Mandated Benefits Review by the Pennsylvania Health Care Cost Containment Council

Senate Bill 146
Colorectal Cancer Screening

Pennsylvania Health Care Cost Containment Council
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EXECUTIVE SUMMARY

The Pennsylvania Health Care Cost Containment Council is required to review current or proposed mandated health benefits on request of the executive and legislative branches of government [Section 9 of Act 14 of July 17, 2003 (P. L. 31, No. 14) (Act 14)]. The Council's role in conducting reviews of this nature is primarily to determine if sufficient evidence is available to proceed to a more formal Mandated Benefits Review Panel as outlined in Act 14, which includes contracting with a panel of outside experts to review the scientific validity of the studies Documentation would be deemed sufficient if it met the necessary requirements for the Panel to fulfill their duties and responsibilities which include: (1) review of the documentation submitted by opponents and proponents, (2) report to the Council on whether the documentation is complete with regard to the eight information categories described in Act 14, whether the research cited meets professional standards, whether all relevant research has been cited in the documentation, and whether the conclusions and interpretation in the document are consistent with the data submitted. Act 14 places the burden of providing scientific data and information regarding the proposed mandate on interested parties. While the Council conducts its own research as appropriate, the reviews rely almost entirely upon outside information as detailed in the enabling legislation.

This document presents the results of the Council's review of Senate Bill 146, which would require health insurance policies, except to the extent already covered by another policy, to provide coverage for colorectal cancer screening for individuals in accordance with the most recently published American Cancer Society guidelines for colorectal cancer screening and consistent with approved medical standards and practices.

In the case of Senate Bill 146, we concluded our review and present the following points to the General Assembly:

- The medical community appears to agree on the general efficacy of colorectal cancer screening, and there is research to suggest that early identification of colorectal cancer leads to decreased treatment costs. Further, documentation presented by the American Cancer Society indicates that colorectal cancer screening rates have risen faster and are significantly higher in states that have mandated coverage.

- A key point, however, centers on whether certain tests are preferred in terms of medical efficacy, the cost effectiveness of each of the tests, and how these issues might affect a health care purchaser's ability to tailor products that emphasize cost containment. The following paragraphs address these points:

  Several studies indicated that while the benefits of screening are evident, a single optimal colorectal cancer screening method could not be identified. One literature review revealed that more "studies of available tests are needed to clarify the optimal screening method and screening intervals," and a second review found that the existing literature does not support the use of one method over another. Additionally, documentation submitted regarding two studies published in the *New England Journal of Medicine* indicated that while flexible sigmoidoscopy may be a "suboptimal" approach, compared to colonoscopy, the two studies could not answer the broad policy question of whether everyone over 50 should have routine colonoscopies. Finally, the U.S. Preventive Services Task Force, while strongly recommending

colorectal cancer screening for men and women 50 years of age or older, suggests that there are insufficient data to determine which particular screening strategy is best in terms of the balance of benefits and harms or cost-effectiveness.

According to the 2007 Legislative Budget and Finance Committee (LBFC) colorectal cancer screening study, research has found that repeated stool blood testing can detect up to 92% of cancers, flexible sigmoidoscopy can identify 80% of cases, and regular colonoscopies can detect 76% to 90% of cases. The LBFC report also found that while colonoscopy was deemed cost-effective by the standard threshold in economic outcomes research, it was found to be less cost-effective than other screening methods.

Thus, given the fact that less expensive tests appear to be effective in detecting colorectal cancer, the Council is concerned that Senate Bill 146, as currently written, would limit the ability of health care purchasers to design products that stress cost containment – especially since the existing literature does not support the use of one method over another.

- The Council received more studies for the review of Senate Bill 146 than it did for a similar review on colorectal cancer screening that was completed in May 2002. However, there were still deficiencies in the information received that would be required for the Council to recommend further study as outlined in Act 14. While some submitters provided actual copies of studies to support their positions, they often did not include accompanying statements with regard to the specific eight points the Council is required to examine as outlined in statute. Others referenced the studies in their accompanying statement but did not include actual copies of the studies. In other instances, only bibliographical citations for studies were listed without any statement regarding their relevance.

- Several opponents found it troubling that Senate Bill 146 gives the American Cancer Society the ability to change or expand upon the mandated coverage without legislative oversight. Opponents also cautioned against putting testing requirements into statute as advancements in screening are likely in the near future, which may be less intrusive, safer and less expensive.

- In reference to concerns about mandated benefits in general, the Council agrees with an important point raised, which is that insurers should be able to tailor their benefit packages as the needs of individual and group customers vary and so low-income individuals can access basic coverage at an affordable price.

- The Council also considered this legislation in light of concerns raised about the cumulative effect of all health care mandates in Pennsylvania. According to a July 2006 Heritage Foundation study, "The Effect of State Regulations on Health Insurance Premiums: A Revised Analysis," health insurance premiums are $80 per month higher in states requiring more than the national average of 26 mandated benefits. In Pennsylvania, there are 30 health benefit and provider mandates.

- Based on PHC4's analysis, the estimated annual costs for the colorectal cancer screening benefits under this mandate ranged from a low of $67 million to a high of almost $122 million. The low estimates were based on a 55% utilization rate among the eligible population, which represents a 10% increase in the estimated current utilization. The high

estimates were based on 100% utilization as called for by the advocates. For these calculations, it was also assumed that, among those opting to comply with screening, 75% would choose colonoscopy, 20% would choose the fecal occult blood test, and 5% would choose sigmoidoscopy, as referenced in the Legislative Budget and Finance Committee report.

The potential increase in cost associated with increased screening may be offset by a decrease in the cost of treating this cancer if diagnosed at an earlier stage. In 2006, there were 3,192 hospital admissions for commercially insured patients, age 40 to 64, in which colorectal cancer was either a principal or a secondary diagnosis. Pennsylvania hospitals received an estimated $45.4 million in revenue from commercial insurers for these hospital admissions.

REVIEW OF SENATE BILL 146

Overview of Bill

Senate Bill 146 would require health insurance policies, except to the extent already covered by another policy, to provide coverage for colorectal cancer screening for individuals in accordance with the most recently published American Cancer Society guidelines for colorectal cancer screening and consistent with approved medical standards and practices.

Mandated Benefits Review Process

PHC4's enabling legislation, Act 89 of 1986 (as re-authorized by Act 34 of 1993 and Act 14 of 2003), provides that PHC4 review current law or proposed legislation regarding mandated health benefits when requested by the executive and legislative branches of government. Senator Donald White, Chairman of the Senate Banking and Insurance Committee, requested that PHC4 review the provisions of Senate Bill 146, PN 191. Senator Robert M. Tomlinson is the bill's prime sponsor.

Notification was published in the *Pennsylvania Bulletin* on August 4, 2007, requesting that interested parties submit documentation and information pertaining to Senate Bill 146 to PHC4. Letters also were sent to potentially interested individuals and organizations informing them of the pending review and inviting them to submit information pursuant to the notice. Following the initial comment period, an opportunity was provided for interested individuals and organizations to examine the responses received and submit additional comments. Final submissions were due to PHC4 on November 19, 2007. The Pennsylvania Department of Health and the Insurance Department were notified of the review and received a copy of the submissions.

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

Act 14 provides for a preliminary PHC4 review to determine if the documentation submitted is sufficient to proceed with the formal Mandated Benefits Review process outlined in the Act. This formal process involves another step beyond PHC4's review by contracting with five additional experts to review the documentation submitted by proponents and opponents.

This report presents the results of PHC4's preliminary review and conclusions regarding whether the material is sufficient to proceed with the formal review process. It should be noted that, in May 2002, the Council reviewed Senate Bill 636, which proposed a similar colorectal cancer screening mandate. For Senate Bill 636, there was not sufficient evidence submitted to the Council to recommend the bill or to continue with the formal review process.

American Cancer Society's Guidelines for Colorectal Cancer Screening

The mandated benefits and coverage proposed in Senate Bill 146 are dependent upon the most recently published guidelines for colorectal cancer screening issued by the American Cancer Society. At this time, the American Cancer Society's guidelines are as follows:

Beginning at age 50, both men and women at average risk should have one of the following five screening options below:

- Yearly fecal occult blood test (FOBT) or fecal immunochemical test (FIT) [for FOBT, the take-home multiple sample should be used]
- Flexible sigmoidoscopy every five years
- Yearly FOBT or FIT *plus* flexible sigmoidoscopy every five years [the combination of FOBT and flexible sigmoidoscopy is preferred over either of the first two tests alone]
- A double-contrast barium enema every five years
- A colonoscopy every ten years

All positive tests should be followed up with colonoscopy.

Individuals should begin colorectal cancer screening earlier and/or undergo screening more often if they have any of the following colorectal cancer risk factors:

- A strong family history of colorectal cancer or polyps,
- A known family history of hereditary colorectal cancer syndromes,
- A personal history of colorectal cancer or adenomatous polyps, or
- A personal history of chronic inflammatory bowel disease.

Overview of Colorectal Cancer Screening Procedures

The *fecal occult blood test* (FOBT) is used to find occult (hidden) blood in feces. Usually, a patient will receive a test kit with instructions that explain how to take a stool sample at home. The kit is then returned to the doctor's office or a medical laboratory for testing.

A *fecal immunochemical test* (FIT), also known as an immunochemical fecal occult blood test (iFOBT), is a newer kind of stool blood test, which detects occult blood in the stool – the “globin” part of the hemoglobin molecule. The test is essentially conducted the same way as FOBT, but it is more specific and reduces the number of false positive results.

A *sigmoidoscopy* is an examination in which a physician uses a sigmoidoscope – a slender, flexible, hollow, lighted tube about the thickness of a finger – to examine the lower part of the colon. The sigmoidoscope is inserted through the rectum and is about two feet long, allowing the physician to see less than half of the colon. The physician can look through the scope, and it can also be connected to a video camera for better viewing.

