Review and Evaluation of Certain Health Benefit Mandates in Connecticut

2013

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December 31, 2013

Commissioner Thomas B. Leonardi
Connecticut Insurance Department
P.O. Box 816
Hartford, CT 06142-0816

Re: Mandated Benefit Review Project 2013

Dear Commissioner Leonardi,

In its 2009 regular session, the Connecticut General Assembly enacted Public Act (P.A.) 09-179, which requires the Connecticut Department of Insurance (CID) to review and evaluate proposed or existing health insurance benefit mandates, as requested by the co-chairs of the Insurance and Real Estate Committee each year. CID is directed in this legislation to contract with the University of Connecticut Health Center, Center for Public Health and Health Policy (CPHHP) to perform such review and evaluation and to assess the insurers licensed in Connecticut to recover the costs of such review. CPHHP is authorized to obtain the services of whatever other entities it needs to perform the review and analysis, both internally and outside the university.

By letter dated July 19, 2013, the co-chairs of the Insurance and Real Estate Committee requested CID to report on four proposed health insurance benefit mandates. At a later date, the Commissioner and the co-chairs of the Committee agreed to extend the reporting date on the fourth mandate until January 24, 2014. Enclosed with this letter is our analysis of the first three mandates.

The analysis consists of four parts: a general overview and a chapter for each of the three proposed mandates. Each of the mandate chapters is written to stand on its own. The analysis has been prepared by CPHHP with the assistance of CID and OptumInsight (Optum), an actuarial consulting firm. The report on the fourth mandate will be provided in January under separate cover.

We have enjoyed working on this analysis and are pleased to present you with our findings. Thank you very much for this opportunity. We look forward to answering your questions and those of the General Assembly.

Sincerely,

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Executive Summary

Pursuant to Public Act 09-179, the Chairs of the Insurance and Real Estate Committee of the Connecticut General Assembly (the Committee) directed the Connecticut Insurance Department (CID) to review four proposed health benefits in a letter dated July 19, 2013. The proposed health benefits listed in the letter to be reviewed include:

- Health insurance coverage for diagnosis and treatment of pediatric autoimmune neuropsychiatric disorder associated with streptococcal infections, or PANDAS, as set forth in S.B. 956 from the 2013 Regular Session.
- Health insurance coverage for lung cancer screening when performed in accordance with the recommendations of the American Lung Association in consultation with the American Cancer Society, as set forth in S.B. 862 from the 2013 Regular Session.
- Health insurance coverage for fertility preservation services for insureds who face likely infertility as a result of a necessary medical procedure for the treatment of cancer or other medical conditions, as set forth in H.B. 5644 from the 2013 Regular Session.
- Health insurance coverage for treatment of mental and nervous conditions that are ordered by a court, similar to the language in S.B. 1091 from the 2013 Regular Session. (This report will be submitted later in January, by agreement with the Committee.)

This review has been performed in accordance with that request. Reviews of proposed health benefits are collaborative efforts of the CID and the University of Connecticut Health Center, Center for Public Health and Health Policy (CPHHP), with the assistance of OptumInsight (Optum), an actuarial consulting firm. Each proposed health benefit was studied separately and the key findings of these studies are reported below. At a date following receipt of the original letter, the CPHHP and the CID agreed to extend the reporting date for the fourth proposed mandate to January 24, 2014.

Brief summary of the proposed health benefits in this report

Pediatric autoimmune neuropsychiatric disorder associated with streptococcal infections (PANDAS): S.B. 956 proposed to mandate coverage for treatment of PANDAS, a mental health condition characterized by obsessive/compulsive disorders and tic disorder symptoms, believed to be caused by streptococcal infection in children. The report assumes coverage of intravenous immunoglobulin, plasma exchange and prophylactic use of antibiotics as treatments for PANDAS.

Lung cancer screening: S.B. 862 proposed to mandate coverage for lung cancer screening for certain long-time smokers, in accordance with the recommendations of the American Lung Association and the American Cancer Society.

