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MANDATED BENEFIT REVIEW OF S.B. 471: AN ACT RELATIVE TO PANCREATIC CANCER SCREENING

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BENEFIT MANDATE OVERVIEW: S.B. 471: PANCREATIC CANCER SCREENING

HISTORY OF THE BILL

The Joint Committee on Financial Services referred Senate Bill (S.B.) 471, "An Act relative to pancreatic cancer screening," sponsored by Sen. Moore of Uxbridge, to the Center for Health Information and Analysis (CHIA) for review. Massachusetts General Laws, chapter 3, section 38C requires CHIA to review and evaluate the potential fiscal impact of each mandated benefit bill referred to the agency by a legislative committee.

WHAT DOES THE BILL PROPOSE?

S.B. 471 requires that health insurance plans defined in the bill "provide coverage for early screening and detection for pancreatic cancer."

MEDICAL EFFICACY OF PANCREATIC CANCER SCREENING

The proposed mandate is intended to provide insurance coverage for early screening and detection for pancreatic cancer. While S.B. 471 is broadly worded in providing coverage for "early screening and detection for pancreatic cancer," the proposed mandate is intended to provide insurance coverage for pancreatic cancer screenings only for high-risk individuals (HRIs), according to the bill's sponsor. For purposes of this analysis, the mandate is interpreted to apply to HRIs only, consistent with the USPSTF's recommendation against broader screening.

Currently, no accurate screening test is available for the general population,[i,ii] and the U.S. Preventive Service Task Force (USPSTF) "recommends against routine screening for pancreatic cancer in asymptomatic adults...," giving such general population-based screenings a grade D recommendation.[iii] Instead of screening the general population, pancreatic cancer researchers are now focusing on surveillance, or the ongoing testing of a narrowly-defined set of asymptomatic individuals at higher risk for pancreatic cancer due to specific familial and genetic factors, estimated to comprise approximately 10% of pancreatic cancer cases..[iv,v] This approach concentrates on identifying individuals with potentially treatable lesions, that is, non-invasive abnormal pancreatic tissue[vi], that can be monitored and managed before they cause symptoms or can be identified by physical examination.[vii,viii,ix] The ACS states that "[f]or now, imaging tests…are options for people with a strong family history of pancreatic cancer.[ix]

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i Johns Hopkins University, Sol Goldman Pancreatic Cancer Research Center (JHU-SGPCRC): Are there screening tests available? Updated 12 November 2012; accessed 29 April 2014: http://pathology.jhu.edu/pc/BasicScreening.php?area=ba.

ii American Cancer Society (ACS): Can pancreatic cancer be found early? Updated 5 February 2014; accessed 29 April 2014: http://www.cancer.org/cancer/pancreaticcancer/detailedguide/pancreatic-cancer-detection.

iii U.S. Preventive Service Task Force (USPSTF): Screening for Pancreatic Cancer. Released February 2004; accessed 29 April 2014: http://www.uspreventiveservicestaskforce.org/uspstf/uspspanc.htm.

iv Canto MI, Harinck F, Hruban RH, et. al. International Cancer of the Pancreas Screening (CAPS) Consortium summit on the management of patients with increased risk for familial pancreatic cancer. Gut. 2013 Mar;62(3):339-47. doi: 10.1136/gutjnl-2012-303108. Epub 2012 Nov 7. Accessed 29 April 2014: http://gut.bmj.com/content/early/2012/11/06/gutjnl-2012-303108.full. Risk factors are defined in the full medical efficacy document.

v *Op. cit.* ACS: Cancer Facts & Figures 2013. Special Section: Pancreatic Cancer.

vi "An abnormal new growth of tissue that grows more rapidly than normal cells and will continue to grow if not treated." JHU-SGPCRC: What are tumors? Updated 12 November 2012; accessed 5 June 2014: http://pathology.jhu.edu/pc/BasicTypes1.php?area=ba.

vii *Op. cit.* Canto MI, Harinck F, Hruban RH, et. al.

viii Canto MI, Hruban RH, Fishman EK, et. al. Frequent detection of pancreatic lesions in asymptomatic high-risk individuals. Gastroenterology. 2012 Apr;142(4):796-804; quiz e14-5. doi: 10.1053/j.gastro.2012.01.005. Epub 2012 Jan 12. Accessed 29 April 2014: http://www.gastrojournal.org/article/S0016-5085(12)00021-2/pdf.

ix *Op. cit.* ACS: Cancer Facts & Figures 2013. Special Section: Pancreatic Cancer.

x ACS: What's new in pancreatic cancer research and treatment? Updated 5 February 2014; accessed 22 May 2014: http://www.cancer.org/cancer/pancreaticcancer/detailedguide/pancreatic-cancer-new-research.

CURRENT COVERAGE

In a recent survey of ten of the largest insurance carriers in Massachusetts, none report coverage for routine screenings for asymptomatic individuals for pancreatic cancer. All note the grade D recommendation of the USPSTF, and some reference the statement of the ACS regarding widespread testing of average risk patients. All cover medically necessary diagnostic and therapeutic services for patients with symptoms, a diagnosis, or a history of pancreatic cancer.

COST OF IMPLEMENTING THE BILL

Requiring coverage for this benefit by fully-insured health plans would result in an average annual increase, over five years, to the typical member's monthly health insurance premiums of between $0.02 (0.00%) and $0.07 (0.01%) per year.

PLANS AFFECTED BY THE PROPOSED BENEFIT MANDATE

Individual and group accident and sickness insurance policies, corporate group insurance policies, and HMO policies issued pursuant to Massachusetts General Laws, as well as the Group Insurance Commission (GIC) covering public employees and their dependents, would be subject to this proposed mandate. The proposed benefit mandate would apply to members covered under the relevant plans, regardless of whether they reside within the Commonwealth or merely have their principal place of employment in the Commonwealth.

PLANS NOT AFFECTED BY THE PROPOSED BENEFIT MANDATE

Self-insured plans (i.e., where the employer policyholder retains the risk for medical expenses and uses an insurer to provide administrative functions) are subject to federal law and not to state-level health insurance benefit mandates. State health benefit mandates do not apply to Medicare and Medicare Advantage plans whose benefits are qualified by Medicare; consequently this analysis excludes members of commercial fully-insured plans over 64 years of age. These mandates also do not apply to federally-funded plans including TRICARE (covering military personnel and dependents), the Veterans Administration, and the Federal Employee's Health Benefit Plan. Finally, this bill does not apply to Medicaid/MassHealth.

PRELIMINARY ESTIMATE OF POTENTIAL MASSACHUSETTS LIABILITY UNDER THE ACA

Analysis of the cost associated with proposed state benefit mandates is important in light of new requirements introduced by the Affordable Care Act (ACA). In accordance with the ACA, all states must set an Essential Health Benefits (EHB) benchmark that all qualified health plans (QHPs), and those plans sold in the individual and small-group markets, must cover, at a minimum. Section 1311(d)(3)(B) of the ACA, as codified in 45 C.F.R. § 155.170, explicitly permits a state to require QHPs to offer benefits in addition to EHB, provided that the state is liable to defray the cost of additional mandated benefits by making payments to or on behalf of individuals enrolled in QHPs. The requirement to make such payments applies to QHPs sold both on and off the Exchange, but not to non-QHP plans. The state is not financially responsible for the costs of state-required benefits that are considered part of the EHB benchmark plan. In Massachusetts, the Benchmark Plan is the Blue Cross and Blue Shield HMO Blue $2000 Deductible (HMO Blue). State-required benefits enacted on or before December 31, 2011 (even if effective after that date) are not considered "in addition" to EHB and therefore will not be the financial obligation of the state, if such additional benefits are *not* already covered benefits under the State's EHB Benchmark Plan, HMO Blue. This ACA requirement is effective as of January 1, 2014 and is intended to apply for at least plan years 2014 and 2015.

