Mandated Benefits Review by the Pennsylvania Health Care Cost Containment Council

Senate Bill 779

Prostate Specific Antigen Tests

Table of Contents

Executive Summary	1
Review of Senate Bill 779	3
Mandated Benefits Review Process	3
Overview of Senate Bill 779	3
Analysis of Act 34 Requirements	4
References	16
List of Submissions for Senate Bill 779	17
Copy of Senate Bill 779	21

EXECUTIVE SUMMARY

After reviewing the analysis of Senate Bill 779, the Pennsylvania Health Care Cost Containment Council does not find sufficient evidence to support this legislation in its present form. While recognizing the importance of preventive screenings, the Council did not find sufficient evidence to recommend that health insurance policies provide coverage for all costs associated with an annual prostate specific antigen (PSA) test for men age 50 and older, or men under age 50 upon a physician's recommendation.

Senate Bill 779 is similar to Senate Bill 39 (of 1997), which the Council was asked to review in 1998. At that time, the Council had concerns about the efficacy of prostate cancer screening. The same concerns remain with regard to Senate Bill 779.

We note the following points about Senate Bill 779:

- Many recognized organizations including the U.S. Preventive Services Task Force, the Centers for Disease Control and Prevention, the American College of Physicians and the National Cancer Institute do not recommend universal prostate cancer screening for asymptomatic men.
- There is no definitive connection between screening for prostate cancer and a reduction in prostate cancer mortality. The National Cancer Institute states, "There is insufficient evidence to establish whether a decrease in mortality from prostate cancer occurs with screening." Concerns were raised about mandating a particular procedure or test that has not been clinically proven to improve the quality or longevity of life for prostate cancer patients. Further, placing a single test or medical procedure into statute might not make good public policy since the test or procedure could be outmoded or disfavored in the future.
- Only one submission was received in support of Senate Bill 779. This submission
 did not provide the needed evidence that Pennsylvanians are denied access to a
 PSA test because of a lack of insurance coverage. According to information
 received by the Council, It appears that many insurers already cover the test.
- Assuming utilization rates ranging between 25 and 75 percent, the costs of providing this coverage may range between \$1.8 million and \$12.2 million annually.
 Insufficient information was provided to determine more precise figures.
- It is the Council's understanding that a series of clinical trials are currently underway to assess the impact of prostate cancer screening. Once completed, these clinical trials can provide much needed information about the efficacy of the PSA test. Until that time, current information does not support the need for the mandate proposed in Senate Bill 779.
- The Council also urges caution when considering health care mandates in general. In particular, attention must be given to the cumulative financial effect of enacting mandates. Further, while mandates impact the cost of health insurance, a state mandate will cover, on average, only 42 percent of the state's population.

 Finally, the Council's enabling legislation provides for a preliminary review of submitted materials to determine if documentation received is sufficient to proceed with the formal Mandated Benefits Review process outlined in Act 34 of 1993. We conclude that neither supporters nor opponents of the bill provided sufficient information to warrant a full review by a Mandated Benefits Review Panel; nor, given the documentation received, do we believe a panel of experts would come to conclusions different than the one reached here.

Review of Senate Bill 779

Overview of Senate Bill 779

Senate Bill 779, PN 871 would require all group and individual health insurance policies that provide hospital or medical/surgical coverage to provide coverage for all costs associated with an annual prostate specific antigen (PSA) test for men age 50 and older and for men under age 50 upon a physician's recommendation.

The Mandated Benefits Review Process

The Pennsylvania Health Care Cost Containment Council's enabling legislation, Act 89 of 1986 (as reauthorized by Act 34 of 1993), provides that the Council review proposed mandated health benefits when requested by the Secretary of Health or appropriate committee chairmen in the Pennsylvania Senate or the House of Representatives.

On June 29, 2001, Senator Edwin G. Holl, Chairman of the Senate Banking and Insurance Committee, requested that the Council review the provisions of Senate Bill 779, PN 871. Senator Michael O'Pake (D, Berks) is the bill's prime sponsor.

Notification was published in the *Pennsylvania Bulletin* on July 21, 2001, requesting that interested parties submit documentation and information pertaining to the bill to the Council by September 21, 2001. Letters were also sent to potentially interested individuals and organizations informing them of the pending review and inviting them to submit documentation pursuant to the notice. The Pennsylvania Department of Health and the Pennsylvania Insurance Department were notified and received copies of the submissions. Following the initial comment period, an opportunity was provided for interested individuals and organizations to examine the responses received and submit additional comments through November 9, 2001 based on that review.

A list of the submissions received and a copy of the bill are attached.

Act 34 provides for a preliminary Council 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 formal process involves another step beyond Council review by contracting with four additional experts to review the documentation submitted by proponents and opponents.

This report presents the results of the Council's preliminary review and the conclusions of the Council regarding whether the material is sufficient to proceed with the formal review process.

Overview of the PSA Test

The main screening tests for prostate cancer are the digital rectal examination (DRE) and the prostate specific antigen (PSA) test. The PSA test measures the level of PSA in the

blood. PSA blood test results are considered normal if under 4 nanograms per milliliter (ng/ml). According to the American Cancer Society, results over 10 ng/ml are high and values between 4 and 10 are considered borderline. The higher the PSA level the more likely the presence of prostate cancer. ¹

Analysis of Documentation Submitted by Opponents and Proponents in Response to the Eight Categories Required by Act 34, Section 9

Act 34 of 1993 provides that the documentation submitted to the Council by opponents and proponents of a proposed mandated benefit should address eight specific areas. In reviewing these eight points, determination is made whether the information received is sufficient to warrant the formal Mandated Benefits Review process outlined in the Act. Following are Council findings pertaining to the documentation received for Senate Bill 779 addressing each of these eight points.