Fertility preservation services: H.B. 5644 proposed to mandate coverage for fertility preservation services for insureds who face likely infertility as a result of necessary medical treatment for cancer or other conditions. The report assumes coverage of sperm, oocyte and embryo cryopreservation as covered fertility preservation methods.

Estimated 2014 premium for proposed health benefits

Optum projected the average 2014 premium for each proposed mandate. The premium estimates include paid medical cost, administrative fees, risk factor, and profit or surplus. The average 2014 group plan premium for the three proposed mandates, shown below, is estimated to be $0.338 per member per month (PMPM). The estimated total premium applicable to individual policies would be $0.323 PMPM.

Proposed Mandate	Fully Insured Group Plans	Individual Policies
PANDAS	$0.013	$0.014
Lung Cancer Screening	$0.266	$0.247
Fertility Preservation	$0.059	$0.062
Total	**$0.338**	**$0.323**

Note: Due to small database, individual policy estimates are less reliable than group plan estimates.

The vast majority of the incremental expense of these mandates is medical cost. The total 2014 medical cost for group plans is estimated to be $0.287 PMPM. The estimated total medical cost applicable to individual policies would be $0.264 PMPM.

Non-medical cost includes administrative costs and risk/profit charges. For non-medical costs in group plans, the 2014 estimated cost of the three proposed health benefits is estimated to be $0.051 PMPM. The estimated non-medical cost applicable to individual policies is $0.058 PMPM.

Existing health insurance coverage for the proposed health benefits

Six health insurers and managed care organizations (MCOs) domiciled in Connecticut were surveyed regarding existing insurance coverage for the proposed health benefits under their fully insured group and individual policies. Five insurers/MCOs provided information about existing health insurance coverage. Carrier responses suggest variation as to whether each proposed benefit is a covered benefit or excluded benefit.

Proposed Mandate	Health Insurance Coverage for Proposed Benefit Mandate
PANDAS	◆ Two carriers cover the diagnosis of PANDAS ◆ One carrier covers plasma exchange and prophylactic antimicrobial therapy ◆ No carrier routinely covers intravenous immunoglobulin
Lung Cancer Screening	◆ Three of the carriers cover lung cancer screening in a manner similar to the proposed mandate; another carrier includes coverage under some policies ◆ One carrier does not provide coverage
Fertility Preservation	◆ Three carriers exclude coverage for cryopreservation ◆ One carrier covers cryopreservation of oocytes or embryos for women facing chemotherapy or radiation therapy ◆ Another carrier covers sperm and embryo cryopreservation if the medical necessity criteria is met, but did not define the threshold for medical necessity

Financial burden on insureds if no coverage

The financial burden of paying for the proposed benefits is influenced by the amount paid for treatment, family income, and other medical and non-medical expenses. Individuals with higher incomes will experience lower burdens, and those with lower incomes will experience higher burdens. A $2,000 threshold for unreimbursed medical payments is used as a proxy to identify significant medical distress.

PANDAS	◆ Can be significant for immune-based therapy due to high cost of treatment, exceeding $2,000
Lung Cancer Screening	◆ Not likely to be significant since screening costs less than 1 percent of a $50,000 family income and is below the $2,000 medical distress threshold
Fertility Preservation	◆ Can be significant for females due to high cost of embryo cryopreservation and oocyte cryopreservation ◆ Not likely to be significant for males since cost of sperm cryopreservation is below the $2,000 medical distress threshold

Impact of proposed health benefit on use of procedure, service or equipment

These estimates of the impact on use are based on the Optum Actuarial Report.

PANDAS	◆ None expected until NIMH study completed
Lung Cancer Screening	◆ Up to 22 percent of eligible individuals are expected to use screening annually; Current utilization is unknown
Fertility Preservation	◆ 10 to 15 percent increase per year

Medical cost to state employee health benefits plan

The following table shows the estimated 2014 cost to the State of Connecticut employee health plan, if the mandates are enacted and the state employee plan comply with them. The actual cost of the mandates to the State plan may be higher or lower, based on the actual benefit design of the State plan and the demographics of the covered lives (e.g., level of cost-sharing, average age of members, etc.).