To provide additional information about the potential state liability under the ACA associated with mandating this benefit, CHIA generated a preliminary estimate of the incremental annual premium costs to QHPs associated with this benefit mandate; incremental premium costs exclude the cost of services already provided absent the mandate, already required by other federal or state laws, or already provided under the Massachusetts benchmark plan, HMO Blue. CHIA's review of the proposed health benefit mandate is not intended to determine whether or not this mandate is subject to state liability under the ACA.[xi] CHIA generated this estimate to provide neutral, reliable information to stakeholders who make decisions that impact health care access and costs in the Commonwealth.

CHIA applied the mid-range PMPM (per-member per-month) actuarial projection for 2015 cost ($0.04) to an estimated maximum of 800,000 potential QHP members. [xii] This results in an estimated maximum potential incremental premium increase to QHPs of approximately $32,000 per month or $384,000 per year. An estimate and eventually a final determination of the Commonwealth's liability will require a detailed analysis by the appropriate state agencies, including an assessment of whether this mandate is subject to state liability under the ACA and the actual number of QHP enrollees.

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xi The Health Connector, in consultation with the Massachusetts Division of Insurance, will need to be consulted to provide an analysis of estimated state liability associated with a given proposed mandated benefit bill.

xii Estimated maximum QHP membership provided by the Massachusetts Division of Insurance.

CHIA.

S.B. 471 MEDICAL EFFICACY ASSESSMENT: PANCREATIC CANCER SCREENING

Massachusetts Senate Bill (S.B.) 471 requires health insurance plans to "provide coverage for early screening and detection for pancreatic cancer." M.G.L. c. 3 § 38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with reviewing the medical efficacy of proposed mandated health insurance benefits. Medical efficacy reviews summarize current literature on the effectiveness and use of the mandated treatment or service and describe the potential impact of a mandated benefit on the quality of patient care and the health status of the population.

PANCREATIC CANCER

Pancreatic cancer occurs when the cells of the glands in the pancreas grow out of control.[1] Nationally, cancer of the pancreas is the tenth most common cancer for men and the ninth most common for women.[2] Between 2006 and 2010, the annual incidence rate for pancreatic cancer in Massachusetts was 12.7 per 100,000.[3] The death rate during this time period was 11.4 per 100,000.[4] As discussed in more detail below, only 10 percent of these cases are estimated to occur in individuals with certain genetic or family history factors that identify high-risk individuals (HRIs) recommended for screening. While relatively rare compared to other cancers[5], pancreatic cancer is the fourth most deadly type of cancer, with the majority of patients dying within the first year after diagnosis and less than 6% surviving five years after diagnosis.[6] The median survival period for pancreatic cancer is six months after diagnosis.[7] Moreover, while the incidence of many types of cancer has been declining, cases of pancreatic cancer have been slowly rising over the past decade.[8]

RISK FACTORS AND PREVENTION OF PANCREATIC CANCER

Pancreatic cancer is caused by DNA damage (mutations), which can result from a person's genetics or can be acquired as a person ages, through behavior (e.g., by smoking), interacting with the environment (e.g., pollution), or by chance.[9] A person's lifetime risk for developing pancreatic cancer is approximately 1.3 percent, or 1 in 78, and may vary depending on certain risk factors.[10] While still under study, some risk factors for pancreatic cancer are considered "non-modifiable," including age, gender, race, chronic pancreatitis, diabetes, some infections, and other medical conditions, as well as family history and genetic factors which are linked to approximately 10 percent of pancreatic cancers.[11,12] And while no established guidelines for the prevention of pancreatic cancer currently exist, some risk factors are considered "modifiable," such as tobacco use, obesity and physical activity, alcohol use, and dietary factors.[13,14]

PANCREATIC CANCER SCREENING

Part of the explanation for the poor prognosis for patients with pancreatic cancer is that it is rarely identified early. The pancreas is a gland located deep in the abdomen that produces hormones, including insulin, which regulate blood sugar levels in the body, and digestive enzymes.[15,16,17] Given the location of the pancreas, pancreatic masses are not usually identified during routine examinations; further, patients do not usually experience symptoms until the cancer has metastasized, or spread to other organs.[18] These symptoms most commonly include mid-back pain, unexplained weight loss and appetite loss, mild abdominal discomfort, and jaundice, which is yellowing of the skin or whites of the eyes.[19,20] And while "[s]urgery remains the only treatment that offers a chance of cure…", according to a special pancreatic cancer report published by the American Cancer Society (ACS) in 2013, "only about 15% to 20% of pancreatic cancer cases are diagnosed early enough to be eligible for surgery."[21]

At this time, no accurate screening test is available for the general population.[22,23] In fact, the U.S. Preventive Service Task Force (USPSTF) "recommends against routine screening for pancreatic cancer in asymptomatic adults using abdominal palpation, ultrasonography, or serologic markers," giving such general population-based screenings a grade D recommendation.[24] The specific rationale of the USPSTF states:

> The USPSTF found no evidence that screening for pancreatic cancer is effective in reducing mortality. There is a potential for significant harm due to the very low prevalence of pancreatic cancer, limited accuracy of available screening tests, the invasive nature of diagnostic tests, and the poor outcomes of treatment. As a result, the USPSTF concluded that the harms of screening for pancreatic cancer exceed any potential benefits.[25]

These statements, last updated in 2004, were directed at programs for screening the general public, and the USPSTF acknowledged that while the risk of developing cancer is higher for individuals with hereditary pancreatitis, the Task Force did not review screening programs for these patients.[26] The ACS also states that "widespread testing of people at average risk who do not have any symptoms" is not recommended.[27]

Blood tests for valid and timely early detection of pancreatic cancer are still not available. In recent years, a blood test to detect the substance CA 19-9 (carbohydrate antigen 19-9, an indication that the immune system has responded to a tumor for certain types of the most common pancreatic cancer) has been suggested as a possible screening tool. However, while useful for assessing the stage of a case of pancreatic cancer, by the time the level of CA 19-9 in the blood stream is detectable through the test, the cancer has progressed past its early stages when it is most likely to be treatable.[28] Other blood tests have been suggested to detect other markers of the disease, but the accuracy of these tests in identifying people with pancreatic cancer is even less than the 80% accuracy of the CA 19-9 test.[29]

SCREENING HIGH-RISK INDIVIDUALS

Instead of screening the general population, pancreatic cancer researchers are now focusing on surveillance, or the ongoing testing of a narrowly-defined set of asymptomatic individuals at higher risk for pancreatic cancer due to specific familial and genetic factors, estimated to comprise approximately 10% of pancreatic cancer cases.[30,31] This approach, acknowledged by the ACS, concentrates on identifying individuals with potentially treatable lesions, that is, non-invasive pancreatic abnormal tissue[32], that can be monitored and managed before they cause symptoms or are identified by physical examination.[33,34,35] The ACS states that "[f]or now, imaging tests…are options for people with a strong family history of pancreatic cancer."[36]

Specifically, in 2012, the International Cancer of the Pancreas Screening (CAPS) Consortium, a group of 49 international multi-disciplinary experts, recommended imaging tests aimed at identifying pancreatic lesions or cysts in a narrowly-defined group of high-risk individuals (HRIs) whose lifetime risk for developing pancreatic cancer is greater than 5 percent, or five times higher than that of the general population.[37,38] While disagreement remains on appropriate treatment for identified asymptomatic lesions and cysts, given the risks of such treatment, the organization developed a list of statements for the management of HRIs. These statements answer questions as to who should be screened and how, and when surgery should be performed, and likewise define the goals and successful outcomes of screening.[39]

HRIs are generally those with a strong family history of pancreatic cancer, or certain inheritable genetic mutations.[40,41] Because early-stage lesions and tumors are rarely found during routine examination and individuals with such lesions usually show no symptoms, researchers currently believe that including HRIs in an identification and monitoring surveillance program is the best opportunity for finding potentially curable precancerous and early cancerous pancreatic abnormalities.[42] Other patients are already currently monitored for pancreatic lesions with ongoing imaging tests, specifically those patients in whom abnormalities are detected during a scan conducted for other diagnostic reasons, such as when a pancreatic cyst appears in an abdominal CT scan.[43,44] According to CAPS Consortium guidelines, HRI patients should be screened either with an endoscopic ultrasonography (EUS), a magnetic resonance imaging/cholangiopancreatography study (MRI/MRCP), or both.[45] Follow up screenings are recommended using these methods as well, with the majority of the Consortium suggesting annual follow-up.[46]

