act 34 of 1993, the Council did not receive the necessary and required information on the social and financial impact or the medical efficacy to warrant recommending approval of the mandated health benefits proposed under Senate Bill 1057.

One important point needs to be stressed: **There seems to be a significant need for public education in osteoporosis prevention.** Thirty percent of American women surveyed in 1991 did not associate osteoporosis with disabling hip fractures, and 90% did not know death was a potential outcome. The lack of awareness of potential osteoporosis risk factors as well as alternative prevention and treatment options is also a problem.

In addition to the suggestion that there is a need for improvement in public education and awareness of osteoporosis prevention; we note the following:

- Neither supporters nor opponents of the bill provided sufficient information to warrant a full review of the proposal; nor, given the documentation received, do we believe a panel of experts would come to conclusions different than the ones reached here.
- Our research has found there to be no universal level of bone mineral density at which osteoporosis is defined;
- There does not appear to be sufficient proof that coverage of bone density testing actually improves preventive efforts or reduces the incidence of osteoporotic fractures;
- We assert that using perimenopausal status as a definition for the clinical indication of bone density testing would result in very broad-based screening using methods for which there does not appear to be solid research to support efficacy. (Even the National Osteoporosis Foundation does not recommend universal screening.); and

- The potential cost of the proposal could reach as high as \$275 million annually, and while it is likely that an increase in prevention and early detection of osteoporosis could result in saved health care dollars from fractures, no information was provided that could be used to determine the degree to which the long-term *savings* from prevention would outweigh the cost of the benefit.

APPENDIX A — WORKS CITED

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- University of Wisconsin Comprehensive Cancer Center, "Breast Cancer Answers".
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APPENDIX B — DOCUMENTATION RECEIVED

1. Magee-Womens Hospital Osteoporosis Prevention & Treatment Center (Jean Johnson, Women's Health Advocate and Osteoporosis Program Coordinator)
 - A. "State Burden of Fractures Model"
 - B. "Fast Facts on Osteoporosis"
 - C. "Osteoporosis: The Human and Socioeconomic Impact"
 - D. "1996 and 2015 Osteoporosis Prevalence Figures State-by-State Report" National Osteoporosis Foundation
 - E. "Consensus Development Conference: Prophylaxis and Treatment of Osteoporosis" *The American Journal of Medicine*, Jan. 1991
 - F. "Hip Fractures: A Worldwide Problem Today and Tomorrow" *Bone*, 14, S1-S8. L.J. Melton, III
 - G. "Bone density at various sites for prediction of hip fractures." Cummings et al. *The Lancet*, Jan 9, 1993
 - H. "How Many Women Have Osteoporosis?" L.J. Melton, III, et al. *Journal of Bone and Mineral Research*, 1992
 - I. "Survival and Ambulation Following hip Fracture" Charles W. Miller, MD. *The Journal of Bone and Joint Surgery*, October 1978
2. National Osteoporosis Foundation (Susan Davidson, MS, RD, Senior Policy Analyst)
 - A. Letter addressing Section 9 issues
 - B. "State Burden of Fractures Model" - Pennsylvania
 - C. Amendments to 42 USC 1395 §1861 regarding Medicare Coverage of Bone Mass Measurements
 - D. "ORBD-NRC/National Osteoporosis Foundation Quality of Life + densitometry, bone density Annotated Bibliography - November 1997"
 - E. "Osteoporosis State Legislation" - List and summary of similar legislation in other states
 - F. Model Legislation, "Osteoporosis Bone Mass Measurement Coverage Act"
 - G. "Fast Facts on Osteoporosis"
 - H. "Impact of Osteoporosis in the United States: Key Citations Selected by the National Osteoporosis Data Group - Annotated"
 - I. "1996 and 2015 Osteoporosis Prevalence Figures State-by-State Report"
3. Highmark Blue Cross Blue Shield (Bruce R. Hironimus, Vice President Government Affairs)
 - A. Brief Letter
 - B. Paper addressing Section 9 issues
 - C. "Issue Review - States Turning to Evaluation Laws to Curb Mandated Benefits"
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 - F. "Health policy on bone density measurement technology in Sweden and Australia" Marshall, et al., *Health Policy* 35 (1996) 216-238 -- Journal Article
 - G. "The Cost of Health Insurance Mandates," National Center for Policy Analysis, Brief Analysis No. 237.

- H. "As Premiums Grow, More Workers Decline Health Insurance," The Washington Post, November 13, 1997 -- Newspaper Article
 - I. "Employer Health Care Costs--A Comparative Study of Its Role in Pennsylvania's Business Climate," by the Pennsylvania Economy League, Capital Division. April 1996
 - J. "Assessment of the Risk of Osteoporosis at Menopause: Therapeutic Consequences," L.G. Raisz, *Osteoporosis International* (1994) Suppl. 1:S53-57 -- Journal Article
 - K. "Bone densitometry assessment," Catalan Agency for Health Technology Assessment. Report Summary
 - L. "Osteoporosis: A cost (and bone) breakdown," Marilyn Dix Smith and William F. McGhan. *Business and Health*, September 1997 -- Journal Article
4. The Insurance Federation of Pennsylvania (John R. Doubman, Secretary & Counsel)
 - A. Letter addressing issues of Section 9
 - B. "Recommended use of Bone Densitometry Measurements," Document submitted to HCFA by the ad hoc committee of the Scientific Advisory Board of the National Osteoporosis Foundation that identifies the indications for bone mass measurement as justified by current research..
 - C. "Review of Assembly 201 by the Advisory Board to the Health Wellness Promotion Act"
 5. Mercy Hospital Of Pittsburgh (Susan N. Heck, Vice President, Institute Services)
 - A. Letter from B.J. Kruman, MPH, Manager Mercy Osteoporosis Center with attached documentation
 - B. Letter from Kathleen L. McDonald, MD, Director, Nuclear Medicine and Bone Densitometer Services
 - C. Letter from Diann Westrick, MD, Internal Medicine, Geriatrics
 - D. Letter from Lisa Zeman, RN, BSN, Clinical Coordinator, Osteoporosis Center
 - E. Letter from Camille Buonocore, MD, Medical Director, The Osteoporosis Center
 - F. Letter from John D. Brungo, MD, Chairman, Department of Medicine
 - G. Information addressing Section 9 issues
 6. Managed Care Association of Pennsylvania (Kimberly J. Kockler, Executive Director)
 - A. "The Cost of Health Insurance Mandates," National Center for Policy Analysis, Brief Analysis No. 237.
 - B. "The use of bone density measurement in the diagnosis and management of osteoporosis," William Sturtridge, MD, Ph.D., et al. *Canadian Medical Association Journal*, October 1, 1996 -- Journal Article
 - C. "Clinical practice guidelines for the diagnosis and management of osteoporosis," Scientific Advisory Board, Osteoporosis Society of Canada, *Canadian Medical Association Journal*, October 15, 1996 -- Journal Article -
 - D. "Noninvasive Assessment of Bone Mineral and Structure: State of the Art," Harry K.Genant, et al., *Journal of Bone and Mineral Research*, Vol. II, No 6, 1996 -- Journal Article
 - E. "Postmenopausal Osteoporosis: Diagnosis, Treatment, and Prevention," Marie A. Savard, MD, et al. *JCOM*, September/October 1996 -- Journal Article

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Findings of the Pennsylvania Health Care Cost Containment Council:
Mandated Benefits Review of Senate Bill 1057



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