(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.

While prostate cancer can occur in men of any age, the cancer usually develops in men over age 50. The American Cancer Society reports that more than eight out of ten men with prostate cancer are over the age of 65.

According to 1999 statistics from the Pennsylvania Department of Health, there are 910,223 men in the 50-64 age bracket who would be eligible for the benefits proposed in Senate Bill 779. The vast majority of men over age 65 already have coverage for prostate cancer screening through Medicare Part B.

The Pennsylvania Department of Health reports there were 9,626 prostate cancer cases reported in the Commonwealth in 1998 as compared to 5,437 in 1988—an increase of 77 percent. In 1998, there were 1,779 Commonwealth deaths attributed to prostate cancer as compared to 1,719 deaths reported in 1989. Based on information from the American Cancer Society, as submitted by Highmark, in 2001 there will be an estimated 10,900 new prostate cancer cases in Pennsylvania and 1,700 men will die from the disease.

Looking at this issue by age-adjusted information, Pennsylvania's age-adjusted *incidence* rate for invasive prostate cancer increased dramatically between 1988 and 1998, where the 1998 age-adjusted rate of 136.8 (per 100,000) was 70 percent higher than the 1988 rate of 80.3 (per 100,000). In contrast, the state's age-adjusted *mortality* rate due to prostate cancer (20.1 per 100,000 in 1999) has for the most part been declining since 1990 when the rate was 27.0. The Commonwealth's age-adjusted mortality rates for prostate cancer have generally been similar to or lower than the national average for the past several years. Nonetheless, the Department of Health reports prostate cancer is the second most common cause of male cancer deaths in Pennsylvania. ³

In addition to age, race is also a factor when determining the risk for getting prostate cancer. For example, African-American men have a high risk of developing prostate cancer. Information submitted by Highmark indicates prostate cancer occurs 70 percent more often in African-American men than it does in white American men. According to the Department of Health, the average annual (1994-98) *age-adjusted death rate* among African-American males was more than twice the rate for white males.

According to the 2000 survey conducted by the Pennsylvania Department of Health's Behavioral Risk Factor Surveillance System, 74 percent of men age 50 and older responded in the positive when asked if they ever had a PSA test. A higher percentage of men aged 65-74 (86 percent) reported having ever had a PSA test compared to 67 percent of men aged 50-64.

In an overall comment about the impact of benefit mandates and their availability to the Commonwealth's residents, information submitted by the Insurance Federation of Pennsylvania indicates state mandates that apply to all private group plans and individually purchased policies will cover only 42 percent of a state's population.

The submission from the Insurance Federation notes that determining the availability and use of the mandated benefit proposed in Senate Bill 779 is difficult to predict because many insurers already cover the test. They also questioned whether a mandate is necessary to encourage wider use or availability of the procedure.

Additional information regarding availability of the proposed benefit is discussed under section (ii) of this review.

(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.

Currently, men enrolled in Medicare have coverage for prostate cancer screening tests. Medicare supplement Part B provides coverage for a digital rectal exam (DRE) and PSA test (once every 12 months) for all men with Medicare age 50 and older. Information supplied by the Pennsylvania Department of Public Welfare indicates the Medical Assistance program provides coverage for the PSA test based upon the advice of the member's physician and the medically accepted periodicity of preventive tests.

Blue Cross of Northeastern Pennsylvania (BCNEPA) said PSA tests are a covered benefit for males age 50 and older for members enrolled in First Priority Health, their managed care plan. While not covered specifically for First Priority Health members under age 50, PSA tests requested for this population are generally approved. According to BCNEPA medical management, approvals for those under age 50 are based upon a physician's recommendation and established medical necessity criteria.

Blue Cross of Northeastern Pennsylvania reported a testing rate of 6.4 percent for those members age 50 and older who specifically had coverage for the PSA test (January 1 – July 31, 2001). BCNEPA noted that testing rates of those who are eligible remain low despite the availability of coverage for PSA tests under First Priority Health.

Geisinger Health Plan indicates the plan covers all PSA exams ordered by network physicians, but noted that the ultimate decision for testing must occur between the patients and their primary care provider.

Highmark reports that PSA tests are covered for its members if there are indicators that testing is needed, regardless of age. However, the PSA test is not a recommended routine screening for their HMO, point-of-service and PPO plans. For their traditional fee-for-service plan, the PSA test is not considered a standard benefit unless the employer group purchases a preventive benefits rider.

According to the Managed Care Association of Pennsylvania (MCAP), some commercial managed care plans consider prostate examinations as part of their preventive care services. In addition, commercial plans often provide coverage for the PSA test without a referral from a primary care physician.

According to supporters of the proposed legislation, a key population impacted by Senate Bill 779 would be the men enrolled in fee-for-service Medicaid. Based on information provided by the Pennsylvania Prostate Cancer Coalition, 1.3 million Pennsylvanians were eligible for Medical Assistance in 1998—including 94,548 men over the age of 45. It is anticipated that once enrollment in HealthChoices, the state's mandatory managed care program for Medical Assistance recipients, is complete, only five percent of the Medicaid population will remain in traditional fee-for-service Medicaid and thus eligible for the coverage offered in Senate Bill 779.