A *colonoscopy* is an examination similar to a sigmoidoscopy, but it allows a physician to examine the entire colon. A colonoscope, which is a long version of a sigmoidoscope, is inserted through the rectum up into the colon. The colonoscope is connected to a video camera and display monitor so the physician can closely examine the inside of the colon. If a polyp is found, the physician may remove it during the colonoscopy. A wire loop is passed through the colonoscope to cut the polyp from the wall of the colon with an electrical current. The polyp can then be sent to a lab to be checked under a microscope to see if it has any areas that have changed into cancer.

A *double-contrast barium enema* is a procedure in which barium sulfate, a chalky substance, is used to partially fill and open up the colon. Once the colon is expanded, x-rays are taken to examine the colon.

Analysis of Documentation Submitted by Opponents and Proponents in Response to the Eight Categories Required by Act 14, Section 9

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.

Affected population. Citing the American Cancer Society's "Cancer Prevention and Early Detection Facts & Figures 2007," Highmark reported that colorectal cancer is the second leading cause of cancer death in the United States and that, in 2007, there will be an estimated 153,760 new cases of colorectal cancer nationwide (112,340 colon cancer cases and 41,420 rectal cancer cases). According to the same source, the estimated number of U.S. deaths from colorectal cancer for 2007 is 52,180, and for Pennsylvania, it is estimated that 8,220 new colorectal cancer cases will occur in 2007.

Highmark also referenced the January 2007 Pennsylvania Legislative Budget and Finance Committee (LBFC) report, "A Study on Various Aspects of Colorectal Cancer Screening," which found that Pennsylvania has a colorectal cancer incidence rate of 57.9 per 100,000, which is significantly higher than the national rate of 52.0 per 100,000.

According to the LBFC report, the state's mortality rate for colorectal cancer (22.2 cases per 100,000 population per year) also is higher than the U.S. mortality rate (20.0 cases per 100,000 population per year). The report stated there would be an estimated 8,000 new cases of and 2,970 deaths from colorectal cancer in 2006. The lifetime risk of developing colorectal cancer is approximately 6%, and more than 90% of all cases are diagnosed in persons age 50 and older.

Additionally, the LBFC report indicated that the risk of being diagnosed "is greater among individuals with a personal or family history of colorectal cancer and or colorectal polyps, a personal history of inflammatory bowel disease and certain inherited genetic characteristics (e.g., familial adenomatous polyposis [FAP] and hereditary nonpolyposis colorectal cancer [HNPCC])." The report noted that 25% to 30% of the population is at increased risk for colorectal cancer due to heredity factors.

In his submission, Dr. Thomas J. McGarrity, Professor of Medicine & Chief of the Division of Gastroenterology/Hepatology at the Penn State Milton S. Hershey Medical Center, reported that there will be an estimated 2,730 deaths from colorectal cancer in Pennsylvania in 2007. As in the LBFC report, he indicated that the average lifetime risk for developing colorectal cancer is approximately 6%. He also noted that the risk of developing cancers increases by 12% to 18% if a person has a first-degree relative (mother, father, brother, sister, child) with colorectal cancer.

Using U.S. Census Bureau population and insured estimates for 2006, the projected number of Pennsylvanians who would potentially benefit from this legislation is 1,187,377, which was calculated as follows:

Population to Benefit from Senate Bill 146

Population Groups	
A. Pennsylvanians age 50 to 64 years[1]	2,329,052
B. Pennsylvanians age 40 to 49 years at increased risk[2]	530,306
C. Total eligible for colorectal cancer screening	2,859,358
D. Total commercially insured (C x 76.9%)[3]	2,198,846
E. Minus population in self-insured, ERISA-exempt plans (D x 46%)[4]	- 1,011,469
F. Total population affected by mandate	1,187,377

Notes:

1. People age 65 and over were excluded as the vast majority has coverage for colorectal cancer screening through Medicare.
2. According to the U.S. Census Bureau, there were 1,928,386 Pennsylvanians age 40 to 49 in 2006. The 40-to-49 age bracket was used for people at increased risk since the most recent guidelines of the American Cancer Society and gastroenterological societies endorse screening beginning at age 40 or 10 years before the youngest first-degree relative was diagnosed. For the number of persons age 40 to 49 at increased risk, the 1,928,386 figure was multiplied by 27.5% (the mid-point between 25% and 30% reported by the LBFC as the population at increased risk for colorectal cancer due to heredity factors).
3. The U.S. Census Bureau reports that 76.9% of Pennsylvanians are covered by commercial insurance.
4. It was estimated that 46% or 1,011,469 of the commercially insured patients were in self-insured (ERISA-exempt) health plans not eligible for mandated benefits. This estimate was based on figures presented by M. Diane Koken, former Commissioner of the Pennsylvania Insurance Department, in testimony to the House of Representatives on April 5, 2005.

Availability. The issue of colorectal cancer screening availability as it relates to insurance coverage is included in section (II) below. In terms of availability as it relates to capacity, the LBFC report found that adequate capacity exists in Pennsylvania should the number of people who undergo colorectal cancer screening increase. According to the report:

> A statewide survey of hospitals and ambulatory surgery centers [conducted in 2006] showed that there is excess capacity in the state for the performance of 387,646 colonoscopy procedures per year. Analysis of the survey data also indicates that flexible sigmoidoscopy screening is not commonly recommended or performed [so] there is substantial excess capacity for the performance of this procedure. Stool blood testing is relatively inexpensive and widely available. In relation to this screening test, capacity does not present a problem.

More specifically, the researchers used three scenarios to estimate the level of demand for colorectal cancer screening – a 2.5%, 5% and 10% increase. They used these projected levels based on reports from the Centers for Disease Control and Prevention (CDC) regarding state and national rates of increase in screening. According to the CDC, the average rate of increase in screening nationwide from 2002 to 2004 was 5%, or 2.5% annually. The LBFC report noted that a rise of 5% per year approximates the rate of increase in states where demand increased most quickly between 2002 and 2004. A 10% increase was characterized as optimistic as "no state has progressed at this rate nor reached a screening rate as high as 70%."

Under the three scenarios, it was estimated that demand for *all* types of colorectal cancer screening could increase as follows: 113,887 individuals (2.5% increase in screening); 227,774 individuals (5% increase in screening); and 455,548 individuals (10% increase in

screening). Using 2004 data from the CDC, the LBFC researchers estimated that 75% of new compliers with screening in the above scenarios would choose colonoscopy, 20% would select stool blood testing, and 5% would choose flexible sigmoidoscopy.

For colonoscopy screening only, it was estimated that demand could increase as follows: 91,401 procedures (2.5% increase in screening); 182,803 procedures (5% increase in screening); and 365,506 procedures (10% increase in screening). Therefore, the LBFC report found that excess capacity currently exists to easily absorb either a 2.5% or a 5% increase in colonoscopy screenings based on the statewide survey of hospitals and ambulatory surgery centers, which showed excess capacity for the performance of 387,646 colonoscopies. The current capacity for colonoscopies would only be challenged in the extreme 10%-increase scenario. The report also found that an increase in demand for screening should not have a significant impact on the pricing or safety of screening procedures. Additional information from the LBFC on screening-related costs is included in section (VIII, A).

A 2004 *Gastroenterology* study – "Is There Endoscopic Capacity to Provide Colorectal Cancer Screening to the Unscreened Population in the United States?" – found that sufficient capacity exists to screen the unscreened population in the United States within one year using fecal occult blood testing (FOBT) followed by diagnostic colonoscopy for positive tests. While the study found that there was ample capacity for FOBT screening, its findings also suggested that there are capacity limitations for sigmoidoscopy and colonoscopy.

Utilization. According to the American College of Gastroenterology, only about 51% of Pennsylvanians have been screened for colorectal cancer. This percentage was repeated in the submission from Dr. Thomas McGarrity. According to the American Cancer Society, only 53.9% of eligible Pennsylvanians have undergone colorectal cancer screening.

The LBFC report estimated that 44% of persons age 50 and older are unscreened – based on 2006 figures from a CDC *Morbidity and Mortality Weekly Report*. Additionally, the LBFC report referenced data from another CDC source – the Behavioral Risk Factor Surveillance System (BRFSS). The 2006 BRFSS findings (from the Pennsylvania Department of Health Web site) indicate that 22.0% of Pennsylvanians 50 years of age or older reported having a stool blood test within the past two years, 57% of Pennsylvanians age 50 and older reported ever having a sigmoidoscopy or colonoscopy, and 49% of Pennsylvanians age 50 and older reported having a sigmoidoscopy or colonoscopy in the past five years.

None of the submissions from insurers included utilization rates among their members who already have coverage for screening tests. Highmark, however, did reference a July 19, 2000 Associated Press article, "Cancer-Screening Tool Misses Many Cases," which reported that approximately 75% of patients with insurance coverage do not get screened for colorectal cancer.

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.

Existing coverage. With respect to existing coverage, the Pennsylvania Chamber of Business and Industry cited findings from PHC4's May 2002 review of a similar proposed mandate (Senate Bill 636). Documentation submitted to PHC4 for its review of Senate Bill 636 indicated that colorectal cancer screening tests are already widely covered by managed

care plans, Medicare covers periodic screening, traditional fee-for-service plans may provide screening coverage, and all insurance products generally cover medically necessary diagnostic screening.

Capital BlueCross stated that the mandates required in Senate Bill 146 are included in most of the policies they offer. Capital BlueCross noted that most of its products include the following tests beginning at age 40: an annual fecal occult blood test; a flexible sigmoidoscopy every five years; and a colonoscopy every 10 years. Medically necessary diagnostic tests also are permitted, and factors used to determine necessity include: a close relative who has had colorectal cancer or an adenomatous polyp; a family history of familial adenomatous polyposis or hereditary nonpolyposis colorectal cancer; or a personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn's Disease or Ulcerative Colitis. Other tests, such as virtual colonoscopy, may be considered medically necessary in some cases. Colorectal cancer screening is not covered for groups that do not elect to have preventive coverage. Capital BlueCross also pointed out that about half of its one million subscribers participate in self-insurance plans and would not be affected by Senate Bill 146.