However, certain elements of such a screening program are still being researched. For example, the ages at which screening should begin and end for HRIs has not yet been explicitly defined. While the majority of the CAPS Consortium agreed that screening should begin at age 50 for most HRIs, some researchers feel that screening should begin sooner.[47] Moreover, for those individuals in a surveillance program with no evidence of a lesion, disagreement as to the age at which screening should stop has not yet been defined, although a majority believe screening should stop by age 80 for these individuals.[48] The average age at diagnosis for pancreatic cancer is 68, and increased age is a recognized risk factor of the disease.[49]

Other areas in which the Consortium is continuing study and has not yet reached consensus include additional categories of HRIs, when surgery should be performed, the precise goals of screening, and what outcomes should be defined as "success".[50] The published summit findings state that "the group acknowledged that until there are additional studies we will not know if screening HRIs saves lives"; however, the Consortium agrees that success at this stage should be defined by the early detection and treatment of certain non-invasive abnormal pancreatic tissues and cancers that are surgically treatable.[51]

Acknowledgements

Primary CHIA staff for this publication:

Catherine West, MPA, Director of External Research Partnerships

Joseph Vizard, Legislative Liaison

ENDNOTES

1 American Cancer Society (ACS): What is pancreatic cancer? Updated 5 February 2014; accessed 29 April 2014: http://www.cancer.org/cancer/pancreaticcancer/detailedguide/pancreatic-cancer-what-is-pancreatic-cancer.

2 ACS: Cancer Facts & Figures 2013. Special Section: Pancreatic Cancer. Atlanta: American Cancer Society; 2013. Accessed 28 April 2014: http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-036845.pdf.

3 National Cancer Institute: State Cancer Profiles, Massachusetts, Pancreas. Created 20 May 2014: http://statecancerprofiles.cancer.gov/cgi-bin/quickprofiles/profile.pl?25&040#incidence.

4 *Ibid.*

5 National Cancer Institute: Surveillance, Epidemiology and End Results Program, SEER Stat Fact Sheets: Pancreas Cancer. Updated April 2014; accessed 11 June 2014: http://seer.cancer.gov/statfacts/html/pancreas.html.

6 *Op cit.* ACS: Cancer Facts & Figures 2013. Special Section: Pancreatic Cancer.

7 Gemmel C, Eickhoff A, Helmstädter L, et. al. Pancreatic cancer screening: state of the art. Expert Rev Gastroenterol Hepatol. 2009 Feb;3(1):89-96. doi: 10.1586/17474124.3.1.89. Accessed 2 May 2014: http://www.medscape.com/viewarticle/589056.

8 Cleveland Clinic Center for Continuing Education (CC-CCE): Pancreatic Neoplasms. Accessed 29 April 2014: http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/gastroenterology/pancreatic-neoplasms/.

9 Johns Hopkins University, Sol Goldman Pancreatic Cancer Research Center (JHU-SGPCRC): What causes pancreatic cancer? Updated 12 November 2012; accessed 29 April 2014: http://pathology.jhu.edu/pc/BasicCauses.php?area=ba.

10 ACS: What are the key statistics about pancreatic cancer? Updated 5 February 2014; accessed 28 April 2014: http://www.cancer.org/cancer/pancreaticcancer/detailedguide/pancreatic-cancer-key-statistics.

11 These include chronic infection with hepatitis B, hepatitis C or *Helicobacter pylori*; history of cholecystectomy (surgical gallbladder removal) or partial gastrectomy (partial surgical removal of stomach); cystic fibrosis and periodontal disease. *Ibid.*

12 Type of cancer followed by specific gene in parentheses. Exocrine pancreatic cancers: Hereditary breast and ovarian cancer syndrome (BRCA2); Familial melanoma (p16/CDKN2A); Familial pancreatitis (PRSS1); Lynch syndrome: Hereditary non-polyposis colorectal cancer [HNPCC] (MLH1, MSH2, MLH3, MSH6, TGBR2, PMS1, PMS2); Peutz-Jeghers syndrome [PJS] (STK1); Von Hippel-Lindau syndrome (VHL). Pancreatic neuroendocrine tumors and cancers: Neurofibromatosis, type 1 (NF1); Multiple endocrine neoplasia, type 1 (MEN1). ACS: What are the risk factors for pancreatic cancer? Updated 5 February 2014; accessed 28 April 2014: http://www.cancer.org/cancer/pancreaticcancer/detailedguide/pancreatic-cancer-risk-factors.

13 ACS: Cancer Facts & Figures 2013. Special Section: Pancreatic Cancer. Atlanta: American Cancer Society; 2013. Accessed 28 April 2014: http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-036845.pdf.

14 ACS: Can pancreatic cancer be prevented? Updated 5 February 2014; accessed 29 April 2014: http://www.cancer.org/cancer/pancreaticcancer/detailedguide/pancreatic-cancer-prevention.

15 Johns Hopkins University, Sol Goldman Pancreatic Cancer Research Center (JHU-SGPCRC): The pancreas. Updated 12 November 2012; accessed 28 April 2014: http://pathology.jhu.edu/pc/BasicOverview1.php?area=ba.

16 JHU-SGPCRC: Parts of the pancreas. Updated 12 November 2012; accessed 28 April 2014: http://pathology.jhu.edu/pc/BasicOverview2.php?area=ba.

17 JHU-SGPCRC: Function of the pancreas. Updated 12 November 2012; accessed 28 April 2014: http://pathology.jhu.edu/pc/BasicOverview3.php?area=ba.

18 ACS: Can pancreatic cancer be found early? Updated 5 February 2014; accessed 29 April 2014: http://www.cancer.org/cancer/pancreaticcancer/detailedguide/pancreatic-cancer-detection.

19 *Op. cit.* ACS: Cancer Facts & Figures 2013. Special Section: Pancreatic Cancer.

20 JHU-SGPCRC: Is this symptom or side-effect unusual? Updated 12 November 2012; accessed 2 May 2014: http://pathology.jhu.edu/pc/BasicSymptom.php?area=ba.

21 *Op. cit.* ACS: Cancer Facts & Figures 2013. Special Section: Pancreatic Cancer.

22 JHU-SGPCRC: Are there screening tests available? Updated 12 November 2012; accessed 29 April 2014: http://pathology.jhu.edu/pc/BasicScreening.php?area=ba.

23 *Op. cit.* ACS: Can pancreatic cancer be found early?

24 U.S. Preventive Service Task Force (USPSTF): Screening for Pancreatic Cancer. Released February 2004; accessed 29 April 2014: http://www.uspreventiveservicestaskforce.org/uspstf/uspspanc.htm.

25 USPSTF: Screening for Pancreatic Cancer Recommendation Statement. Released February 2004; accessed 30 April 2014: http://www.uspreventiveservicestaskforce.org/3rduspstf/pancreatic/pancrers.htm.

26 *Ibid.*

27 ACS: What's new in pancreatic cancer research and treatment? Updated 5 February 2014; accessed 22 May 2014: http://www.cancer.org/cancer/pancreaticcancer/detailedguide/pancreatic-cancer-new-research.

28 *Op. cit.* ACS: Can pancreatic cancer be found early?

29 *Op. cit.* JHU-SGPCRC: Are there screening tests available?

30 Canto MI, Harinck F, Hruban RH, et. al. International Cancer of the Pancreas Screening (CAPS) Consortium summit on the management of patients with increased risk for familial pancreatic cancer. Gut. 2013 Mar;62(3):339-47. doi: 10.1136/gutjnl-2012-303108. Epub 2012 Nov 7. Accessed 29 April 2014: http://gut.bmj.com/content/early/2012/11/06/gutjnl-2012-303108.full.