According to the Department of Public Welfare, the Medicaid program provides coverage for both preventive and diagnostic testing for prostate cancer. As long as determined to be medically necessary, reimbursement would be based upon the advice of the member's physician and the medically accepted periodicity of preventive tests. Such screenings would also be covered at an earlier age for patients at specific risk.

With regard to whether the lack of this benefit results in financial hardship, the Insurance Federation states that it would be difficult to make the case for financial hardship if the proposed benefit would not be covered. This statement was made in response to the \$73 estimate provided by the Insurance Federation. Furthermore, the Insurance Federation reports, "the (PSA) test is a predictive, not a curative measure, and on its own is not 100 percent determinative." However, they further note, any procedure which assists people in detecting the onset of prostate cancer is an important one.

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

Demand for Senate Bill 779

The Pennsylvania Prostate Cancer Coalition was the only submission received in support of Senate Bill 779. According to the Coalition, those who oppose the PSA mandate have an issue with the screening of asymptomatic men which leads to the detection and costly treatment of latent tumors that would have remained clinically silent and only discovered on autopsy. The Coalition submission indicates 87 percent of aggressive prostate cancer

tumors could be diagnosed within the first four years on annual testing. The Coalition suggests that an aggressive screening program would help to catch cancers early, enabling health professionals to intervene before they spread and thus prevent premature deaths. Further, the Coalition reports the PSA test has reduced the proportion of prostate tumors that are not detected until it is too late to treat them, especially in African-American men.

Supporters of Senate Bill 779 also point out that there appears to be a disproportionate allocation of resources for breast cancer and mammography when prostate cancer incidences are comparable but resources to screen are markedly less.

Opposition to Senate Bill 779

There is no consensus in the medical community about prostate cancer screening. For example, the American Cancer Society recommends that both the PSA blood test and a digital rectal exam should be offered annually at age 50, to men who have at least a ten year life expectancy. Men in high risk groups (African-American men and men with a family history) should begin testing at 45 years. The American Urological Association endorses the American Cancer Society's position. However, groups such as the U.S. Preventive Services Task Force, the Centers for Disease Control and Prevention, the American College of Physicians and the National Cancer Institute do not recommend universal prostate cancer screening.

The disparity in screening recommendations is due in part to the PSA test itself. According to several organizations, including the National Cancer Institute, the PSA test is controversial since it is not yet known if the process actually saves lives. Another concern involves the high false-positive rates of PSA screening tests. False positive test results occur mostly in men 50 and older. In this age group, 15 of every 100 men will have elevated PSA levels; of those 15 men, 12 will be false positives and three will have cancer.²

False positive results may lead to additional unnecessary medical procedures and anxiety for the patient and his family. The National Cancer Institute also reports that it is not clear if the benefits of PSA screening outweigh the risks of follow-up diagnostic tests and cancer treatments. As several opponents suggest in their submissions, medical experts have questioned the need for and benefits of routine prostate cancer screening.

In general, when it comes to cancer prevention and treatment, the medical community agrees that early detection and effective treatment leads to a longer life. With prostate cancer, where there is inconsistent information that early detection and treatment help most men, the issue is not as clear.

In addition to opponent's concerns about the lack of consensus in the medical community on this issue, they point out:

- There is insufficient evidence to establish where a decrease in mortality from
 prostate cancer occurs with screening by DRE, transrectal ultrasound or serum
 markers (PSA). (National Cancer Institute, National Institute of Health, "PDQ
 Screening for Prostate Cancer")
- Decisions regarding early detection of prostate cancer should be individualized and benefits and consequences should be discussed with the patient before PSA testing occurs. (Recommendations summarized by the National Guideline Clearinghouse)

Blue Cross of Northeastern Pennsylvania (BCNEPA) expressed concern that this legislation would give the impression that mass screening is favorable at a time when numerous professional organizations, including the National Cancer Institute, American College of Physicians and U.S. Preventive Services Task Force publicly oppose testing for prostate cancer. BCNEPA further notes that the Pennsylvania Department of Health takes a neutral position on prostate cancer screening but encourages men to discuss the issue and testing with their physicians.

Even with the relatively low cost of the test, Blue Cross of Northeastern Pennsylvania questions the need for the proposed mandate since a relatively small percentage of BCNEPA enrollees take advantage of PSA testing despite the existing availability of coverage.

Another concern expressed by opponents is that placing a single test or medical procedure into statute might not make good public policy since the test or procedure could be outmoded or disfavored in the future.

The American Family Life Assurance Company (AFLAC), while not opposing the mandate in general, suggests that supplemental insurance policies be excluded from the bill.

Overall, insurers cited concern with mandating coverage for a controversial procedure that has not been clinically proven to improve the quality or longevity of the life of prostate cancer patients.

Lastly, as currently written, Senate Bill 779 would apply to all group, individual health, sickness or accident insurance policies as well as *employee welfare benefit plans as defined in section 3 of the Employee Retirement Income Security Act (ERISA) of 1974* (Public law 93-406, 88 Stat. 829) providing hospital or medical/surgical coverage. The opponents question the ability of the state to enforce this provision as self-insured plans are preempted by federal law (ERISA) and therefore, exempt from state regulatory oversight.