In terms of its own coverage, Highmark noted that benefits for colorectal cancer screening vary depending on the product, but the vast majority of its products – including managed care and preferred provider organization (PPO) plans – routinely cover the following tests for members age 50 and older: an annual fecal occult blood test (FOBT); a flexible sigmoidoscopy every five years; an annual FOBT *plus* flexible sigmoidoscopy every five years; a double-contrast barium enema every five years; and a colonoscopy every ten years Testing also is available for symptomatic members under age 50. Highmark's indemnity plan customers can elect to have the same preventive coverage as its managed care and PPO customers. For customers enrolled in individual direct pay products, excluding traditional indemnity plans, colorectal cancer screening benefits are covered.

The American Cancer Society included findings from a 2002 Lewin Group analysis of the Federal Employees Health Benefits Program (FEHBP) and the 248 health plans that participate in this program. The purpose of the review was to ascertain the extent to which insurers cover fecal occult blood testing (FOBT), flexible sigmoidoscopy, colonoscopy and double contrast barium enema. This analysis found that, based on survey results from FEHBP-affiliated plans, it is reasonable to conclude that most health insurance plans cover FOBT and flexible sigmoidoscopy to a great extent, but are not providing comprehensive screening coverage that includes colonoscopy.

The 2007 Legislative Budget and Finance Committee (LBFC) colorectal cancer screening study found that insurance coverage for screening is not uniform in the state. The report noted:

> The majority of insurers reported "always" covering the recommended colorectal cancer screening tests. The remaining insurers, however, reported that the screening tests were covered "sometimes." A small number of insurers restricted coverage for colonoscopy screening to enrollees who are at increased risk. Deductibles and co-payment varied considerably by type of screening test.

In its submission, Highmark pointed out that the researchers conducting the LBFC study did not survey all insurers in the state, only those with the largest market shares. According to the LBFC report, all 13 insurers who were sent surveys responded; these plans had enrollments of about 8.3 million members. Highmark also noted that the LBFC report did not address the

ERISA issue (i.e., self-insured plans are exempt from state health mandates by federal law – the Employee Retirement Income Security Act (ERISA) of 1974), a point critical to the mandated benefits debate.

A March 2007 issue of *Counter Details,* a Pennsylvania Medical Society newsletter submitted by the American Cancer Society, also mentioned the lack of uniformity of colorectal cancer screening coverage by Pennsylvania insurers. While the source of the following passage was not cited, one newsletter article noted that on the national landscape:

> Health insurance coverage for colorectal cancer screening is not uniform across all plans, nor are all the options affirmed by guidelines covered by all plans. Even when all the recommended options are covered, deductibles and co-pays may be large enough to prohibit patients from carrying out screening.

Inadequate care. Noting that colorectal cancer can be treated successfully if caught early, Highmark and other opponents of Senate Bill 146 do not question the general efficacy of colorectal cancer screening and its ability to save lives. Highmark cited the Centers for Disease Prevention and Control, which found that 50% to 60% of colorectal cancer deaths could have been prevented if all adults age 50 and older were screened routinely. Highmark, however, does question the need to mandate coverage and whether mandating coverage will translate to more individuals being screened; these issues will be discussed in section (III).

The LBFC report also stated colorectal cancer screening tests are effective. LBFC authors cited research, which found that periodic stool blood testing can reduce the risk of death from colorectal cancer by 15% to 33% and that repeated annual stool blood testing can detect up to 92% of cancers. Additionally, flexible sigmoidoscopy can identify 80% of all colorectal cancers, and regular colonoscopies can detect 76% to 90% of cases.

While screening test efficacy addresses the issue of inadequate care because early detection and prevention is clearly preferable to disease progression, the American Cancer Society touched upon how lack of insurance coverage can be a barrier to screening. It stated that a recent analysis found that screening rates have risen faster and are significantly higher in states that have mandated coverage. The analysis, which looked at the 11 states that passed coverage laws between 1999 and 2001, revealed that, by 2004, screening rates in these states rose 40% faster than in states without such laws. The actual analysis was not submitted, just a summary of the findings.

According to the American Cancer Society's "Cancer Prevention and Early Detection Facts & Figures 2007," whereas 44.4% of all Pennsylvanians age 50 and older had a recent sigmoidoscopy or colonoscopy in 2004, that number decreased to 13.8% among the same age group who reported that they did not have any kind of health insurance. The same report noted that whereas 16.6% of Pennsylvanians age 50 and older had a recent fecal occult blood test, that number decreased to 7.7% among those without health insurance. As persons who are uninsured would not benefit from this mandate, it is not expected that the low percentages among the uninsured would change with the passage of Senate Bill 146. The American College of Gastroenterology also stated that inadequate insurance coverage is one of the main reasons that approximately half of Americans do not get screened, but they did not provide studies to support this statement.

Financial hardship. As Dr. Thomas McGarrity pointed out, prior to routine screening, the majority of patients would present with advanced disease and require costly multiple surgeries and chemotherapy. Citing figures from "The Price Tag on Progress – Chemotherapy for Colorectal Cancer," a July 2004 *New England Journal of Medicine* study, McGarrity recounted:

> In the mid-1990's, chemotherapy, given after surgical resection in patients with advanced stage disease, included the combination therapy Fluorouracil plus Leucovorin **with an estimated drug cost of $60-$300 every eight weeks.** After 2000, newer cytotoxic chemotherapeutic agents became available…[and] can range in costs **up to $30,000 for an 8-week course of therapy.** In patients with advanced stage disease, chemotherapy is usually continued indefinitely.

McGarrity also reported that for the 56,000 Americans diagnosed with colorectal cancer with metastasis (Stage 4) or recurrent metastasis disease this year, the cost for an eight-week course of initial treatment will be approximately $1.2 billion when monoclonal antibody therapy is added to the newer cytotoxic chemotherapy agents.

The LBFC study also addressed financial hardship in terms of treating early versus late stage cancers. Analyzing data provided by PHC4, the researchers found that, in 2005, hospital costs for treating colorectal cancer totaled $763 million and that higher levels of screening would reduce these costs. **[Special note: While the LBFC report uses the term treatment "costs," it is important to point out that the data provided by PHC4 for their study reflects hospital *charges*. While hospital charges reflect the amount that hospitals report on billing forms, they do not represent what it actually costs the hospitals to provide treatment, nor do they reflect the amount hospitals receive in payment for delivered services. Hospitals usually receive less in actual payments than the listed charge.]** The LBFC report went on to say, in 2005, there were 14,614 hospital admissions in Pennsylvania for which colorectal cancer was the primary (9,287) or secondary (5,327) diagnosis, and the cost of treating the disease increased with the stage of disease. For admissions with a primary diagnosis, average treatment costs increased in accordance with disease stage as follows: Stage 1 ($36,395), Stage 2 ($54,938), and Stage 3 and expired ($62,845). For admissions with a secondary diagnosis, average treatment costs increased in accordance with disease stage as follows: Stage 1 and reported history of CRC ($28,400), Stage 2 ($40,248), and Stage 3 and expired ($43,944).

While it did not provide the study that generated this result, an American College of Gastroenterology analysis found that treatment costs are significantly lower – $30,000 per patient compared to $120,000 per patient – when colorectal cancer is detected early. **[Special note: If the figures provided by the American College of Gastroenterology are actual treatment *costs*, then they cannot be compared to the *hospital charge* figures from the LBFC study, above.]**

Several submissions argued that, by imposing additional costs to employers, Senate Bill 146 could in and of itself cause a financial burden for some individuals and employers in the Commonwealth. This issue will be discussed more in section (III).

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

Support for Senate Bill 146. PHC4 received five submissions in support of Senate Bill 146; these submissions were from two cancer advocacy organizations (the American Cancer Society – Pennsylvania Division and the Colon Cancer Alliance), the American College of Gastroenterology, Dr. Thomas McGarrity of the Penn State Milton S. Hershey Medical Center, and Dr. Ronald Myers of Thomas Jefferson University's Jefferson Medical College. The support stems primarily from the impact of colorectal cancer in terms of the people affected and death rates and from the fact that this type of cancer is one of the most preventable and treatable cancers.

The impact of colorectal cancer is discussed more fully in section (I). As previously mentioned, colorectal cancer is the second leading cause of cancer death among adults in the United States. For 2007, there will be an estimated 8,220 new cases of colorectal cancer in Pennsylvania with 2,730 deaths.

In addressing the importance of regular screening, the American Cancer Society reported:

> The relative 5-year survival rate for colorectal cancer, when diagnosed at an early stage before it has spread is greater than 90%. But only 39% of colorectal cancers are found at that early stage. Once the cancer has spread to nearby organs or lymph nodes, the 5-year relative survival rate goes down, and if cancer has spread to distant organs (like the liver or lung) the 5-year survival is less than 10%.

The American College of Gastroenterology stated that recent data from the Centers for Disease Control and Prevention (CDC) shows that cancer mortality declined an average of 2.1% per year between 2002 and 2004, which is almost double the average annual decrease from 1993 to 2003. The American College of Gastroenterology did not submit the CDC study that included this data, but it reported that the CDC found that "[t]he main factor in the accelerated decline was a drop in the death rate from colorectal cancer in men and women, mostly attributable to more widespread colonoscopy screening."

Proponents pointed out that in addition to colorectal cancer screening being effective in detecting disease, it is also cost-effective. The American Cancer Society stated:

> Studies have shown that the cost-effectiveness of colorectal screening is consistent with many other kinds of preventive services and is lower than some common interventions. For example, a polyp can be removed during screening for around a few thousand dollars, but if the patient is not diagnosed until the disease has metastasized, the patient's survival drops to 10 percent and the costs of care can add up to many thousands of dollars over the patient's lifetime. With sharp cost increases possible as new treatments become standards of care, the cost-effectiveness of screening is likely to become even more attractive.