Risk factors as defined in the consensus statements:
Who should be screened?

A1 Individuals with three or more affected blood relatives, with at least one affected FDR, should be considered for screening.

A2 Individuals with at least two affected FDRs with PC, with at least one affected FDR, should be considered for screening once they reach a certain age.

A3 Individuals with two or more affected blood relatives with PC, with at least one affected FDR, should be considered for screening.

A4 All patients with Peutz–Jeghers syndrome should be screened, regardless of family history of PC.

A5 p16 carriers with one affected FDR should be considered for screening.

A6 BRCA2 mutation carriers with one affected FDR should be considered for screening.

A7 BRCA2 mutation carriers with two affected family members (no FDR) with PC should be considered for screening.

A8 PALB2 mutation carriers with one affected FDR should be considered for screening.

A9 Mismatch repair gene mutation carriers (Lynch syndrome) with one affected FDR should be considered for screening.

31 *Op. cit.* ACS: Cancer Facts & Figures 2013. Special Section: Pancreatic Cancer.

32 "An abnormal new growth of tissue that grows more rapidly than normal cells and will continue to grow if not treated. These growths will compete with normal cells for nutrients. This is a non-specific term that can refer to benign or malignant growths. A synonym for tumor." JHU-SGPCRC: What are tumors? Updated 12 November 2012; accessed 5 June 2014: http://pathology.jhu.edu/pc/BasicTypes1.php?area=ba.

33 *Op. cit.* Canto MI, Harinck F, Hruban RH, et. al.

34 Canto MI, Hruban RH, Fishman EK, et. al. Frequent detection of pancreatic lesions in asymptomatic high-risk individuals. Gastroenterology. 2012 Apr;142(4):796-804; quiz e14-5. doi: 10.1053/j.gastro.2012.01.005. Epub 2012 Jan 12. Accessed 29 April 2014: http://www.gastrojournal.org/article/S0016-5085(12)00021-2/pdf.

35 *Op. cit.* ACS: Cancer Facts & Figures 2013. Special Section: Pancreatic Cancer.

36 *Op. cit.* ACS: What's new in pancreatic cancer research and treatment?

37 U.S. centers included Dana Farber Cancer Institute (Boston, MA); Johns Hopkins Hospital (Baltimore, MD); Mayo Clinic (Rochester, MN); University of California (Los Angeles, CA); MD Anderson Cancer Center (Houston, TX). Clinicians included Carlos Fernandez-Del Castillo, MD: Professor, Department of Surgery, Harvard Medical School;

Visiting Surgeon, Surgery, Massachusetts General Hospital; and Sapna Syngal, MD, MPH: Associate Professor, Department of Medicine, Harvard Medical School; Associate Physician, Medicine, Brigham And Women's Hospital; Director, Gastroenterology DFCI/BWH Cancer Center, Medical Oncology, Dana-Farber Cancer Institute.

38 *Op. cit.* Canto MI, Harinck F, Hruban RH, et. al.

39 *Ibid.*

40 *Op. cit.* Canto MI, Hruban RH, Fishman EK, et. al.

41 *Op. cit.* ACS: What are the risk factors for pancreatic cancer?

Type of cancer followed by specific gene in parentheses. Exocrine pancreatic cancers: Hereditary breast and ovarian cancer syndrome (BRCA2); Familial melanoma (p16/CDKN2A); Familial pancreatitis (PRSS1); Lynch syndrome: Hereditary non-polyposis colorectal cancer [HNPCC] (MLH1, MSH2, MLH3, MSH6, TGBR2, PMS1, PMS2); Peutz-Jeghers syndrome [PJS] (STK1); Von Hippel-Lindau syndrome (VHL). Pancreatic neuroendocrine tumors and cancers: Neurofibromatosis, type 1 (NF1); Multiple endocrine neoplasia, type 1 (MEN1).

42 *Op. cit.* Canto MI, Harinck F, Hruban RH, et. al.

43 The University of Chicago Medicine: Early Detection of Pancreatic Cancer. Accessed 30 April 2014: http://www.uchospitals.edu/specialties/cancer/pancreatic/screening.html.

44 Tanaka M, Chari S, Adsay V, et. al. International consensus guidelines for management of intraductal papillary mucinous neoplasms and mucinous cystic neoplasms of the pancreas. Pancreatology. 2006;6(1-2):17-32.

45 *Op. cit.* Canto MI, Harinck F, Hruban RH, et. al.

46 *Ibid.*

47 For those individuals with a family history of pancreatic cancer, the CAPS Consortium recommends screening begin 10 years younger than the earliest pancreatic cancer in the family. For patients with Peutz-Jegher syndrome, the Consortium recommends that screening begin between 30-40 years of age, although consensus was not reached on the exact age. *Ibid.*

48 *Ibid.*

49 *Ibid.*

50 Appendix – Web Only Publication, Statements for the Management of High Risk Individuals, Without Consensus Agreement or Disagreement. Canto MI, Harinck F, Hruban RH, et. al. International Cancer of the Pancreas Screening (CAPS) Consortium summit on the management of patients with increased risk for familial pancreatic cancer. Accessed 30 April 2014: http://gut.bmj.com/content/suppl/2012/11/06/gutjnl-2012-303108.DC1/gutjnl-2012-303108supp_appendix.pdf.

51 *Op. cit.* Canto MI, Harinck F, Hruban RH, et. al.

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APPENDIX

Actuarial Assessment of Senate Bill 471:
"An Act relative to pancreatic cancer screening"

Prepared for
Commonwealth of Massachusetts
Center for Health Information and Analysis

July 2014

Prepared by
Compass Health Analytics, Inc.

Actuarial Assessment of Senate Bill 471:
"An Act relative to pancreatic cancer screening"

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Actuarial Assessment of Senate Bill 471:
"An Act relative to pancreatic cancer screening"

Executive Summary

Massachusetts Senate Bill (S.B.) 471 requires health insurance plans to "provide coverage for early screening and detection for pancreatic cancer."[1] Massachusetts General Laws (M.G.L.) c. 3 § 38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with, among other duties, reviewing the potential impact of proposed mandated health care insurance benefits on the premiums paid by businesses and consumers. CHIA has engaged Compass Health Analytics, Inc. to provide an actuarial estimate of the effect enactment of the bill would have on the cost of health care insurance in Massachusetts.

Background

According to the American Cancer Society (ACS), pancreatic cancer is one of the most deadly types of cancer, with the majority of patients dying within a year of diagnosis, and only 6% surviving five years.[2] Part of the explanation for the poor prognosis for patients with pancreatic cancer is that it is rarely identified early. Given the location of the pancreas, pancreatic masses are not usually identified during routine examinations; further, patients do not usually experience symptoms until the cancer has metastasized, or spread to other organs.[3] And while "[s]urgery remains the only treatment that offers a chance of cure…," according to a special pancreatic cancer report published by the ACS in 2013, "only about 15% to 20% of pancreatic cancer cases are diagnosed early enough to be eligible for surgery."[4]

At this time, however, no accurate screening test is available for the general population, and the U.S. Preventive Service Task Force (USPSTF) "recommends against routine screening for pancreatic cancer in asymptomatic adults," giving such general population-based screenings a grade D recommendation.[5,6,7] The USPSTF acknowledged that while the risk of developing cancer is higher for individuals with hereditary risk factors for pancreatitis, the Task Force did not review screening programs for these patients.[8] The ACS also states that "widespread testing of people at average risk who do not have any symptoms" is not recommended.[9]

Instead of screening the general population, pancreatic cancer researchers and clinicians are now focusing on surveillance, or the ongoing testing of a narrowly-defined set of asymptomatic individuals at higher risk for pancreatic cancer due to specific familial and genetic factors.[10,11] This approach concentrates on identifying individuals with potentially treatable lesions, that is, non-invasive abnormal pancreatic tissue,[12] that can be monitored and managed before they become cancerous and/or cause symptoms or are identified by physical examination.[13,14,15] In such a program, identified high-risk individuals (HRIs) are annually screened either with an endoscopic ultrasonography (EUS), a magnetic resonance imaging/cholangiopancreatography study (MRI/MRCP) or both, beginning at age 50 for most individuals. [16,17]

While S.B. 471 is broadly worded in providing coverage for "early screening and detection for pancreatic cancer," the proposed mandate is intended to provide insurance coverage for pancreatic cancer screenings only for HRIs, according to the bill's sponsor. For purposes of this analysis, the mandate is interpreted to apply to HRIs only, consistent with the USPSTF's recommendation against broader screening, the recommendations and focus of most current research on pancreatic cancer, and the likelihood that a broader strategy would fail a medical necessity assessment among carriers and practicing physicians.