Opposition to mandates in general

Historically, the business community and the health insurance industry are the organizations that resist the passage of new mandates. They cite concerns about mandates' impact on the cost of health insurance and how they limit purchasers' ability to select benefit packages. The Insurance Federation notes that insurers create benefit packages based on market demands. This allows insurers to be flexible in the benefit design and meet the needs of the particular groups purchasing the benefits.

Highmark reports that most businesses and insurers oppose mandated benefits because they increase premium costs and they "do not take into account whether the group workforce even desires or needs the coverage, depending upon the demographic profile of the group."

In noting that mandates interfere with the insurance marketplace, the Managed Care Association of Pennsylvania (MCAP) writes: "health insurance was never intended to cover any and all possible conditions that may arise. Insurers design benefit packages in response to purchaser demands. The cost of additional mandates is borne by those purchasers and their employees."

Potential increases in the number of uninsured is also a concern. MCAP reports that as health insurance costs rise, employers and individuals may drop coverage, thereby contributing to the increasing number of uninsured.

Blue Cross of Northeastern Pennsylvania provided information that indicates in Pennsylvania, for every one percent real increase in premium prices, 120,000 more working people will be added to the rolls of the uninsured by the year 2003. (Barents Group, LLP, 1998)

Opponents are also concerned about the cumulative, negative financial impact of all mandates imposed in Pennsylvania where there are approximately 30 benefit and provider reimbursement mandates in place—of which 11 mandates were passed during the 1990's. While one mandate may have minimal impact on costs, the cumulative impact of 30 or more mandates would impact the affordability of insurance coverage.

Other insurers reported that large employers might become self-insured in order to control health care costs and to avoid state-mandated benefits. Small employers, who generally do not have the ability to self-insure, must choose between cost sharing with employees or eliminating health insurance coverage altogether.

The Insurance Federation of Pennsylvania suggests that the restrictions resulting from benefit mandates can affect the business environment and detract from the state retaining or attracting businesses.

Highmark provided information from the Record of the Society of Actuaries' (Vol. 16, No. 1) that summarizes the concerns insurers and business have about mandates:

- State benefit mandates increase premiums which may, in turn, cause more employers to drop health benefits for employees;
- A study has demonstrated that each new benefit increases by 1.5 percent the likelihood that a small business may not be able to afford or offer coverage;
- State benefit mandates may cause an increasing number of large employers to self-insure, thus avoiding the need to implement such mandates;
- State benefit mandates tend to disproportionately advantage specific provider groups;
- State mandates increase administrative costs of both insurers and employers, particularly for multi-state employers; and,
- Legislatively mandated benefits further escalate the cost of health care coverage.

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

The Pennsylvania Prostate Cancer Coalition provided numerous examples of how African-American men are impacted by prostate cancer at a higher rate than other races. They reported that African-American men have a 61 percent greater incidence of prostate cancer than do Caucasian men.

Other submissions suggest the availability of such screenings appears adequate, but not utilized. Several commentators suggest that public health campaigns would be a way to better educate men and their families about health issues, including regular physician visits.

The impact of a lack of the proposed benefit is not clear since many insurers, such as HMOs and Medicare, already provide coverage for PSA screenings. It also appears the traditional indemnity plans such as those provided by Highmark and Blue Cross of Northeastern Pennsylvania provide coverage for PSA tests if the test is requested for diagnostic purposes when symptoms or risk factors are present.

(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.

Senate Bill 779 focuses on a particular *test*, not a therapy. No studies on controlled trials comparing the results of PSA testing versus not having the test were submitted to the Council.

(vi) Where the proposed benefit would mandate coverage of an additional class of practitioners, the results 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 the benefits.

Senate Bill 779 does not mandate coverage of an additional class of practitioners.

(vii) The results of any other relevant research.

Blue Cross of Northeastern Pennsylvania suggests the ideal way to assess the efficacy of screening is with prospective randomized clinical trials. While Blue Cross of Northeastern Pennsylvania reports trials of this nature on prostate cancer screening have not been conducted, the Pennsylvania Prostate Cancer Coalition submission included information about a series of clinical trials that are currently underway. According to the Coalition, the clinical trials are assessing the impact of prostate cancer screening on morbidity and mortality as well as assessing the impact of prostate cancer screening and treatment of early stage cancers compared to "watchful waiting."

Information about a long-term study conducted in Canada was provided by supporters. In 1988, researchers studied 46,289 male residents of Quebec City between the ages 45 and 80 who were randomized between screening and no screening. The first screening consisted of a digital rectal exam (DRE) and PSA test. If the PSA or DRE were abnormal, a transrectal echography of the prostate was performed. In eight years of follow-up, there were six deaths from prostate cancer found among the 8,129 who were screened, compared with 138 deaths among the 38,160 men not screened. The annual death rates

due to prostate cancer were calculated at 48.9 (unscreened) and 18.1 (screened) per 100,000 person-year.

Several commentators cited the U.S. Department of Health and Human Services' "Guide to Clinical Preventive Services" which does not recommend screening the general male population for prostate cancer. The guide further reports that there is currently no evidence that prostate cancer screening results in reduced morbidity or mortality, "in part because few studies have prospectively examined the health outcomes of screening."