A 2002 *Annals of Internal Medicine* study, "Cost-Effectiveness Analyses of Colorectal Cancer Screening: A Systematic Review for the U.S. Preventive Services Task Force," concluded that screening for colorectal cancer by any of the common strategies appears to be cost-effective compared with no screening, but a single optimal method cannot be determined from the current literature. It found that "[t]he cost per life-year saved for colorectal cancer screening ($10,000 to $25,000 for most strategies compared with not screening) compares favorable

with other commonly endorsed preventive health care interventions, such as screening mammography…"

Similarly, the LBFC report found that all of the recommended colorectal cancer screening tests are cost-effective. Annual stool blood testing was cited as the most cost-effective approach. And while colonoscopy was found to be less cost-effective than other methods, it was still deemed cost-effective by the standard threshold in economic outcomes research. Dr. Ronald Myers, one of the authors of the LBFC report, stated:

> In the cost-effectiveness literature, the standard threshold in economic outcomes research holds that an average cost-effectiveness ratio of less than $50,000 signals a relatively worthwhile investment. For cancer screening, this ratio relates the total cost of using a specific screening method to the total number of life years saved by using this method.

According to the LBFC, with the standard threshold for cost-effectiveness being $50,000 per year of life saved (YLS): stool blood testing costs $5,980 to $11,632 per YLS; combined stool blood testing and flexible sigmoidoscopy (every five years) costs $13,922 to $24,570 per YLS; and colonoscopy (every 10 years) costs $14,181 to $23,570 per YLS.

In addition to the submissions addressed above, the Council notes the most recent recommendation for colorectal cancer screening from the U.S. Preventive Services Task Force (USPSTF), an independent panel of experts convened by the Agency for Health Care Research and Quality in the U.S. Department of Health and Human Services. The USPSTF gives colorectal cancer screening its strongest – "A" classification – recommendation:

> **The USPSTF strongly recommends that clinicians screen men and women 50 years of age or older for colorectal cancer.**
>
> **Rating: A recommendation**.
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> *Rationale:* The USPSTF found fair to good evidence that several screening methods are effective in reducing mortality from colorectal cancer. The USPSTF concluded that the benefits from screening substantially outweigh potential harms, but the quality of evidence, magnitude of benefit, and potential harms vary with each method.
>
> The USPSTF found good evidence that periodic fecal occult blood testing (FOBT) reduces mortality from colorectal cancer and fair evidence that sigmoidoscopy alone or in combination with FOBT reduces mortality. The USPSTF did not find direct evidence that screening colonoscopy is effective in reducing colorectal cancer mortality; efficacy of colonoscopy is supported by its integral role in trials of FOBT, extrapolation from sigmoidoscopy studies, limited case-control evidence, and the ability of colonoscopy to inspect the proximal colon. Double-contrast barium enema offers an alternative means of whole-bowel examination, but it is less sensitive than colonoscopy, and there is no direct evidence that it is effective in reducing mortality rates. The USPSTF found insufficient evidence that newer screening technologies (for example, computed tomographic colography) are effective in improving health outcomes.
>
> There are insufficient data to determine which strategy is best in terms of the balance of benefits and potential harms or cost-effectiveness. Studies reviewed by the USPSTF

indicate that colorectal cancer screening is likely to be cost-effective (less than $30,000 per additional year of life gained) regardless of the strategy chosen.

It is unclear whether the increased accuracy of colonoscopy compared with alternative screening methods (for example, the identification of lesions that FOBT and flexible sigmoidoscopy would not detect) offsets the procedure's additional complications, inconvenience, and costs.

Opposition to Senate Bill 146. PHC4 received submissions from five organizations (three insurers, the Insurance Federation of Pennsylvania, and the Pennsylvania Chamber of Business and Industry) that oppose mandating coverage for colorectal cancer screening.

Several key arguments against the bill were repeated throughout several submissions: 1) mandates, in general, increase total health care costs, 2) mandates limit the ability of purchasers to select benefit packages, 3) there is currently sufficient coverage from insurers, 4) increased coverage may not necessarily lead to increased screening, 5) the legislation gives a single interest organization the ability to change the mandated coverage without legislative oversight and puts testing requirements into statute, and 6) there is still some disagreement regarding the recommended screening methods.

- *Mandates, in general, increase total health care costs*

  Rather than ensure better health care, opponents stated that mandates increase premium costs, reduce health coverage for some individuals, and force others to become uninsured. The opponents suggest the following scenario as one of the mechanisms that increase the total cost of health care:

  - Large employers become self-insured to avoid mandates.
  - This increases the burden on medium-size and small businesses that are already struggling to provide their employees with health care coverage.
  - These smaller employers are forced to pass on the costs to their employees.
  - Employees' real wages are affected through higher contributions toward health care coverage and/or lowered hourly rates or salaries.
  - Some employees may not be able to afford the increases and join the ranks of the working uninsured.
  - Others may be laid off and join the ranks of the unemployed uninsured.
  - Either way, health care costs are increased.

  The Pennsylvania Chamber of Business and Industry noted that Senate Bill 146 could actually result in fewer people being screened because mandates raise the costs of health insurance, forcing more employers and individuals to drop health coverage altogether.

  In its submission, Highmark stated that mandates increase utilization by encouraging individuals to seek therapies not covered before and they insulate people from the cost of that care. Another problem caused by mandates, in general, is that they give the impression that covered treatments are always effective in treating the condition. Still, Highmark reported that it is the cumulative effect of Pennsylvania's 30 benefit and provider mandates "that causes the most pain."

Other opponents also noted, while one individual mandate may have minimal cost implications, their cumulative effect is concerning. Three studies that opponents cited regarding the collective impact of all types of mandates are noted below:

Health Insurance Mandates in the States (Council for Affordable Health Insurance, March 2007)

- Mandated benefits increased the costs of basic coverage from slightly less than 20% to more than 50%, depending on the state (over 1,900 mandates analyzed).

New York State Mandated Health Insurance Benefits (Novak, May 2003)

- In New York, mandated benefits increased premiums by 12.2%, an increase of $444.57 per year for single coverage and $1,066.37 per year for family coverage.
- For every 1% increase in private insurance premiums nationally, it is estimated that 400,000 more people will become uninsured.

The Effect of State Regulations on Health Insurance Premiums: A Revised Analysis (The Heritage Foundation, July 2006)

- Health insurance premiums are $80 per month higher in states requiring more than the national average of 26 mandated benefits.

- *Mandates limit the ability of purchasers to select benefit packages*

  Both Highmark and the Pennsylvania Chamber of Business and Industry argued that screening should remain an optional benefit so employers and individuals seeking the broadest and most affordable coverage possible still have access to care. The Insurance Federation of Pennsylvania noted that variations in coverage are dictated by the selections of groups and individuals in the marketplace and this mandate would infringe on market choice.

- *There is currently sufficient coverage from insurers*

  As mentioned previously in section (II), with respect to existing coverage, the Pennsylvania Chamber of Business and Industry cited findings from PHC4's May 2002 review of Senate Bill 636. Documentation submitted for that review indicated that colorectal cancer screening tests are already widely covered by managed care plans, Medicare covers periodic screening, traditional fee-for-service plans may provide screening coverage, and all insurance products generally cover medically necessary diagnostic screening. Capital BlueCross and Highmark stated that colorectal cancer screening coverage is included in most of the policies they offer. While the LBFC colorectal cancer screening study found that insurance coverage for screening is not uniform in the state, Highmark also noted that the majority of the state's 13 largest insurers that were surveyed for the study reported "always" covering the recommended screening tests.

- *Increased coverage may not necessarily lead to increased screening*

  Another point from PHC4's review of Senate Bill 636 that the Pennsylvania Chamber of Business and Industry found applicable again was that "while there is a general consensus about the medical efficacy of screening for colorectal cancer, there is disagreement about the need to mandate coverage and whether mandated coverage would bring about a desired increase in screening utilization." The Chamber argued that since so many

insurers already cover these tests, the availability of the benefit does not necessarily result in a high percentage of patients taking advantage of it. The Chamber said it agrees that mandating coverage will not necessarily increase colorectal cancer screening because many people are fearful of these exams. It also noted that "low utilization rates may stem from a low level of awareness about colorectal cancer risks" and that "more attention should be given to public health campaigns that educate the public."

The Insurance Federation of Pennsylvania echoed this concern, noting that its "mantra of 'Educate, don't Mandate' has fallen on deaf ears." The Federation stated that, as it pointed out during the review of Senate Bill 636, the main problem with increasing screening rates has not been insurance coverage; it is people's reluctance to undertake the procedures. As the Federation put it, "No benefits legislation can ever force people to use tests which they do not want to undergo."

Highmark also said that mandating coverage will not necessarily guarantee that people get screened per the recommended guidelines. It quoted a 2002 *New England Journal of Medicine* editorial, "Going the Distance – The Case for True Colorectal Cancer Screening," which stated, "No doubt, aversion to the nature of the problem and the procedures used for screening have presented major barriers to compliance with the recommendations." Highmark also emphasized the importance of its own educational efforts and other national public awareness campaigns in encouraging people to adhere to testing standards.

- *The legislation gives a single interest organization the ability to change the mandated coverage without legislative oversight and puts testing requirements into statute*

  Several opponents found it troubling that Senate Bill 146 gives the American Cancer Society the ability to change or expand upon the mandated coverage without legislative oversight. The Pennsylvania Chamber of Business and Industry stated that the making of statutory standards should never be delegated to a single interest organization, no matter how well-intentioned the group. In addition, according to the Chamber, "There is the possibility that if the American Cancer Society changes its policy on the frequency or nature of colorectal screening recommendations, the costs imposed could be significantly higher."

  On a related note, Highmark also voiced serious concerns about putting testing requirements into statute, mainly because medical technology is constantly evolving. Highmark pointed out that its medical directors and physicians advise on changing medical standards, and the company is committed to making changes in benefits when warranted.