In a recent survey of insurance carriers in Massachusetts, none report coverage for routine screenings for asymptomatic individuals for pancreatic cancer. All note the grade D recommendation of the USPSTF previously described, with some referencing the statement of the ACS regarding widespread testing of asymptomatic, average risk patients. All cover medically necessary diagnostic and therapeutic services for patients with symptoms, a diagnosis, or a history of pancreatic cancer.

Analysis

Compass estimated the impact of S.B. 471 by performing the following steps:

- Estimate the fully-insured Massachusetts population under age 65, projected for the next five years (2015 to 2019)
- Estimate the number of cases of pancreatic cancer for the study period
- Estimate the number of high-risk individuals (HRIs) to be screened annually for pancreatic cancer
- Estimate the average annual per-patient cost of genetic screening and HRI pancreatic imaging tests
- Calculate the proposed mandate's incremental effect on carrier medical expenses
- Estimate the impact of insurer's retention (administrative costs and profit) on premiums
- Project the estimated cost over the next five years

Factors affecting the analysis include:

- Estimates of the number of HRIs, and the proportion of HRI's who will undergo screening, are imprecise.
- Estimates of the costs of screening depend on the genetic and/or imaging tests performed.

Even with these sources of uncertainty, under a reasonable range of assumptions, a relatively small number of people are likely to be tested during the study period, producing relatively modest cost estimates even at the high end of estimated cases and costs.

Summary results

Table ES-1 summarizes the effect of S.B. 471 on premium costs for fully-insured plans, averaged over five years. This analysis estimates that the mandate, if enacted, would likely increase fully-insured premiums by as much as 0.01 percent on average over the next five years.

The degree of precision achievable in this analysis is hindered by the issues outlined in section 4; to account for the uncertainty in the number of individuals who will be screened and for the number and types of genetic and imaging tests utilized, the high scenarios allow for a combination of more-expensive assumptions which still result in a relatively small percentage of overall annual premium.

Finally, the impact of the bill on any one individual, employer-group, or carrier may vary from the overall results depending on the current level of benefits each receives or provides, and on how the benefits will change under the proposed mandate.

Table ES-1:
Summary Results

	2015	2016	2017	2018	2019	Average	5 Yr Total
Members (000s)	2,144	2,121	2,096	2,071	2,045		
Medical Expense Low ($000s)	$268	$347	$430	$519	$612	$435	$2,176
Medical Expense Mid ($000s)	$581	$753	$935	$1,128	$1,331	$946	$4,728
Medical Expense High ($000s)	$981	$1,271	$1,578	$1,903	$2,246	$1,596	$7,979
Premium Low ($000s)	$302	$392	$486	$587	$692	$492	$2,459
Premium Mid ($000s)	$657	$851	$1,057	$1,274	$1,504	$1,068	$5,342
Premium High ($000s)	$1,108	$1,436	$1,783	$2,151	$2,538	$1,803	$9,015
PMPM Low	$0.01	$0.02	$0.02	$0.02	$0.03	$0.02	$0.02
PMPM Mid	$0.03	$0.03	$0.04	$0.05	$0.06	$0.04	$0.04
PMPM High	$0.04	$0.06	$0.07	$0.09	$0.10	$0.07	$0.07
Estimated Monthly Premium	$512	$537	$564	$592	$622	$566	$566
Premium % Rise Low	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Premium % Rise Mid	0.00%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%
Premium % Rise High	0.01%	0.01%	0.01%	0.01%	0.02%	0.01%	0.01%

Executive Summary Endnotes

[1] The 188th General Court of the Commonwealth of Massachusetts. Bill S. 471: An Act relative to pancreatic cancer screening. Accessed 6 June 2014: https://malegislature.gov/Bills/188/Senate/S471.

[2] American Cancer Society (ACS): Cancer Facts & Figures 2013. Special Section: Pancreatic Cancer. Atlanta: American Cancer Society; 2013. Accessed 28 April 2014: http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-036845.pdf.

[3] ACS: Can pancreatic cancer be found early? Updated 5 February 2014; accessed 29 April 2014: http://www.cancer.org/cancer/pancreaticcancer/detailedguide/pancreatic-cancer-detection

[4] *Op. cit.* ACS: Cancer Facts & Figures 2013. Special Section: Pancreatic Cancer.

[5] JHU-SGPCRC: Are there screening tests available? Updated 12 November 2012; accessed 29 April 2014: http://pathology.jhu.edu/pc/BasicScreening.php?area=ba.

[6] *Op. cit.* ACS: Can pancreatic cancer be found early?

[7] USPSTF: Screening for Pancreatic Cancer. Released February 2004; accessed 29 April 2014: http://www.uspreventiveservicestaskforce.org/uspstf/uspspanc.htm.

[8] *Ibid.*

[9] ACS: What's new in pancreatic cancer research and treatment? Updated 5 February 2014; accessed 22 May 2014: http://www.cancer.org/cancer/pancreaticcancer/detailedguide/pancreatic-cancer-new-research.

[10] Canto MI, Harinck F, Hruban RH, et. al. International Cancer of the Pancreas Screening (CAPS) Consortium summit on the management of patients with increased risk for familial pancreatic cancer. Gut. 2013 Mar;62(3):339-47. doi: 10.1136/gutjnl-2012-303108. Epub 2012 Nov 7. Accessed 29 April 2014: http://gut.bmj.com/content/early/2012/11/06/gutjnl-2012-303108.full.

[11] *Op. cit.* ACS: Cancer Facts & Figures 2013. Special Section: Pancreatic Cancer.

[12] "An abnormal new growth of tissue that grows more rapidly than normal cells and will continue to grow if not treated." JHU-SGPCRC: What are tumors? Updated 12 November 2012; accessed 5 June 2014: http://pathology.jhu.edu/pc/BasicTypes1.php?area=ba.

[13] *Op. cit.* Canto MI, Harinck F, Hruban RH, et. al.

[14] Canto MI, Hruban RH, Fishman EK, et. al. Frequent detection of pancreatic lesions in asymptomatic high-risk individuals. Gastroenterology. 2012 Apr;142(4):796-804; quiz e14-5. doi: 10.1053/j.gastro.2012.01.005. Epub 2012 Jan 12. Accessed 29 April 2014: http://www.gastrojournal.org/article/S0016-5085(12)00021-2/pdf.

[15] *Op. cit.* ACS: Cancer Facts & Figures 2013. Special Section: Pancreatic Cancer.

[16] Generally those with a family history of pancreatic cancer or certain germline mutations. *Op. cit.* Canto MI, Hruban RH, Fishman EK, et. al.

[17] *Op. cit.* Canto MI, Harinck F, Hruban RH, et. al.

Actuarial Assessment of Senate Bill 471:
"An Act relative to pancreatic cancer screening"

1. Introduction

Massachusetts Senate Bill (S.B.) 471 requires health insurance plans to "provide coverage for early screening and detection for pancreatic cancer."[1] Massachusetts General Laws (M.G.L.) c. 3 § 38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with, among other duties, reviewing the potential impact of proposed mandated health care insurance benefits on the premiums paid by businesses and consumers. CHIA has engaged Compass Health Analytics, Inc. to provide an actuarial estimate of the effect enactment of the bill would have on the cost of health care insurance in Massachusetts.