The Highmark submission included several articles which addressed the medical consequences of prostate cancer screening. One article reviewed the appropriateness of screening for prostate cancer based on the burden of suffering from the disease, and on the effectiveness, potential harms and costs of screening. The article stated that "even though screening tests, such as the PSA, can detect early stages of disease, there is no evidence that clinical outcomes are improved by early detection."

Another article submitted by Highmark reviewed prostate cancer screening to determine if it improves mortality or alters the quality of life for men where a dormant cancer was discovered. The author of the article noted that screening for prostate cancer is a complex issue and needs additional research. Until that time, the author suggests that other influences, not just scientific facts, are impacting medical practices and that "more emphasis needs to be placed on educating the public about the risks and benefits of screening and treatment."

(viii) Evidence of the financial impact of the proposed legislation

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

According to information submitted by the Pennsylvania Prostate Cancer Coalition, the Medicare costs of prostate cancer testing which include a PSA and digital rectal exam is approximately \$35. The Insurance Federation of Pennsylvania indicates a PSA test costs \$73, while Blue Cross of Northeastern Pennsylvania (BCNEPA) submitted information indicating the average cost of \$33 per PSA test.

Supporters of the mandate submitted information suggesting that researchers have calculated both financial savings and determined that hardship exists from not screening for prostate cancer. Researchers estimated the cost per life year saved by screening with both the DRE and PSA was \$2,339 to \$3,005 for men age 50 to 69; \$3,822 to \$4,956 when only the PSA was used for men age 50 to 70. In comparison, supporters provided the range for other screenings including: breast (\$27,273 to \$55,887), colon (\$28,848 to \$113,348) and cervix (\$33,527). The Pennsylvania Prostate Cancer Coalition provided a study that determined that the cost of *not* screening for prostate cancer is approximately \$30,000 per case--which is calculated by subtracting the cost of treating early stage disease detected through screening from the cost of treating late stage disease. (Benoit & Naslund)

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

There are 26 states that have enacted laws requiring insurers to include coverage for PSA testing. These states are: Alaska, California, Colorado, Connecticut, Delaware, Georgia, Illinois, Indiana, Kansas, Louisiana, Maine, Maryland, Minnesota, Missouri, New Jersey, New York, North Carolina, North Dakota, Oklahoma, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Virginia and Wyoming. In addition, Utah passed a resolution encouraging private insurers and employers to include prostate cancer screening coverage in health benefit plans.

The only information submitted concerning the financial impact of similar legislation in other states was a fiscal analysis for Maryland House Bill 1040. The fiscal note was prepared in 1997 before the benefit was mandated and discusses only the expected impact on expenditures as part of the state employee benefit health plan. According to the Maryland Department of Fiscal Services, the estimated cost for covering state employees enrolled in the State employee health benefit plans would be \$314,600 in fiscal year 1998. Under the proposal, Medicaid would not be affected because the Medicaid program reimburses providers only for medically necessary health services.

The fiscal analysis did not contain a cost impact for small businesses. However, it noted that 40 percent of small businesses were covered under the state's Comprehensive Standard Health Benefit Plan, which is exempt from state mandated benefits. For the remaining 60 percent of small businesses, the analysis reports health insurance costs would increase if the business offers health insurance and their health plan is subject to mandated benefits. Further, the fiscal analysis reports that less than 36 percent of insured Maryland residents would be affected by the bill since state mandated benefits do not apply to self-insured health plans and federal programs such as FEHPB, CHAMPUS, Medicaid and Medicare (with the exception of enrollees who receive care through an HMO).

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

It is unknown how many men will voluntarily have the test if covered by insurance. According to Highmark, "the controversy surrounding the use of mass prostate cancer screening could potentially result in a number of men being tested unnecessarily." Blue Cross of Northeastern Pennsylvania is concerned that mandating the benefit will likely increase the demand for the test and utilization without any improvement in quality of care. Highmark noted, too, when a particular testing method is mandated, the insurer sees a correlating spike in the utilization rate for the test.

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

Highmark actuaries estimate that they will realize approximately \$300,000 - \$500,000 annually in administrative costs associated with the proposed mandate.

According to Highmark, "mandates always provide challenges in regard to administration since many man-hours are expended to prepare for the new benefit including claims processing system changes, revising benefit booklets and summary plan descriptions as well as communicating information to groups during the renewal process."

While no other insurer provided specific administrative cost estimates, others commented on this issue in general.

The Managed Care Association of Pennsylvania expressed concern that recent regulatory changes and numerous benefit mandates are "significantly increasing insurance costs." The Association also notes, "since the passage of Act 68 in 1998, as well as, the resultant regulations promulgated by the Departments of Insurance and Health, managed care plans are under increasing pressure to provide benefits while making numerous changes in their internal systems, policies and procedures in order to ensure compliance."

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

Highmark provided actuarial projections that indicate the cost of mandating the proposed benefit to its 6.5 million subscribers and members will exceed \$3 million to \$5 million annually.

If the proposed mandate would be enacted, Blue Cross of Northeastern PA theorized the following cost impact for its traditional fee-for-service plan:

For those 91,609 male members in the age range for PSA testing, a 10 percent increase in screenings would result in an increase of \$302,308; a 30 percent increase in usage would result in a \$906,924 increase; a 50 percent increase would result in a \$1,511,540 increase and 100 percent increase in screenings could result in \$3,023,081 rise in costs.