  The Insurance Federation of Pennsylvania said "the bill thrusts the legislature into the role of prescribing specific medical tests and procedures" and that it is dangerous to write specific medical techniques into law. The Federation argued that "the mix of [the] healthcare testing marketplace should be left to the marketplace in the same fashion as the selection of insurance policy provisions." In its submission, the Federation included articles about the growing use of virtual colonoscopies to exemplify that screening tests are constantly evolving.

- *There is still some disagreement regarding the recommended screening methods*

  While most opponents did not dispute the general efficacy of colorectal cancer screening, some drawbacks of the recommended screening methods were identified. Fecal occult blood testing can render false positives. A sigmoidoscopy only allows for examination of the lower half of the colon. Colonoscopy carries a small risk of injury to the colon, such as gastrointestinal bleeding and perforation.

  Only the Insurance Federation of Pennsylvania said that "[t]here is increasing skepticism in the medical community about the efficacy of some of these tests." The Federation also pointed out the irony that virtual colonoscopy – which may be a "less intrusive, more palatable, safer and cheaper" option – is not part of the currently recommended guidelines.

  Several research studies noted in sections (V) and (VII) address the limitations of the various screening tests. Other issues raised by certain studies are that no screening method is perfect, more studies are needed to determine optimal methods, and new technologies may affect screening guidelines in the near future.

While not specifically opposing the mandate contained in Senate Bill 146, the American Family Life Assurance Company of Columbus (AFLAC) suggested that supplemental insurance policies be excluded from the bill. AFLAC argued that "[t]he role of supplemental insurance benefits is to pay cash benefits to the insured to fill the gaps between what is covered by comprehensive insurance and the total financial impact of an illness or injury" and that these policies "are not intended to be…substitutes for comprehensive, major medical health insurance."

IV. All relevant findings bearing on the social impact of the lack of the proposed benefit.

The American Cancer Society reported that the quality of life of every person with cancer is affected from the time of diagnosis. Quality-of-life factors affecting patients and their families can be social, psychological, physical and spiritual:

> The concerns that individuals most often express are fear of recurrence; chronic and/or acute pain; sexual problems; fatigue; guilt for delaying screening or treatment, or for doing things that may have caused the cancer; changes in physical appearance; depression; sleep difficulties; changes in what they are able to do after treatment; and the impact of cancer on the finances of loved ones. People with colorectal cancer are often concerned with bowel dysfunction and the associated stigma, as well as the effects of chemotherapy and radiation.

While Highmark could not identify any specific findings bearing on the social impact, it did list several issues that it thought should be considered. As previously discussed in section (III), Highmark reiterated that mandating coverage for colorectal cancer screening does not necessarily mean more people will get screened. It encourages elected officials and advocacy organizations to combat lack of public awareness and fearfulness of the tests with health campaigns that teach the importance of regular testing at the recommended intervals. Highmark also stated that the public needs to understand the potential risks and benefits associated with various testing methods and that patients must carefully select which

physician performs their screening as “the reliability of results depends on the experience and expertise of the physicians actually performing the procedure.”

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.

Based on the documentation received, it was unclear, in some cases, whether all of the studies referenced in this section are professionally accepted, controlled trials. Additional research studies that are not identified in this section or incorporated elsewhere in the review are included in section (VII).

In his submission, Dr. Ronald Myers referenced three studies that address “the impact of evidence-based behavioral interventions on colorectal cancer screening use, the cost-effectiveness of such interventions, and the potential impact of increased colorectal cancer screening use on colorectal cancer mortality.” Since neither copies of the actual studies nor excerpts were included with his submission, the references are simply listed below:

- Myers RE, Sifri R, Hyslop T, Rosenthal M, Vernon SW, Cocroft J, Wolf T, Andrel J, and Wender R. (2007). “A Randomized Controlled Trial of the Impact of Targeted and Tailored Intervention Impact on Colorectal Cancer Screening.” *Cancer*, 110(8), 2083-2091.

- Lairson DR, DiCarlo M, Myers RE, Wolf T, Cocroft J, Sifri R, Rosenthal M, Vernon SW, and Wender R. (In Press). “Cost-effectiveness of Targeted and Tailored Interventions on Colorectal Cancer Screening Use.” *Cancer*.

- Vogelaar I, Ballegooijen MV, Schrag D, Boer R, Winawer SJ, Habbema JDF, and Zauber AG. (2006). “How Much Can Current Interventions Reduce Colorectal Cancer Mortality in the US? Mortality Projections for Scenarios of Risk-Factor Modification, Screening and Treatment.” *Cancer*, 107(7), 1624-1633.

While copies of complete studies were not included, Highmark submitted excerpts from or summaries of the following studies:

- Itzkowitz SH, Jandorf L, Brand R, Rabeneck L, Schroy PC, Sontag S, Johnson D, Skoletsky J, Durkee K, Markowitz S, and Shuber A. (2007). “Improved Fecal DNA Test for Colorectal Cancer Screening.” *Clinical Gastroenterology & Hepatology, 5* (1), 111-117.

  The study evaluated 162 patients who provided stool samples, 40 individuals with colorectal cancer and 122 subjects with normal colonoscopies. The study found that the stool DNA test demonstrated an 88% sensitivity for colorectal cancer. With this new assay, cancers were detected regardless of stage or location in the colon.

- Brenner H, Hoffmeister M, Arndt V, and Haug U. (2007). “Gender Differences in Colorectal Cancer: Implications for Age at Initiation of Screening.” *British Journal of Cancer,* 96(5), 828-931.

  This study suggested that gender differences in age at colorectal cancer diagnosis should influence screening. The researchers accessed population-based cancer registry data

from the United States and national mortality statistics from various countries to examine the cumulative 10-year incidence and mortality of colorectal cancer reached among men at 50, 55 and 60 years of age. They found that women reached equivalent levels four to eight years older than men and that gender differences were very constant across populations and over time. This suggests that gender differentiation of age at initiation may be worthwhile in using colorectal cancer screening resources more efficiently.

- De La Chapelle A. (2004). "Genetic Predisposition to Colorectal Cancer." *Nature Reviews Cancer*, 4(10), 769-780.

  According to this study's abstract, "High-penetrance mutations in several genes have been identified that contribute to hereditary colorectal cancer. The role of these mutations in cancer pathogenesis is well understood and their detection is successfully used in clinical diagnosis." While less is known about the influence of low-penetrance mutations, current research efforts are beginning to bear fruit in this area and will have important implications regarding future diagnostic and treatment strategies.

- Ponz de Leon M, Benatti P, Di Gregorio C, Pedroni M, Losi L, Genuardi M, Viel A, Fornasarig M, Lucci-Cordisco E, Anti M, Ponti G, Borghi F, Lamberti I, and Roncucci L. (2004). "Genetic Testing Among High-Risk Individuals in Families with Hereditary Nonpolyposis Colorectal Cancer." *British Journal of Cancer*, 90(4), 882-887.

  The researchers found "that a large fraction of high-risk individuals in mutation-positive HNPCC [hereditary nonpolyposis colorectal cancer] families does not undergo genetic testing, despite the benefits of molecular screening and endoscopic surveillance." They concluded that this indicates that barriers to genetic testing still exist and that doctors are unable to adequately protect these families against cancer development.

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 benefits.

Senate Bill 146 does not mandate coverage for an additional class of practitioners.

VII. The results of any other relevant research.

While one of the following articles is referenced earlier, this section generally includes research and related articles not incorporated elsewhere in the report.

The American Cancer Society submitted a column from *Gastrointestinal Endoscopy* (Volume 54, No. 4, 2001), which abstracted the following two studies. The studies themselves were not submitted.

- Sonnenberg A, Delco F, and Inadomi JM. (2000). "Cost-Effectiveness of Colonoscopy in Screening for Colorectal Cancer." *Annals of Internal Medicine*, 133, 573-584.

- Frazier AL, Colditz GA, Fuchs CS, and Kuntz KM. (2000). "Cost-Effectiveness of Screening Colorectal Cancer in the General Population." *Journal of the American Medical Association*, 284, 1954-1961.

  According to the commentary in *Gastrointestinal Endoscopy*, both Sonnenberg et al. and Frazier et al. concluded "that colon screening with any of the recommended programs is cost-effective relative to other medical interventions," and "[w]hen these analyses are combined with other recently published cost-effectiveness studies, there is a compelling story: colon screening saves lives and is cost effective."

The American Cancer Society did, however, submit copies of several other studies that examine various aspects of colorectal cancer screening, but it did not attach an accompanying statement regarding their relevance. These studies are noted below, along with conclusions from the articles themselves.

- Nicholson FB, Barro JL, Atkin W, Lilford R, Patnick J, Williams CB, Pignone M, Steele R, and Kamm MA. (2005). "Review Article: Population Screening for Colorectal Cancer." *Alimentary Pharmacology & Therapeutics*, 22, 1069-1077.

  Nicholson et al. reviewed the literature to consider "who should be screened, which test to use and how often to screen." Among their conclusions were that "screening for average risk individuals has been shown to be beneficial, resulting in decreased mortality from, and a lower incidence of [colorectal cancer]" and that "[f]uture studies of available tests are needed to clarify the optimal screening method and screening intervals."

- Loeve F, Brown ML, Boer R, Van Ballegooijen M, Van Oortmarssen GJ, and Habbema JD. (2000). "Endoscopic Colorectal Cancer Screening: A Cost-Saving Analysis." *Journal of the National Cancer Institute*, 92(7), 557-563.

  Loeve et al. concluded, "Given the present, limited knowledge of the disease process of colorectal cancer, test characteristics, and costs, it may well be that the induced savings by endoscopic colorectal cancer screening completely compensate for the costs."