Assessing the impact of this bill entails analyzing the incremental effect of the bill on spending by insurance plans. This in turn requires comparing spending under the provisions of the proposed law to spending under current statutes and current benefit plans for the relevant services.

Section 2 of this analysis outlines the provisions of the bill. Section 3 summarizes the methodology used for the estimate. Section 4 discusses important considerations in translating the bill's language into estimates of its incremental impact on health care costs. Finally, Section 5 describes the calculation of the estimate.

2. Interpretation of S.B. 471

The following subsections describe the provisions of S.B. 471, as drafted for the 188th General Court.

2.1. Plans affected by the proposed mandate

The bill amends the statutes that regulate insurers providing health insurance in Massachusetts. The following five sections of the bill, each addressing statutes dealing with a particular type of health insurance policy, were interpreted as relevant to this analysis:[2]

- Section 1: Insurance for persons in service of the Commonwealth (creating M.G.L. c. 32A, § 17K)
- Section 2: Accident and sickness insurance policies (creating M.G.L. c. 175, § 47CC)
- Section 3: Contracts with non-profit hospital service corporations (creating M.G.L. c. 176A, § 8FF)
- Section 4: Certificates under medical service agreements (creating M.G.L. c. 176B, § 4FF)

- Section 5: Health maintenance contracts (creating M.G.L. c. 176G, § 4X)

The bill requires coverage for members under the relevant plans, regardless of whether they reside within the Commonwealth or merely have their principal place of employment in the Commonwealth.

Self-insured plans are subject to federal law and not to state-level health insurance benefit mandates. State mandates do not apply to Medicare, and this analysis assumes that this proposed mandate does not affect Medicare extension/supplement plans even to the extent they are regulated by state law. Finally, this bill does not apply to Medicaid/MassHealth.

2.2. Covered services

According to the American Cancer Society (ACS), pancreatic cancer is one of the most deadly types of cancer, with the majority of patients dying within a year of diagnosis, and only 6% surviving five years after diagnosis.[3] Part of the explanation for the poor prognosis for patients with pancreatic cancer is that it is rarely identified early. Given the location of the pancreas, pancreatic masses are not usually identified during routine examinations; further, patients do not usually experience symptoms until the cancer has metastasized, or spread to other organs.[4] And while "[s]urgery remains the only treatment that offers a chance of cure…," according to a special pancreatic cancer report published by the ACS in 2013, "only about 15% to 20% of pancreatic cancer cases are diagnosed early enough to be eligible for surgery."[5]

At this time, however, no accurate screening test is available for the general population, and the U.S. Preventive Service Task Force (USPSTF) "recommends against routine screening for pancreatic cancer in asymptomatic adults," giving such general population-based screenings a grade D recommendation.[6,7,8] Instead of screening the general population, pancreatic cancer researchers and clinicians are now focusing on surveillance, or the ongoing testing of a very narrowly defined set of asymptomatic individuals known to be at higher risk for pancreatic cancer due to specific familial and genetic factors.[9,10] This approach, acknowledged by the ACS, concentrates on identifying individuals with potentially treatable lesions, that is, non-invasive pancreatic abnormal tissue[11], that can be monitored and managed before they cause symptoms or are identified by physical examination.[12,13,14] In such a program, identified high-risk individuals (HRIs) are annually screened either with an endoscopic ultrasonography (EUS), a magnetic resonance imaging/cholangiopancreatography study (MRI/MRCP) or both, beginning at age 50 for most individuals.[15,16]

In a recent survey of ten of the largest insurance carriers in Massachusetts, none report coverage for routine screenings for asymptomatic individuals for pancreatic cancer. All note the grade D recommendation of the USPSTF previously described, with some referencing the statement of the ACS regarding widespread testing of asymptomatic, average risk patients. All cover diagnostic and therapeutic services that are medically necessary for patients whose symptoms may indicate pancreatic cancer, or for those with a diagnosis or history of pancreatic cancer.

While S.B. 471 is broadly worded in providing coverage for "early screening and detection for pancreatic cancer," the proposed mandate is intended to provide insurance coverage for pancreatic cancer screenings only for HRIs, according to the bill's sponsor. For purposes of this analysis, the mandate is interpreted to apply to HRIs only, consistent with the USPSTF's recommendation against broader screening, the recommendations and focus of most current research on pancreatic cancer, and the likelihood that a broader strategy would fail a medical necessity assessment among carriers and practicing physicians.

2.3. Existing laws affecting the cost of S.B. 471

No existing federal or state mandates related to the specific subject matter of this bill have been identified. Current Massachusetts law does mandate insurance "[c]overage for patient care services provided under qualified clinical trials,"[17] but "clinical trial" is defined as cancer treatments and not screening or diagnostic procedures; the law specifically states that "[t]he clinical trial is intended to treat cancer in a patient who has been so diagnosed."[18]

The federal Affordable Care Act (ACA)[19] requires coverage for certain preventive health services with no cost-sharing by all health insurance plans,[20] including self-insured, individual, and small and large group market plans.[21] Plans must cover, at a minimum, evidence-based preventive health services or items that have an "A" or "B" rating in the current recommendations of the United States Preventive Services Task Force (USPSTF) with no deductible, copayment, or coinsurance payments by the beneficiary. As previously noted, the current recommendation of the USPSTF regarding pancreatic cancer screening for the general population received a "D" rating, and is therefore not required under the ACA to be covered by health insurance plans.[22]

3. Methodology

3.1. Steps in the analysis

Compass estimated the impact of S.B. 471 by performing the following steps:

- Estimate the fully-insured Massachusetts population under age 65, projected for the next five years (2015 to 2019)
- Estimate the number of cases of pancreatic cancer for the study period
- Estimate the number of high-risk individuals (HRIs) to be screened annually for pancreatic cancer
- Estimate the average annual per-patient cost of genetic screening and HRI pancreatic imaging tests
- Calculate the proposed mandate's incremental effect on carrier medical expenses
- Estimate the impact of insurer's retention (administrative costs and profit) on premiums

- Project the estimated cost over the next five years

3.2. Data sources

The primary data sources used in the analysis were:

- Responses from the bill's sponsors or legislative staff to questions regarding legislative intent
- Information from clinical providers and billing staff
- Information from a survey of private health insurance carriers in Massachusetts
- Academic literature, including population data
- Massachusetts insurer claim data from CHIA's Massachusetts All-Payer Claim Database (APCD) for calendar years 2010 to 2012, for plans covering the majority of the under-65 fully insured population subject to the proposed mandate[23]

The following step-by-step description of the estimation process addresses limitations in some of these sources and the uncertainties they contribute to the cost estimate.

4. Factors Affecting the Analysis

Several issues arise in translating the provisions of S.B. 471 into an analysis of incremental cost.

4.1. Number of high-risk individuals to be screened

Compared to other cancers, pancreatic cancer is relatively rare, with an annual incidence rate of 12.7 cases per 100,000 people in Massachusetts.[24] Of these cases, only 10% are estimated to be linked to the genetic or familial risk factors that are used to identify high-risk individuals (HRIs) who may benefit from screening.[25,26,27] Currently, the size of the population of HRIs not yet diagnosed with pancreatic cancer is unknown, especially as many of the categories are comprised of several risk factors combined, such as "BRCA2 mutation carriers with one affected first-degree relative."[28] The number of first-degree relatives of those who have had pancreatic cancer, or the number of those with "affected blood relatives," are especially difficult to estimate and are currently unknown.

Overall, though, the initial group to be screened is estimated to be small, as the criteria for defining HRIs are very narrow and specific. Most depend on a combination of an individual's family history and a genetic mutation. Family history indicators include combinations of first-degree and/or "affected blood relatives," and many people may not be aware of either the medical history of these relations, or of their own subsequent increased risk of pancreatic cancer. Likewise, most people are not aware of the relationship between certain genetic syndromes and pancreatic cancer, and are further unlikely to know of the existence of these mutations in their own genetic make-up.