PANDAS	$20,568
Lung Cancer Screening	Currently covered*
Fertility Preservation	$96,228

* The Office of the Comptroller reported that the state already provides coverage for LDCT lung cancer screening for those identified as being at "high-risk" to develop lung cancer. Assuming coverage did not exist, Optum estimated a total paid cost of $438,240.

Required Coverage in Other States

At the time of completion for this review, no other states require coverage for diagnosis and treatment of PANDAS, lung cancer screening or fertility preservation. This is subject to change as other states continue to consider, enact and implement additional mandates.

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General Overview

Over the last 60 years, the Connecticut General Assembly has enacted numerous health insurance benefit mandates and limitations on health insurers licensed to sell insurance in Connecticut. In keeping with a growing trend among the states, the General Assembly in 2009 directed the Connecticut Insurance Department (CID) to review and evaluate both proposed and existing mandates, as requested by the co-chairs of the Insurance and Real Estate Committee of the General Assembly (P.A. 09-179). This statute directed CID to contract with the University of Connecticut Health Center, Center for Public Health and Health Policy (CPHHP) to perform such reviews, and authorized CID to recover the costs of such contract through assessments on the insurers. It also authorized the CPHHP to obtain whatever expertise it needed to perform the reviews, whether from inside or outside the university. P.A. 09-179 is attached to this report as Appendix II.

By letter dated July 19, 2013, the co-chairs of the Insurance and Real Estate Committee (Committee) requested CID to report on four proposed health insurance benefit mandates. A copy of this letter is attached to this report as Appendix I. By agreement between CID and the co-chairs of the Committee, the deadline for the report on the first three is December 31, 2013. However, the deadline for the report on the fourth mandate has been extended to January 24, 2014.

This report is comprised of four parts: the general overview and three chapters. Each chapter contains an analysis of one of the first three proposed mandates. Each of the three chapters can stand on its own, since insurance benefit mandates generally are raised separately in individual proposed legislation. The chapter on the fourth mandate will be provided under separate cover in January 2014.

P.A. 09-179 detailed 25 issues to be addressed in the review of each mandate. These issues are divided into those which affect primarily the social impact of a mandate and those which affect primarily the financial impact, although a good deal of overlap exists among the two categories. Each chapter of this report addresses these issues for the respective proposed mandate. In addition, each chapter contains a background section that describes the condition, services, equipment or supplies addressed by the mandate proposal and the segment of the general population most affected by the condition, service, equipment or supplies.

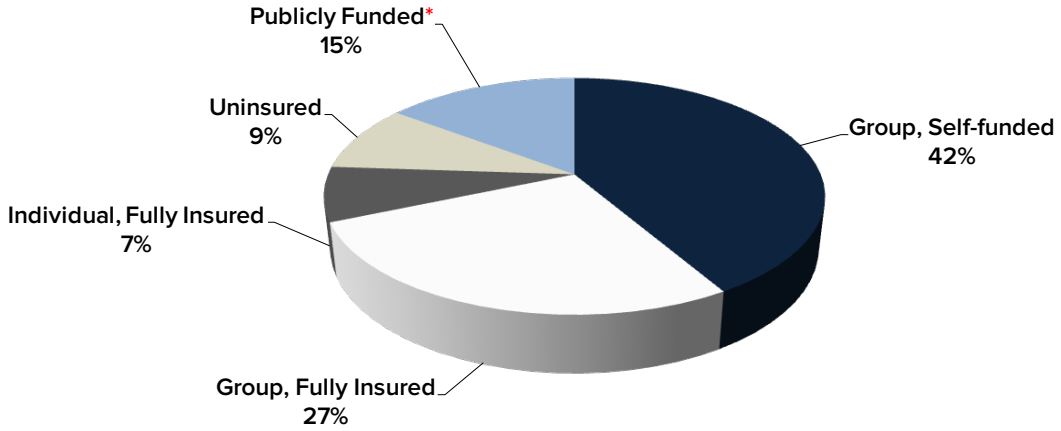
Caveat: States only have the power to mandate health insurance benefits in fully insured products, which are regulated by the states as the business of insurance. Health plans provided by employers or organizations that do not purchase insurance policies to fund them are beyond the reach of state insurance regulation and are only subject to federal regulation under the Employee Retirement Income Security Act (so-called ERISA pre-emption). This is so even if the employer or group sponsor contracts with an insurance company to provide "administrative services only," because the employer retains the risk of funding the benefits itself and does not purchase insurance to fund the plan. So-called administrative services only (ASO) contracts are not considered insurance policies and therefore are not subject to state insurance regulation.