- Collins FJ, Lieberman DA, Durbin TE, and Weiss DG. (2005). "Accuracy of Screening for Fecal Occult Blood on a Single Stool Sample Obtained by Digital Rectal Examination: A Comparison with Recommended Sampling Practice." *Annals of Internal Medicine,* 142(2), 81-85.

  Collins et al. stated that a single fecal occult blood test performed in part of a digital rectal examination in an office "is a poor screening method for colorectal neoplasia and cannot be recommended as the only test." The researchers also found that negative results from this type of screening method do not decrease the chances of advanced neoplasia. Therefore, they concluded that "[p]ersons with these results should be offered at-home 6-sample FOBT or another type of screening test."

- Hobley J, Lengerich EJ, Lindsay JA, and McGarrity TJ. (2006). "Disparities Between Blacks and Whites in Stage at Diagnosis, Incidence, and Anatomic Subsite of Colorectal Cancer." *Gastroenterology & Hepatology*, 2(7), 498-502.

Hobley et al. found that a higher percentage of colorectal cancer cases were diagnosed at a late stage among blacks (54.6%) than whites (51.3%), and that efforts to increase colorectal cancer screening should be enhanced, especially among blacks.

- Walsh JME, and Terdiman JP. (2003). "Colorectal Cancer Screening: Scientific Review." *Journal of the American Medical Association,* 289(10), 1288–1296.

  This literature review assessed the evidence for use of available screening tests, including methods likely to be widely available in the near future. Walsh and Terdiman found that "[t]he recommendation that all men and women aged 50 years or older undergo screening for colorectal cancer is supported by a large body of direct and indirect evidence," but that the existing literature does not support the use of one method over another.

- Levin B, Brooks D, Smith RA, and Stone A. (2003). "Emerging Technologies in Screening for Colorectal Cancer." *CA: A Cancer Journal for Clinicians*, 53, 44-55.

  The American Cancer Society's Colorectal Cancer Advisory Group reviewed new technologies for early screening, including CT colonography, immunochemical fecal occult blood tests, screening stool for DNA markers, and capsule video endoscopy. The group found that, with the exception of immunochemical stool testing, there was insufficient evidence to incorporate these tests into the recommended screening guidelines. As a result of this review, the American Cancer Society proposed updating its Recommendations for Screening and Surveillance for the Early Detection of Adenomatous Polyps and Colorectal Cancer. The proposed change was "to append the guideline regarding fecal occult blood testing to include: 'in comparison with guaiac-based tests for the detection of occult blood, immunochemical tests are more patient-friendly, and are likely to be equal or better in sensitivity and specificity.'"

- Podolsky DK. (2000). "Going the Distance – The Case for True Colorectal-Cancer Screening [Editorial]." *New England Journal of Medicine,* 343(03), 207-208.

  In this editorial previously referenced in section (III), Podolsky argued that, based upon some of the limitations of sigmoidoscopy, "[t]he failure of insurance companies to cover the costs of colonoscopic screening is no longer tenable." In addition to the American Cancer Society, Highmark referenced this editorial in its submission, citing the following excerpts:

  > Although the studies reported by Imperiale et al. and Lieberman et al. fall short of proving that life expectancy is increased by performing colonoscopic screening of persons 50 years of age or older who are at average risk for colorectal cancer, such an extrapolation of the data is virtually irresistible.
  >
  > The barrier to reducing the number of deaths from colorectal cancer is not a lack of scientific data but a lack of organizational, financial and societal commitment. …However, ensuring that all persons undergo some form of comprehensive screening is even more important than deciding whether colonoscopy or barium enema is used for the screening evaluation.

Highmark also included excerpts from and news articles about the two studies that accompanied the aforementioned editorial in the *New England Journal of Medicine*. Copies of the actual studies were not included with its submission. Highmark noted that it cited both the

editorial and the next two studies, which address the benefits of flexible sigmoidoscopy versus colonoscopy, in its 2001 submission on Senate Bill 636 as they are still relevant today.

- Lieberman DA, et al. (2000). "Use of Colonoscopy to Screen Asymptomatic Adults for Colorectal Cancer." *New England Journal of Medicine,* 343(03), 162-168.

  Lieberman et al. concluded, "Colonoscopic screening can detect advanced colonic neoplasms in asymptomatic adults. Many of these neoplasms would not be detected with sigmoidoscopy."

- Imperiale TF, Wagner DR, Lin CY, Larkin GN, Rogge JD, and Ransohoff DF. (2000). "Risk of Advanced Proximal Neoplasms in Asymptomatic Adults According to the Distal Colorectal Findings." *New England Journal of Medicine,* 343(03), 169-174.

  Imperiale et al. concluded:

  > Asymptomatic persons 50 years of age or older who have polyps in the distal colon are more likely to have advanced proximal neoplasia than are persons without distal polyps. However, if colonoscopic screening is performed only in persons with distal polyps, about half the cases of advanced proximal neoplasia will not be detected.

  In reference to these two studies, Podolsky wrote in his editorial that they "reinforce the growing suspicion among physicians that in recommending flexible sigmoidoscopy to screen persons for colorectal cancer, we are promoting a suboptimal approach." In a July 19, 2000 Associated Press article, "Cancer-Screening Tool Misses Many Cases," Dr. Thomas Imperiale, lead author of the second study, was quoted as saying that while he favors broader use of colonoscopy for high risk and older patients, "[t]o go to a strategy of screening everyone with colonoscopy doesn't make sense." A July 19, 2000 University of North Carolina-Chapel Hill News Services article about these studies, "Studies: Sigmoidoscopy Fails to Show Proportion of Colon Cancers, Polyps," stated:

  > You have to make decisions about screening colonoscopy based on safety and cost and the additional benefit of colonoscopy compared with other strategies. These two studies address only one small piece of the puzzle…the two studies cannot by themselves be used to answer the larger policy question of whether screening colonoscopy should be routinely recommended for everybody over age 50.

Highmark did, however, submit copies of the following articles in their entirety:

- Boland CR. (2006). "Conjugating Colorectal Cancer Screening: Past, Present, Future and Perfect." American Gastroenterological Association.

  This article explores the various screening strategies used for colorectal cancer and their limitations. Incomplete compliance and choosing among the various options are noted as two limitations. According to the author, "[n]o approach is perfect. Each of the currently used approaches fails to detect some large lesions even in the best hands. …However, compared to most other cancers, CRC [colorectal cancer] is perhaps the most amendable to intervention, and it will remain the focus of our attention for years to come."

- Winawer SJ. (2005). "Colorectal Cancer Screening: 'The Future Ain't What it Used to Be'." *AGA Perspectives*.

  This article explores some of the issues raised in the American Gastroenterological Association's report, "Colorectal Cancer: A Qualitative Review of Emerging Screening and Diagnostic Technologies." While looking at the clinical application of new technology, the report points out that "rigorous studies will be required to demonstrate the effectiveness and cost-effectiveness of these technological developments," and that "much of the current scientific and technological advances will not be ready to have an impact on clinical practice for years." Additionally, the report questions the adequacy of current training programs to meet the new developments in colorectal cancer screening. In terms of future directions in screening, the author stated that he believes that "colonoscopy will not be done in the distant future as it is today and will become a therapeutic instrument for biopsy and polypectomy."

VIII. Evidence of the financial impact of the proposed legislation.

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

As previously reported in section (I), the Legislative Budget and Finance Committee (LBFC) colorectal cancer screening study looked at screening demand under three scenarios – a 2.5%, 5%, and 10% increase in demand. Using the same three scenarios, the report analyzed both the costs of screening alone (with polypectomy) and the costs of treating newly diagnosed cancer cases. The costs associated with screening were found to be $40,629,379 (2.5% increase in screening), $81,384,757 (5% increase in screening) and $162,771,172 (10% increase in screening). These costs include the extra colonoscopies that would be necessary because of positive findings from either a stool blood test or flexible sigmoidoscopy. Adding screening costs to the treatment costs for newly discovered colorectal cancer cases yielded the following totals: $61,993,058 (2.5% increase in screening), $123,986,114 (5% increase in screening), and $247,974,728 (10% increase in screening). For all of the cost figures noted above, the researchers excluded costs for Medicare eligible persons over age 65.

In detailing these costs, the LBFC report also stated, "There are substantial offsetting costs to be considered." As previously mentioned in section (II), the 2005 hospital costs for treating colorectal cancer in Pennsylvania totaled $763 million. Thus, the report's authors emphasized that:

> Increases in cost related to higher [colorectal cancer] screening use would be offset by the long-term reduction in cancer incidence and all the associated costs of treatment. While initially, treatment costs would be expected to rise because of cases that are newly diagnosed as the result of additional screenings, the longer term impact would be a fall in the number of cases, a decrease in the late stage cancers, a fall in mortality, and a decrease in treatment expenditures.

[Special note: While the LBFC report uses the term treatment "costs," it is important to point out that the data provided by PHC4 for their study reflects hospital *charges*. While hospital charges reflect the amount that hospitals report on billing forms, they <u>do not</u> represent what it actually costs the hospitals to provide treatment, nor do they

reflect the amount hospitals receive in payment for delivered services. Hospitals usually receive less in actual payments than the listed charge.]

Citing a 2004 Maryland Department of Health and Hygiene report within their study, the researchers noted that some states have already seen a decline in incidence or mortality rates and related costs while experiencing increased screening rates. They added that while it is difficult to predict the extent and time of such reductions, the cost effectiveness of colorectal cancer screening has been clearly established. In fact, the National Commission on Prevention Priorities recently identified "[colorectal cancer] screening as one of the four most recommended screening tests based on two criteria: the clinically preventable disease burden and cost effectiveness."

The American College of Gastroenterology stated that every dollar spent by Medicare for colonoscopy cuts approximately $3.00 in long-term medical costs and added that savings among the non-Medicare population would likely be larger. The study from which this conclusion was drawn was not included.