Several other considerations further reduce the likely number of annual screenings. "Screening" in the context of the intended meaning of S.B. 471, more appropriately termed "surveillance" as it is targeted at HRIs, is focused on asymptomatic people. Further narrowing this population is the International Cancer of the Pancreas Screening (CAPS) Consortium recommendation that screenings should only be offered to those who are candidates for surgery and are, therefore, otherwise healthy.[29] Asymptomatic, healthy people may not be motivated to undergo imaging tests, especially as they may require sedation and are not entirely without risk. Additionally, the current recommendation schedule of annual imaging may be considered burdensome by some patients.

In addition, some patients may forego these tests because the next steps after a cyst, neoplasm, or other anomaly is found are not clear or without risk. Significantly, the CAPS Consortium reached little consensus upon which lesions require surgery versus monitoring, and expressed concern that the "risk of overtreatment using available screening tests...is magnified by the risks of morbidity and mortality (~1-2%) of pancreatic surgery."[30] This lack of clear direction among experts on how to act on imaging test results, and the inherent risks, explain some patients' unwillingness to discover these anomalies at all. Put differently, if it is unclear that the early discovery of certain lesions will result in saving a patient's life through early treatment, patients may be less willing to undergo the risks and inconvenience of the screening tests in the first place.

While these factors serve to reduce the assumed number of individuals screened, the number screened presumably will increase over time as availability of screening coverage becomes more widely known. The analysis assumes that over the five-year time period projected, additional research will be published on the results of such screening, and awareness of risk factors and their association with pancreatic cancer will continue to grow. Programs, such as the one currently in place at the Dana Farber Cancer Institute's Center for Cancer Genetics and Prevention,[31] will continue outreach to HRIs, informing those who are eligible of the potential benefits of such testing, and increasing the percentage of the population who undergo the screens over time.

4.2. Cost of pancreatic cancer screening

As previously described, asymptomatic, high-risk individuals are most accurately screened through annual MRI/MRCP, EUS, or both.[32] While research is ongoing as to the most effective test approach, each test provides slightly different information to clinicians, and providers themselves may prefer one test over another.[33] Though the cost of each individual test is similar, physicians may choose to conduct both tests as part of a screen, either as baseline and/or annually. The precise pattern of testing that physicians may employ is not specified in current guidelines and is difficult to predict.

The language of the bill does not specifically narrow screening to HRIs, nor does it define those tests to be conducted during screening. Published research and guidelines, such as those defined by the CAPS Consortium, do not include recommendations specifically for genetic screens but are instead focused on imaging tests;[34] however, in some cases it is expected that genetic testing will be performed. Screening recommendations in general consider an individual's genetic profile, including mutations and syndromes linked to an increased risk of pancreatic cancer, as previously understood, but it is difficult to predict how many of these genetic tests will be performed.

5. Analysis

To estimate the overall impact of the proposed legislation, the following calculations were executed. The analysis includes development of a best estimate "mid-level" scenario, as well as a low-level scenario using assumptions that produced a lower estimate, and a high-level scenario using more conservative assumptions that produced a higher estimated impact.

5.1. Projected fully-insured population in Massachusetts

Table 1 shows the fully-insured population in Massachusetts ages 0 to 64 projected for the next five years. Appendix A describes the sources of these values.

Table 1:
Projected Fully-Insured Population in Massachusetts, Ages 0-64

Year	Total (0-64)
2015	2,144,066
2016	2,120,558
2017	2,096,250
2018	2,071,138
2019	2,045,433

The five-year projection required in this analysis uses the estimates of utilization and cost in the following subsections. These are measured/estimated for the specified baseline period and are then adjusted appropriately when incorporated into the final forward-looking projections.

5.2. Projected incidence of pancreatic cancer

Table 2 shows the number of pancreatic cases in Massachusetts projected for the next five years, based on current ACS reporting of an incidence rate of 12.7 per 100,000 residents.[35] Of cases of pancreatic cancer, approximately 10% are related to high-risk familial and genetic factors, shown as HR cases in Table 2.[36]

Table 2:
Projected Cases of Pancreatic Cancer and Those Resulting from High-Risk Factors in Massachusetts

Year	Cases	HR Cases
2015	272.3	27.2
2016	269.3	26.9
2017	266.2	26.6
26.3	263.0	26.3
2019	259.8	26.0

5.3. Estimated high-risk individuals who will be screened

As noted previously, there are no current published estimates of the total number of HRIs who have either a family history of pancreatic cancer and/or an identified genetic risk factor in such combination as would make them eligible for screening. This analysis, therefore, estimates the number of HRIs who will seek screening (using low, mid and high scenarios) as a multiple of the number of incident cases of pancreatic cancer resulting from these high-risk factors, calculated as HR cases in Table 2. In effect, the model estimates the size of the "ripple" that an individual diagnosed with pancreatic cancer identified with high risk factors will produce in the number of screened individuals among relatives. It is important to note that individuals diagnosed with pancreatic cancer outside teaching settings may not have genetic testing performed as part of ongoing research, and so may not know they are high risk, reducing the degree to which incident cases generate identified HRIs.

When an individual becomes aware that he or she is at high risk, for example when a close relative is diagnosed with pancreatic cancer, the clinical and counseling assessment of a screening program may lead to genetic testing. Based on the considerations discussed in Section 4.1, the model estimates the multiples applied to annual HRI incident cancer cases to be 2, 4, and 6 times for the low, medium, and high scenarios. So, for example, the mid-level scenario assumes that four persons will receive genetic testing for each HRI diagnosed with pancreatic cancer.

For pancreatic diagnostic imaging tests, the model uses multiples of 1, 2, and 3 times the annual incident cancer diagnoses for HRIs for the low, medium, and high scenarios, assuming that through genetic testing and counseling, a number of individuals will be ruled out as HRI, reducing the number who will receive annual imaging tests to detect pancreatic anomalies.

These estimates of those who will receive imaging tests are further adjusted over time to account for three additional factors: 1) an increase in the proportion of the HRI population screened during the study period, as available information and outreach/recruitment continue for such screenings; 2) continued annual screens for some individuals for up to a ten-year period for whom no anomalies were found on previous screens; and 3) a decrease in the number of the previously-tested population for whom the imaging tests found anomalies which now must be monitored or treated outside of the screening program.

Table 3 displays the number of HRIs to be screened with genetic and/or imaging tests over time under each scenario used in this analysis.

Table 3:
Estimated Number of HRIs To Be Screened by Year

	2015	2016	2017	2018	2019
Low Scenario	116	143	171	197	222
Mid Scenario	232	287	341	394	445
High Scenario	347	430	512	591	667

5.4. Average cost of screening

The average cost of screening depends on whether a provider chooses to screen HRIs using an MRI/MRCP, EUS, or both, as described previously, as well as upon which genetic test(s) may be performed. Table 4 displays the average cost of each scenario based on claims data for the baseline year 2012.

Table 4:
Average Imaging Test Cost,
Baseline Year 2012

Low scenario	$1,500
Mid scenario	$1,800
High scenario	$3,300

For this analysis, three scenarios were developed to estimate the percent of each test or combination used for screening. These assumptions are displayed in Table 5.

Table 5:
Percent of Screens Performed by Test Type

	Testing Mix		
	Low cost test	High cost test	Both
Low Scenario	50.0%	25.0%	25.0%
Mid Scenario	33.3%	33.3%	33.3%
High Scenario	25.0%	25.0%	50.0%

The baseline cost for each test was then projected for the study period 2015 to 2019 using an annual medical inflation rate of 4.5%; each of these projections was then multiplied by the assumed percentage of screens performed by test type under the scenarios outlined in Table 5. The result is the projected average cost per screen by year under each scenario, shown in Table 6.