The Insurance Federation expressed concern that Senate Bill 779 is proposed at a time when employers are facing HMO health care cost increases of between 20 percent and 50 percent. Submissions reported additional costs would be passed on in the form of higher insurance premiums to employers which could result in increased employee cost-sharing or employers and individuals dropping health insurance coverage.

Information submitted by opponents about the overall cost of mandates to purchasers included a 1998 study that estimates that workers in Pennsylvania would lose more than \$5.2 billion in wages by the year 2003 if health care costs increase by 10 percent (Barents Group, LLC, 1998).

The Pennsylvania Prostate Cancer Coalition submission reports no direct data on mandated prostate cancer screening is available to analyze the cost increases to purchasers. However, the Coalition suggests using extrapolated data on mammography screening to obtain a rough cost estimate on prostate cancer screening. Citing a 1997 study conducted by Milliman and Robertson that analyzed the cost of health insurance mandates, mammography screening was estimated to increase the cost by less than one percent at an annual cost of less than \$35 for a family policy. (National Center for Policy Analysis, 1997).

Opponents cited the same Milliman and Robertson study, which reported the estimated cost of twelve of the most common mandates (including mammography) to have the potential to increase the cost of a family policy between \$525 and \$1,050 a year. This point supports the opponents' concerns about the cumulative cost of mandates.

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

Prostate Cancer Screening Costs

Population to be Affected. According to 1999 information from the Department of Health, Pennsylvania's male population age 50 and older is estimated to be 1.6 million. Of that total, 910,223 men in the 50-64 age bracket would be eligible for the benefits proposed in Senate Bill 779. The vast majority of men over age 65 already have coverage for the screening through Medicare Part B.

Percentage of Population Already Covered. Based on information submitted by the Insurance Federation, mandates such as this (i.e., those which apply to all private group plans and individually purchased policies) will cover only about 42 percent of the state's population due to ERISA. In addition it was estimated that 42 percent of the eligible population already has coverage for the proposed screening through gatekeeper managed care plans (which are likely to already offer PSA tests as a preventive screening). It is also estimated that approximately 8.3 percent of the population does not have insurance coverage. The potential pool of beneficiaries, therefore, after accounting for ERISA exemptions, the uninsured and existing coverage, is approximately 203,327. The Council received insufficient information to estimate the number of men under age 50 who will have the test upon a physician's recommendation.

Prostate Cancer Screening Procedure Costs. Cost estimates ranging between \$33 and \$73 for PSA tests were provided to the Council. Insurer administrative expenses would add approximately an additional 10 percent per year to the cost of the mandate.

Projected Costs. Because the Council was not provided with information to determine the number of men who would likely undergo a PSA test if the proposed mandate is enacted, various assumptions were made to estimate the potential costs associated with utilization increases. Among those potentially eligible for the mandate (e.g., those who already don't have coverage), the following annual estimates were calculated:

Assuming 25 percent utilization - \$1.8 - 4.1 million Assuming 50 percent utilization - \$3.7 - \$8.1 million Assuming 75 percent utilization - \$5.5 - \$12.2 million

Potential Cost Savings. Supporters of Senate Bill 779 claim prostate cancer testing is cost effective when compared to the costs associated with breast cancer screening. According to information submitted by the Pennsylvania Prostate Cancer Coalition, a study was performed comparing Medicare costs for the combined costs of a DRE and PSA (\$35) and a mammogram (\$58). It was also noted that the cost of treating early stage prostate cancer is approximately \$20,000 versus \$50,000 for late stage disease.

The Pennsylvania Prostate Cancer Coalition suggests that the impact of a prostate cancer screening mandate would have minimal financial impact on the total cost of health care in Pennsylvania. The Coalition submission reports the benefit of the mandate would be "the lives saved from offering a screening benefit to those whom presently have none, and from the financial savings of detecting earlier and easier to treat disease versus advanced disease usually found in those who never undergo screening."

References

¹"Prostate Cancer Treatment Guidelines for Patients," American Cancer Society, January 2001.

²"Questions and Answers about the Prostate-Specific Antigen (PSA) Test," National Cancer Institute, January 11, 2001, http://search.nci.nih.gov.

³"Prostate Cancer in Pennsylvania," Pennsylvania Department of Health, Bureau of Health Statistics, August 2001.

⁴ Health Insurance Coverage: 2000," U.S. Census Bureau, September 2001.

Submissions for Senate Bill 779

AFLAC - American Family Life Assurance Company of Columbus (Mr. Richard J. Gmerek of the Law Offices of Gmerek & Hayden)

- 1. Cover letter regarding SB 779 dated September 21, 2001.
- "Statement of AFLAC Regarding Health Care Cost Containment Council's Review of Senate Bill 779."
- 3. Excerpt from the Health Insurance Portability and Accountability Act of 1996 at Section 2791(5); Individual Health Insurance Coverage under Subsection C: Excepted Benefits. Public Law 104-191. August 21, 1996.
- National Association of Insurance Commissioners Health Carrier External Review Model Act.
- 5. Omnibus language found in National Association of Insurance Commissioners Health Carrier External Review Model Act.