The American Cancer Society submitted a 2003 *Gastroenterology* study, "Cancer-Attributable Costs of Diagnosis and Care for Persons with Screen-Detected Versus Symptom-Detected Colorectal Cancer," which evaluated the direct medical costs for persons with colorectal cancer who were identified through screening compared with an evaluation of symptoms. This study found that diagnosis costs were substantially lower for screening-detected patients ($7,302) than for symptom-detected patients ($10,261). Additionally, medical costs in the 12 months following diagnosis were also significantly lower for screen-detected patients ($23,344) than for symptom-detected patients ($29,384). Overall, the analysis suggested "health plans that invest in screening programs will realize cost savings from reduced diagnosis costs, from moving persons to earlier stages at diagnosis, and somewhat from reducing costs within stages at diagnosis."

A 2003 Lewin Group study submitted by the American Cancer Society titled, "Short-Term Cost-Impact Analysis of Colorectal Cancer Screening" included estimates of the costs of various types of colorectal cancer screening tests. Citing estimates derived by Khandker et al. (2000), the study noted the following mean unit cost estimates – in 1999 U.S. dollars – for screening on persons under age 65: fecal occult blood test, $12.64; flexible sigmoidoscopy, $201.89; flexible sigmoidoscopy with biopsy and pathology, $342.60; colonoscopy, $768.33; and colonoscopy with polypectomy and pathology $1,125.41.

The LBFC report only listed average endoscopy costs. The average cost of a flexible sigmoidoscopy was reported as $300 and the average cost of colonoscopy as $1,295.

The Insurance Federation of Pennsylvania included an October 4, 2007 *Philadelphia Inquirer* article, "New Test for Colon Cancer is Praised," which reported that the charge of a traditional colonoscopy, without polypectomy, at a Wisconsin hospital is $3,300. The charge of a virtual colonoscopy was reported as $1,186, with insurers paying about 40% of that charge.

No submissions included information about how the costs of these individual tests would increase or decrease with the enactment of Senate Bill 146. Highmark, however, repeated that adding any new mandate would increase health insurance coverage costs. It said the passage of Senate Bill 146 would increase costs for its customers in the form of higher premiums.

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

No submissions addressed the financial impact of similar legislation in other states; however, several submissions provided slightly different lists of which states mandate colorectal cancer screening.

Citing information from the Kaiser Family Foundation Web site, Highmark reported that 22 states and the District of Columbia currently have some form of health insurance mandate for colorectal cancer screening and that half of these were passed in 2001. Highmark listed the following states as requiring health insurers to provide screening coverage: Alaska, Arkansas, Connecticut, Delaware, Georgia, Illinois, Indiana, Louisiana, Maryland, Missouri, Nevada, New Jersey, North Carolina, Oregon, Rhode Island, Texas, Virginia, West Virginia, and Wyoming. Laws in Alabama, Oklahoma and Tennessee require health insurers to offer screening as a purchaser's benefit option, but consumers are not required to purchase the benefits.

The American Cancer Society submitted several documents that provided varying lists. One document it included was the *2007 Colorectal Cancer Legislation Report Card.* Created by a coalition of colon cancer advocacy organizations, the report card provides a snapshot of state efforts to pass mandated benefits legislation. According to the report card, states that received an "A" grade generally provide coverage based on the accepted screening guidelines of the American Cancer Society and gastroenterological societies, allowing the legislation to mandate coverage for future advancements in screening. Scoring an "A" were Arkansas, Alaska, Connecticut, Georgia, Illinois, Indiana, Louisiana, Maryland, Missouri, Nevada, New Jersey, North Carolina, Oregon, Rhode Island, Virginia and Washington, DC. States receiving a "B" grade (Delaware, Texas and West Virginia) meet current screening guidelines but since guidelines are not specifically referenced, the legislation may not mandate coverage for future screening advancements. States with a "C" grade (California and Wyoming) have passed legislation with vague language that does not specifically mention which screening methods are covered. States with a "D" grade (Alabama, Oklahoma, and Tennessee) have passed legislation that recommends that health insurers offer coverage, not require it. The remaining states all received an "F," and have not passed any type of legislation requiring insurers to cover screenings.

The most current list submitted by the American Cancer Society was a September 2007 fact sheet from the National Cancer Institute, which noted that 28 states, including the District of Columbia, had laws addressing third-party colorectal cancer screening coverage as of June 30, 2007. Twenty-four states require certain insurers to provide coverage for certain screening tests and three (Alabama, Oklahoma, and Tennessee) require insurers to offer coverage. Indiana has a unique law that requires certain insurers to provide coverage, but insurers must only offer coverage if the coverage is not employer-based. There are 19 states that specify that coverage must comply with the guidelines of a specific organization, 17 of which conform to American Cancer Society guidelines: Alabama, Alaska, Arkansas, Connecticut, Georgia, Illinois, Indiana, Louisiana, Maryland, Missouri, Nevada, New Jersey, North Carolina, Rhode Island, Tennessee, Virginia, and Washington, DC. There are six states – Delaware, Nebraska, Oklahoma, Oregon, Texas, and West Virginia – that require certain insurers to cover screening tests as specified in each state's individual law. Three states – California, Minnesota and Wyoming – mandate screening coverage, but do not specify the tests covered or age/frequency requirements.

The American Cancer Society also noted that states are authorized to provide colorectal screening coverage under their Medicaid programs. Yet, it pointed out that, unlike Medicare, "there is no federal assurance that all state Medicaid programs must cover colorectal cancer screening in people without symptoms" and coverage under Medicaid varies by state.

As previously reported in section (II), the American Cancer Society has found that state insurance coverage laws are associated with higher screening rates. A recent analysis, which looked at the 11 states that passed coverage laws between 1999 and 2001, revealed that, by 2004, screening rates in these states rose 40% faster than in states without such laws.

In May 11, 2004 testimony delivered to the Senate Banking and Insurance Committee, Dr. Robert Smith, Director of Cancer Screening at the American Cancer Society's national office, said that state action is sometimes needed to ensure full coverage for colorectal cancer screening. He referred to a 2003 Institute of Medicine report, "Fulfilling the Potential of Cancer Prevention and Early Detection," which suggested that "public and private insurers should 'consider evidence-based cancer prevention and early detection services *to be essential benefits and should provide coverage for them*.'" Smith went on to say that the cost impact of state regulations is often overstated and misunderstood. He noted that while policymakers often cite rising insurance costs as the rationale for not enacting such laws, increasing insurance costs for employers can be largely attributed to hospital care, physician care and prescription drugs – not consumer protections.

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

No submissions gave specific figures regarding how many additional people would undergo colorectal cancer screening if coverage is mandated. However, as previously mentioned in sections (I) and (VIII, B), a recent analysis conducted by the American Cancer Society found that state insurance coverage laws are associated with higher screening rates and that rates rose 40% faster in states with mandated coverage than in states without such laws.

While Highmark also noted that states that have mandated this benefit have seen screening rates improve, it reiterated the argument mentioned in section (III) that colorectal cancer screening should remain an optional benefit so employers and individuals seeking the broadest and most affordable coverage possible still have access to care.

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

Highmark actuaries estimated that they will realize approximately $1.13 million annually in increased administrative costs if this mandate is passed. Calculations were not provided for this estimate, and no other insurers provided specific administrative cost estimates.

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

The Colon Cancer Alliance – a non-profit advocacy group – submitted a November 2005 study, which found that "covering and promoting full compliance with established screening recommendations thru employer sponsored programs is low cost and cost effective for employee benefit programs." The study – *Cancer Screening: Payer Cost/Benefit thru*

Employee Benefits Programs – was commissioned by C-Change, an organization of cancer leaders and the American Cancer Society, and it was prepared by Milliman consulting firm. According to the report, "[t]he medical expense of achieving 100% compliance with USPSTF [United States Preventive Services Task Force] guidelines for breast, cervical and colorectal cancer is relative low" and modest utilization management improvements or modest reductions in other benefits could easily offset these costs, which are lower than some routinely covered ancillary benefits.

An employer's screening benefit cost for 100% compliance with USPSTF guidelines for breast, cervical and colorectal cancer was estimated to be $7.50 per member per month (PMPM) for 2006. For colorectal cancer only, an employer's estimated cost for 100% compliance was $2.65 PMPM. The average incremental cost of increasing cancer-screening compliance to 100% for all three cancers was estimated to be $2.95 PMPM. For colorectal cancer only, the projected average incremental cost of 100% compliance was $1.70 PMPM.

In terms of potential benefit trade-offs, the report compared the $2.95 incremental spending figure to reach 100% compliance with other average costs for commonly used benefits. It noted that increasing generic drug utilization by 10% could save between $2.65 and $3.05 PMPM for 2006 and that the typical cost of offering chiropractic coverage was $1.35 to $4.00 PMPM for 2006.

Another issue addressed in the study is that while people with cancer comprise about 1.6% of the commercially insured population, they generate 10% of an employer's/insurer's medical claim costs each year. In fact, the estimated 2006 PMPM claim costs for people with cancer are $2,390, compared to $360 for people without cancer. The study found that employers would actually save between $2.35 and $3.75 PMPM in medical and non-medical (e.g., disability, life insurance, replacing lost employees) expenses by realizing 100% compliance for all three types of screening. In moving to 100% compliance for colorectal cancer screening only, the following medical and non-medical employer savings were estimated:

PMPM Medical Cost Savings	PMPM Disability, Life Insurance Savings	PMPM Total Savings
$1.35 to $2.15	$0.55 to $0.85	$1.90 to $3.00

Previously referenced in section (VIII, A), a 2003 study conducted by the Lewin Group, "Short-Term Cost-Impact Analysis of Colorectal Cancer Screening," calculated the total added costs to a health plan for three colorectal cancer screening methods. Analyzing each in terms of annual and per member per month (PMPM) costs, it found the following results:

Annual Fecal Occult Blood Test (FOBT)	
PMPM	$0.47
Cost per Member per Year	$5.70
Annual FOBT/Flexible Sigmoidoscopy Every Five Years	
PMPM	$0.66
Cost per Member per Year	$7.92
Colonoscopy Every 10 Years	
PMPM	$0.55
Cost per Member per Year	$6.64

This study challenged the assumption that colonoscopy is the most expensive test, finding that FOBT combined with flexible sigmoidoscopy (FSIG) costs 11 cents more PMPM. The Lewin Group, therefore, argued:

> Considering that currently there is wide-spread coverage for FOBT and FSIG, but for colonoscopy to a lesser degree, there is minimal economic justification for a plan to limit coverage of colonoscopy screening. …[Still,] it is important that the full range of screening is offered to members in order to address such issues as screening capacity, patient preference, patient health and physician judgment. …and to facilitate the greatest number of patients getting screened.