Table 6:
Projected Average Cost Per Screen by Year

	2015	2016	2017	2018	2019
Low Scenario	$2,311	$2,415	$2,524	$2,637	$2,756
Mid Scenario	$2,511	$2,624	$2,742	$2,865	$2,994
High Scenario	$2,824	$2,951	$3,084	$3,223	$3,368

5.5. Net increase in carrier medical expense

For each scenario, the number of HRIs estimated to be screened in each year was multiplied by the projected average cost per screen by year. This total was then divided by the projected fully insured membership, yielding the medical expense per member per month (PMPM) displayed in Table 7.

Table 7:
Estimate of Increase in Carrier Medical Expense PMPM

Low Scenario	$0.02
Mid Scenario	$0.04
High Scenario	$0.06

Other costs may result from the screening, including surgeries to treat lesions identified. The already small number of individuals screened each year would lead to a very small number of individuals with lesions identified for treatment, and these treatment costs would have possible offsets in future years for cancers that do not subsequently develop. Identifying these indirect costs is outside the scope of this analysis, and are likely immaterial to the overall net result.

5.6. Net increase in premium

Assuming an average retention rate of 11.5 percent, based on CHIA's analysis of administrative costs and profit in Massachusetts,[37] the increase in medical expense was adjusted upward to approximate the total impact on premiums. Table 8 shows the result.

Table 8:
Estimate of Increase in Premium PMPM

Low Scenario	$0.02
Mid Scenario	$0.04
High Scenario	$0.07

5.7. Five-year estimated impact

For each year in the five-year analysis period, Table 9 displays the projected net impact of the proposed mandate on medical expense and premiums using a projection of Massachusetts fully-insured membership. This analysis estimates that the mandate, if enacted, would likely increase fully-insured premiums by as much as 0.01 percent on average over the next five years.

The degree of precision achievable in this analysis is hindered by the issues outlined in section 4; to account for the uncertainty in the number of individuals who will be screened and for the number and types of genetic and imaging tests utilized, the high scenarios allow for a combination of more-expensive assumptions which still result in a relatively small percentage of overall annual premium.

Finally, the impact of the bill on any one individual, employer-group, or carrier may vary from the overall results depending on the current level of benefits each receives or provides, and on how the benefits will change under the proposed mandate.

Table 9:
Summary Results

	2015	2016	2017	2018	2019	Average	5 Yr Total
Members (000s)	2,144	2,121	2,096	2,071	2,045		
Medical Expense Low ($000s)	$268	$347	$430	$519	$612	$435	$2,176
Medical Expense Mid ($000s)	$581	$753	$935	$1,128	$1,331	$946	$4,728
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Premium Low ($000s)	$302	$392	$486	$587	$692	$492	$2,459
Premium Mid ($000s)	$657	$851	$1,057	$1,274	$1,504	$1,068	$5,342
Premium High ($000s)	$1,108	$1,436	$1,783	$2,151	$2,538	$1,803	$9,015
PMPM Low	$0.01	$0.02	$0.02	$0.02	$0.03	$0.02	$0.02
PMPM Mid	$0.03	$0.03	$0.04	$0.05	$0.06	$0.04	$0.04
PMPM High	$0.04	$0.06	$0.07	$0.09	$0.10	$0.07	$0.07
Estimated Monthly Premium	$512	$537	$564	$592	$622	$566	$566
Premium % Rise Low	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Premium % Rise Mid	0.00%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%
Premium % Rise High	0.01%	0.01%	0.01%	0.01%	0.02%	0.01%	0.01%

5.8. Impact on the GIC

Because the benefit offerings of GIC plans are similar to most other commercial plans in Massachusetts, and likewise do not currently cover pancreatic cancer screening for asymptomatic individuals similarly to other carriers, the estimated PMPM effect of the proposed mandate on GIC coverage is not expected to differ from that calculated for the other fully-insured plans in Massachusetts. Note that the total medical expense and premium numbers displayed in Table 9 include the GIC fully-insured membership. To calculate the medical expense separately for the self-insured portion of the GIC, the medical expense per member per month was applied to the GIC self-insured membership; the results are displayed in Table 10.

Table 10:
GIC Self-Insured Summary Results

	2015	2016	2017	2018	2019	Average	5 Yr Total
Members (000s)	259	259	259	258	258		
Medical Expense Low ($000s)	$3	$4	$4	$5	$6	$4	$22
Medical Expense Mid ($000s)	$6	$8	$10	$12	$14	$10	$49
Medical Expense High ($000s)	$10	$13	$16	$20	$24	$16	$82

Appendix A: Membership Affected by the Proposed Mandate

Membership potentially affected by a proposed mandate may include Massachusetts residents with fully-insured employer-sponsored health insurance (including through the GIC), non-residents with fully-insured employer-sponsored insurance issued in Massachusetts, Massachusetts residents with individual (direct) health insurance coverage, and, in some cases, lives covered by GIC self-insured coverage. Membership projections for 2015 to 2019 are derived from the following sources.

Total Massachusetts population estimates for 2012 and 2013 from U. S. Census Bureau data[38] form the base for the projections. Distributions by gender and age, also from the Census Bureau,[39] were applied to these totals. Projected growth rates for each gender/age category were calculated from Census Bureau population projections to 2030.[40] The resulting growth rates were then applied to the base amounts to project the total Massachusetts population for 2015 to 2019.

The number of Massachusetts residents with employer-sponsored or individual (direct) health insurance coverage was estimated using Census Bureau data on health insurance coverage status and type of coverage[41] applied to the population projections.

To estimate the number of Massachusetts residents with fully-insured employer-sponsored coverage, projected estimates of the percentage of employer-based coverage that is fully-insured were developed using historical data from the Medical Expenditure Panel Survey Insurance Component Tables.[42]

To estimate the number of non-residents covered by a Massachusetts policy – typically cases in which a non-resident works for a Massachusetts employer offering employer-sponsored coverage – the number of lives with fully-insured employer-sponsored coverage was increased by the ratio of the total number of individual tax returns filed in Massachusetts by residents[43] and non-residents[44] to the total number of individual tax returns filed in Massachusetts by residents.

The number of residents with individual (direct) coverage was adjusted further to remove the estimated number of people currently covered by Commonwealth Care who will shift into MassHealth due to expanded Medicaid eligibility under the Affordable Care Act beginning in 2014.[45]

Projections for the GIC self-insured lives were developed using GIC base data for 2012[46] and 2013[47] and the same projected growth rates from the Census Bureau that were used for the Massachusetts population. Breakdowns of the GIC self-insured lives by gender and age were based on the Census Bureau distributions.

Endnotes

[1] The 188th General Court of the Commonwealth of Massachusetts. Bill S. 471: An Act relative to pancreatic cancer screening. Accessed 6 June 2014: https://malegislature.gov/Bills/188/Senate/S471.

[2] Meeting with sponsor and legislative, CHIA, and Compass staff 10 December 2013.

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Risk factors as defined in the consensus statements:
Who should be screened?

- A1 Individuals with three or more affected blood relatives, with at least one affected FDR[9], should be considered for screening.
- A2 Individuals with at least two affected FDRs with PC[9], with at least one affected FDR, should be considered for screening once they reach a certain age.
- A3 Individuals with two or more affected blood relatives with PC, with at least one affected FDR, should be considered for screening.
- A4 All patients with Peutz–Jeghers syndrome should be screened, regardless of family history of PC.
- A5 p16 carriers with one affected FDR should be considered for screening.
- A6 BRCA2 mutation carriers with one affected FDR should be considered for screening.
- A7 BRCA2 mutation carriers with two affected family members (no FDR) with PC should be considered for screening.
- A8 PALB2 mutation carriers with one affected FDR should be considered for screening.
- A9 Mismatch repair gene mutation carriers (Lynch syndrome) with one affected FDR should be considered for screening.

[10] *Op. cit.* ACS: Cancer Facts & Figures 2013. Special Section: Pancreatic Cancer.

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[15] Generally those with a family history of pancreatic cancer or certain germline mutations. *Op. cit.* Canto MI, Hruban RH, Fishman EK, et. al.

[16] *Op. cit.* Canto MI, Harinck F, Hruban RH, et. al.

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[29] *Ibid.*

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