<u>Blue Cross of Northeastern Pennsylvania (Ms. Kimberly Kockler, Director, Policy Management)</u>

- 1. Letter regarding Senate Bill 779 and addressing requirements of Act 34 dated September 19, 2001.
- 2. "Prostate cancer in Pennsylvania." PA Department of Health, Bureau of Health Statistics. August 2001.
- "Screening for Prostate Cancer." http://my.webmd.com/content/dmk/dmk_article_3460985.
- 4. "To Screen or Not to Screen." http://prostatepointers.org/ww/toscreen.htm.
- 5. Lefevre, ML. "Prostate cancer screening: more harm than good?" American Family Physician. August 1998.
- 6. "Fundamentals of Prostate Cancer Detection and Treatment." January 27, 1999. http://ww.prostatepointers.org/ww.home.htm.
- 7. "The Prostate Controversy." March 4, 2001. http://abcnews.go.com/onair/WorldNewsTonight/wnt990304 prostate story.html.
- 8. Napoli, M. "Prostate Awareness: Its Perils and Its Benefits." Healthfacts. October, 1999.
- 9. "Impacts of Four Legislative Provisions on Managed Care Consumers: 1999-2003." American Association of Health Plans. Prepared by Barents Group, LLC. April 22, 1998.

Geisinger Health Plan (Duane E. Davis, M.D., Senior Vice President, Medical Director)

1. Letter regarding Senate Bill 779 dated August 20, 2001.

Highmark (Bruce R. Hironimus, Vice President of Government Affairs)

- 1. Cover letter regarding Senate Bill 779 dated September 21, 2001.
- 2. "Mandated Benefits Submission to the Pennsylvania Health Care Cost Containment Council: Senate Bill 779; Prostate Cancer Screening Mandate." September 21, 2001.
- American Cancer Society. "Cancer Facts & Figures 2001."

- 4. "What is Prostate Cancer and Who Gets It?" WebMD Health. http://my.webmd.com/content/article/1680.50799.
- 5. American Cancer Society. "Prostate Cancer: What is it?" http://www3.cancer.org/cancerinfo/load_cont.asp?st=wi&ct=36&language=english.
- 6. American Cancer Society. "Prostate Cancer: Prevention and Risk Factors." http://www3.cancer.org/cancerinfo/load_cont.asp?st=wi&ct=36&language=english.
- 7. American Cancer Society. "Prostate Cancer: Detection and Symptoms." http://www3.cancer.org/cancerinfo/load_cont.asp?st=wi&ct=36&language=english.
- 8. U.S. Census Bureau. "Profile of General Demographic Characteristics: 2000."
- 9. Employee Benefit Research Institute. "Sources of Health Insurance and Characteristics of the Uninsured: Analysis of the March 1999 Current Population Survey." EBRI Issue Brief Number 228. December 2000.
- 10. "Screening for Prostate Cancer Summary of Evidence." WebMD Health. http://webmd.com/content/article/1680.50803.
- 11. "Screening for Prostate Cancer Recommendation." WebMD Health. http://my.webmd.com/content/article/1680.51858.
- 12. National Guideline Clearinghouse. "Prostate specific antigen (PSA): best practice policy." American Urological Association. December 21, 1999. http://www.guideline.gov.
- 13. Symon, Z, MD. "Broadening the Scope of Prostate Cancer Therapies." 37th Annual Meeting of the American Society of Clinical Oncology. May 15, 2001. http://medscape.com.
- 14. "To Screen or Not to Screen." http://www.prostatepointers.org/ww/toscreen.htm.
- 15. National Center for Policy Analysis. "The Cost of Health Insurance Mandates." August 13, 1997.
- 16. The Kaiser Family Foundation and Health Research and Educational Trust. "Employer Health Benefits: 2001 Summary of Findings." September 6, 2001.
- 17. Thorpe, KE and CS Florence. "Why Are Workers Uninsured? Employer-Sponsored Health Insurance in 1997." *Health Affairs*. March/April 1999.
- 18. Employee Benefit Research Institute. "Employment-Based Health Benefits: Who is Offered Coverage vs. Who takes it." EBRI Issue Brief Number 213. September 1999.
- 19. "Microbubble Ultrasound Improves Screening Sensitivity for Prostate Cancer." August 6, 2001. http://www.acurian.com/diseases.
- 20. Alberta Clinical Practice Guidelines Program. "Guideline for Use of PSA and Screening for Prostate Cancer." www.amda.ab.ca.
- 21. Woolf, SH. "Public Health Perspective: The Health Policy Implications of Screening for Prostate Cancer. *The Journal of Urology.* Vol. 152, 1685-1688. November 1994.
- 22. Catalona, WJ., et. al. "Comparison of Digital Rectal Examinations and Serum Prostate Specific Antigen in the Early Detection of Prostate Cancer: Results of a Multicenter Clinical Trial of 6,630 Men." *The Journal of Urology.* Vol. 151, 1283-1290. May 1994.
- 23. Chodak, GW, M.D. "Questioning the Value of Screening for Prostate Cancer in Asymptomatic Men." *Urology*. Vol. 42, No. 2. August 1993.
- 24. Miller, AB. "What is the Role of Early Detection and Screening in Cancer Control." *Journal of Public Health Policy*. Winter 1993.
- 25. Jensen, G, Ph.D. and M. Morrisey. "Mandated Benefit Laws and Employer-Sponsored Health Insurance." The Health Insurance Association of America. January 1999.

- 26. "Analysis of Health Care Mandates and Controls." The Minnesota Council of Health Plans, The Minnesota Chamber of Commerce, The Minnesota Business Partnership. March 18, 1999.
- 27. Seward, JA, Ph.D. and JW. Henderson, Ph.D. "Report on the Cost of Health Care System Mandates." Executive Summary. Baylor University. January 1999.