As a benchmark, colorectal cancer screening costs were compared to screening mammography, which is "protected by law in 49 states." Screening mammography was found to cost $0.75 PMPM, nine cents more PMPM than FOBT/flexible sigmoidoscopy and 20 cents more than colonoscopy.

According to the American Cancer Society, the aforementioned Lewin Group study shows that there is a need for a level playing field among insurers. Plans not covering colorectal cancer screening increase costs for those that do – especially since the privately insured population tends not to stay in one plan. With 25% of the population switching plans annually, costs are shift from plans that do not provide screening coverage to plans that have to pay for treating advanced-stage cancer. In his May 11, 2004 testimony to the Senate Banking and Insurance Committee, Dr. Robert Smith, Director of Cancer Screening at the American Cancer Society's national office, expanded on this point:

> [A] Cigna patient who receives screening and has a non-cancerous polyp removed will become a healthy Kaiser patient tomorrow (and vice-versa). In addition, when plans cover screening, they end up paying for cancers in patients who never got screened as members of other plans. In other words, an uneven playing field penalizes those insurers who do provide coverage. By leveling the playing field, we can help the plans already covering the screening exams.

Highmark actuaries projected that the cost of mandating coverage as outlined in Senate Bill 146 would be $10.3 million annually. Highmark noted that costs would increase, in part, due to increased utilization and that individual customers would be hurt more than large employer groups. Highmark pointed out that while there are many services and treatments that could be covered, they are not because "payers know that the amount of money available to purchase insurance coverage is not endless" and that "[if] 'everything' were to be covered, no one would be able to afford insurance coverage except the very wealthy." Highmark also repeated its concerns, previously discussed in section (III), about the cumulative impact of mandated benefits as a cost driver of health insurance premiums.

Although it did not submit specific cost estimates for Senate Bill 146, the Pennsylvania Chamber of Business and Industry stated that employers in the Commonwealth already struggle to afford health coverage and any expansion of mandated benefits drives up health care costs. The Chamber cited a recent national survey that found that 15% of increases in U.S. heath care costs – or $10 billion – can be attributed to mandated benefits and regulation. It also raised concerns about the cumulative impact of Pennsylvania's mandated benefits [see also section (III)]:

> While one individual mandate, such as that proposed by Senate Bill 146, may have minimal impact on costs, the cumulative impact of 30 or more mandates has a substantial impact on the affordability of health insurance coverage and imposes additional financial burdens [on] the payers of health insurance, whether they are private or public. These burdens would be imposed on the very businesses that are providing good family-sustaining jobs, pay good wages, and offer health care benefits.

According to the Chamber, studies show that, in addition to increasing premium costs, each new mandated benefit increases by 1.5% the likelihood that a small employer may not be able to offer health coverage. Furthermore, it stated that mandates make it harder for Pennsylvania to attract, expand and retain businesses.

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

PHC4's estimate of the impact of Senate Bill 146 is based on several points previously raised. It should be noted that while the legislation would mandate coverage for screening by any of the American Cancer Society recommended methods, cost information was submitted to the Council only for fecal occult blood testing, sigmoidoscopy and colonoscopy.

Population eligible for coverage. As noted earlier in section (I), the projected number of Pennsylvanians who would potentially benefit from this legislation is 1,187,377. This estimate was calculated using U.S. Census Bureau population and insured estimates for 2006, Pennsylvania Department of Insurance statistics, and information submitted to the Council regarding those at increased risk. It should be noted that people age 65 and over were excluded as the vast majority has coverage for colorectal cancer screening through Medicare.

Projected utilization of mandated benefit. Two different utilization rates among the eligible population were assumed: 55% and 100%. A utilization rate of 55% would represent an approximate 10% increase in screening as it was previously reported in section (II) that about 51% of Pennsylvanians have been screened for colorectal cancer. Since advocates call for 100% compliance with the screening guidelines, 100% utilization was assumed, as well.

Cost of screening tests. As noted earlier in section (VIII, A), the average cost of a fecal occult blood test is approximately $13.00, the average cost of a flexible sigmoidoscopy is $300 and the average cost of colonoscopy is $1,295.

Projected cost of screening coverage. Projected costs are displayed in Table 1.

Table 1. Annual Costs

	Totals	
Population Eligible for Coverage	**2,859,358**	
Less non-commercially insured	660,512	
Less self-insured plans	1,011,469	
Total Population Affected by Mandate	**1,187,377**	
Utilization Percentage	**55%**	**100%**
Utilization Population	653,057	1,187,377
Total Annual Costs	**$67,084,748**	**$121,972,710**
20 percent tested using fecal occult blood test [1]	130,611	237,475
100 percent tested on a yearly basis (recommended ever year)	130,611	237,475
Cost of fecal occult blood test	$13	$13
Total fecal occult blood test cost estimate	$1,697,943	$3,087,175
5 percent tested using sigmoidoscopy[1]	32,652	59,368
20 percent tested on a yearly basis (recommended ever 5 years)	6,530	11,873
Cost of sigmoidoscopy	$300	$300
Total sigmoidoscopy cost estimate	$1,959,000	$3,561,900
75 percent tested using colonoscopy[1]	489,792	890,532
10 percent tested on a yearly basis (recommended ever 10 years)	48,979	89,053
Cost of colonoscopy	$1,295	$1,295
Total colonoscopy cost estimate	$63,427,805	$115,323,635

[1]The Legislative Budget and Finance Committee reported the Seef et al. (2006) finding that, of those opting to comply with screening, 75 percent would choose colonoscopy, 20 percent would choose the fecal occult blood test, and 5 percent would choose sigmoidoscopy. Seef et al. based their findings on 2004 data from the CDC. (Seef LC, King J, Pollack LA, and Williams KN. (March 2006). *Morbidity and Mortality Weekly*, [cited 2006 Oct 26]. Available from: www.cdc.gov/mmwr/preview/mmwrhtml/mm5511a4.htm.)

Potential cost savings. In 2006, there were 14,391 hospital admissions in Pennsylvania in which colorectal cancer was either a principal or a secondary diagnosis. In terms of those potentially affected by this mandate, there were 3,192 hospital admissions for commercially insured patients, age 40 to 64, in which colorectal cancer was either a principal or a secondary diagnosis. The total hospital charges for these 3,192 hospital admissions amounted to $168,019,500. [The Legislative Budget and Finance Committee (LBFC) study reported that total hospital charges for colorectal cancer admissions in 2005 were $763 million. The LBFC analysis examined charges among all payor categories, not just those affected by mandates.] It should be noted that a large percentage of the patients who make up these 3,192 admissions could be enrolled in self-insured (ERISA-exempt) plans. Therefore, the number of admissions and the associated hospital charges are likely to be over-estimated as these patients would not be affected by Senate Bill 146. As previously reported in section (I), an estimated 46% of commercially insured patients are in self-insured health plans not eligible for mandated benefits. The data submitted by hospitals to PHC4 does not specify who is self-insured, so these admissions could not be identified. It also is important to note that this $168 million represents hospital charges. While hospital charges reflect the amount that hospitals report on billing forms, they do not represent what it actually costs the hospitals to provide treatment, nor do they reflect the amount hospitals receive in

payment for delivered services. Hospitals usually receive less in actual payments than the listed charge.

A look at the financial data submitted by hospitals to the Council can shed some light on the relationship between the amount hospitals charge or "bill" for inpatient services and the amount they receive in net patient revenue (NPR). Pennsylvania hospitals received, on average statewide, $.27 in NPR for every dollar they charged in fiscal year 2006. Applying this calculation to the $168 million in hospital charges suggests that Pennsylvania hospitals received an estimated $45.4 million in revenue from commercial insurers for the 3,192 hospital admissions.

Submissions for Senate Bill 146

1. American Cancer Society, Pennsylvania Division
    - Letter in support of Senate Bill 146.
    - Research studies, government analyses, testimony, treatment guidelines, fact sheets and personal stories about colorectal cancer screening.

2. American College of Gastroenterology
    - Letter and comments in support of Senate Bill 146.

3. Capital BlueCross
    - Letter and comments in opposition to Senate Bill 146.

4. Colon Cancer Alliance
    - "Cancer Screening: Payer Cost/Benefit thru Employee Benefits Programs."

5. Highmark
    - Statement addressing Section 9 requirements.
    - Research studies, government analyses, fact sheets and news stories about colorectal cancer screening and the cost of mandates.

6. The Insurance Federation of Pennsylvania
    - Letter and comments in opposition to Senate Bill 146.
    - News articles which address virtual colonoscopies.

7. Thomas J. McGarrity, M.D., Professor of Medicine, Chief, Division of Gastroenterology/Hepatology, Penn State Milton S. Hershey Medical Center
    - Letter and comments in support Senate Bill 146.

8. Ronald E. Myers, Ph.D., Professor of Medical Oncology, Jefferson Medical College, Thomas Jefferson University
    - Letter in support of Senate Bill 146.
    - July 2007 Legislative Budget and Finance Committee review of colorectal cancer screening.

9. Pennsylvania Chamber of Business and Industry
    - Letter and comments in opposition to Senate Bill 146.

10. Wolf Block Government Relations
    - Statement by AFLAC noting the importance of excluding certain policies from those affected by Senate Bill 146.