<u>The Insurance Federation of Pennsylvania, Inc. (John R. Doubman, Secretary & Counsel)</u>

- 1. Letter regarding Senate Bill 779 and addressing requirements of Act 34 dated September 19, 2001.
- 2. Guidera, J. "Study Raises Doubts on Tests to Screen for Colon Cancer." *The Wall Street Journal*. August 23, 2001.
- 3. "Employers Face Sticker Shock on Health Costs." http://knowledge.wharton.upenn.edu/whatshot.cfm.
- 4. Jensen, G, Ph.D. and M. Morrisey. "Mandated Benefit Laws and Employer-Sponsored Health Insurance." The Health Insurance Association of America. January 1999.
- 5. "The Effect of Health Plan Mandates on Cost and Access." Health Insurance Association of America. March 29, 1999.
- 6. "Response: NCSL Talking Points on State Mandated Benefits." Health Insurance Association of America.

<u>Managed Care Association of Pennsylvania (Dolores M. Hodgkiss, Executive Director)</u>

1. Letter regarding Senate Bill 779 and addressing requirements of Act 34 dated September 21, 2001.

<u>Pennsylvania Prostate Cancer Coalition (COL (Ret) James E. Williams, Jr. USA, Co-Chairman)</u>

- 1. Cover letter regarding Senate Bill 779 dated November 8, 2001.
- 2. "Documentation presented to the PA Cost Containment Council in accordance with the information categories described in Section 9 of Act 34 of 1993 in review of SB 779." November 8, 2001.
- 3. "American Cancer Society Guidelines for Early Detection of Cancer in Asymptomatic People," PA Department of Health, Cancer Facts and Figures, Pennsylvania, 2001
- 4. "Cancer of the Prostate Data Highlights." Pennsylvania Department of Health. Pennsylvania Cancer Incidence and Mortality 1994-1998. Extract.
- 5. Coverage for Annual PSA Tests in Other States
- 6. "Prostate research finds test effective," *Philadelphia Inquirer*, May 19, 1998.
- 7. Lebrie, F., et.al. "Decrease of Prostate Cancer Death by Screening: First Data from the Quebec Prospective and Randomized Study. Abstract
- 8. "Prostate Cancer Hot Sheet". Us Too! International. January/February 2001.
- 9. Meyer, F., M.D., DSc. and Y. Fradet, M.D. *"Prostate Cancer: Screening."* Canadian Medical Association Journal. October 20, 1998. http://www.cma.ca/cmaj/vol-159/issue-8/0968.htm.
- 10. Senate Bill 428, State of Maryland. 1997 Legislative Session.
- 11. House Bill 1040, State of Maryland. 1997 Legislative Session.

- "Fiscal Note House Bill 1040." Department of Fiscal Services. State of Maryland. February 10, 1997. Reference list. 12.
- 13.

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 779

Session of 2001

INTRODUCED BY O'PAKE, WAGNER, LOGAN, MUSTO, BODACK, TARTAGLIONE, COSTA, LAVALLE, HUGHES, TILGHMAN, GREENLEAF, MELLOW, RHOADES, STOUT, STACK, SCHWARTZ, BOSCOLA AND WILLIAMS, APRIL 4, 2001

REFERRED TO BANKING AND INSURANCE, APRIL 4, 2001

AN ACT

1 2 3 4 5 6 7 8 9 10 11	Amending the act of May 17, 1921 (P.L.682, No.284), entitled "An act relating to insurance; amending, revising, and consolidating the law providing for the incorporation of insurance companies, and the regulation, supervision, and protection of home and foreign insurance companies, Lloyds associations, reciprocal and inter-insurance exchanges, and fire insurance rating bureaus, and the regulation and supervision of insurance carried by such companies, associations, and exchanges, including insurance carried by the State Workmen's Insurance Fund; providing penalties; and repealing existing laws," providing for health insurance reimbursement for prostate specific antigen examinations.
13	The General Assembly of the Commonwealth of Pennsylvania
14	hereby enacts as follows:
15	Section 1. The act of May 17, 1921 (P.L.682, No.284), known
16	as The Insurance Company Law of 1921, is amended by adding a
17	section to read:
18	Section 635.2. Coverage for Prostate Specific Antigen
19	Examinations All group or individual health or sickness or
20	accident insurance policies providing hospital or
21	medical/surgical coverage and all group or individual subscriber

contracts or certificates issued by any entity subject to 40

- 1 Pa.C.S. Ch. 61 (relating to hospital plan corporations) or 63
- 2 (relating to professional health services plan corporations),
- 3 this act, the act of December 29, 1972 (P.L.1701, No.364), known
- 4 <u>as the "Health Maintenance Organization Act" or an employe</u>
- 5 welfare benefit plan as defined in section 3 of the Employee
- 6 Retirement Income Security Act of 1974 (Public Law 93-406, 88
- 7 Stat. 829) providing hospital or medical/surgical coverage shall
- 8 also provide coverage for prostate specific antigen (PSA)
- 9 <u>examinations</u>. The minimum coverage required shall include all
- 10 costs associated with a PSA examination every year for men fifty
- 11 years of age or older and with any PSA examination based on a
- 12 physician's recommendation for men under fifty years of age.
- 13 Section 2. This act shall take effect in 60 days.