In 2014, the federal Patient Protection and Affordable Care Act (ACA) becomes applicable to small group and individual health insurance policies. The relationship of this law to state health insurance benefit mandates will be discussed in more detail below.

Health care coverage of Connecticut residents

In prior years, CID has estimated that approximately 50 percent of Connecticut's workforce is covered by fully insured health plans, and approximately 50 percent are covered by employer-funded health plans. CID has also expressed a concern that the trend is for more and more employers and organizations to opt for self-funded plans, even relatively medium or small employers. This year the CPHHP's survey of Connecticut-domiciled insurers and managed care organizations found that self-funded health plans enrolled substantially more members than fully insured health plans in 2013. Thus, state benefit mandates may be applicable to an ever shrinking number of Connecticut residents. The figure below show the types of health care coverage for Connecticut residents.

Figure 1. Health Care Coverage for Connecticut Residents < 65 years old, 2012



*Publicly funded includes: Medicare, Medicaid, and Military health insurance plans

Source: Actuarial Report for the State of Connecticut on 2014 Health Insurance Mandates. OptumInsight. 2014. See Appendix III, pages 13. Split between group fully insured and self-funded based on: Oliver Wyman "*Annual tax on insurers allocated by state.*" November 2012

Optum's coverage estimate for 2012 (Figure 1) suggests that less than 35 percent of the population under age 65 had fully insured group or individual policies. Some of the fully insured are enrolled in plans/policies issued outside of Connecticut, for which state mandates may not apply.

Mandates

All of the proposed mandates in this report were introduced in the 2013 Session of the legislature. The letter from the Committee co-chairs referenced these bills and they form the basis of the analyses contained in the chapters. The proposed mandates for which the Insurance Committee requested review in 2013 are:

- Health insurance coverage for diagnosis and treatment of pediatric autoimmune neuropsychiatric disorder associated with streptococcal infections, or PANDAS, as set forth in S.B. 956 from the 2013 Regular Session.
- Health insurance coverage for lung cancer screening when performed in accordance with the recommendations of the American Lung Association in consultation with the American Cancer Society, as set forth in S.B. 862 from the 2013 Regular Session.
- Health insurance coverage for fertility preservation services for insureds who face likely infertility as a result of a necessary medical procedure for the treatment of cancer or other medical conditions, as set forth in H.B. 5644 from the 2013 Regular Session.

- Health insurance coverage for treatment of mental and nervous conditions that are ordered by a court, similar to the language in S.B. 1091 from the 2013 Regular Session.

Copies of this legislation are attached to this report as Appendix III.

Process

Reviews of health insurance benefit mandates are a collaborative effort of CID and CPHHP, pursuant to a Memorandum of Agreement. The CID also contracts with the actuarial firm Optum to conduct an analysis of claims data related to the mandate. Optum was selected through a competitive bidding process managed by CID.

The CPHHP staff researched medical issues, including the conditions addressed by the proposed mandates, the available treatments for those conditions and the medical efficacy of the treatment addressed by the mandate. CPHHP also researched the existence of other types of coverage for the conditions addressed by the mandates, including mandates in other states, Medicare and Medicaid coverage, and programs of other units of state government and non-profit organizations. Optum performed the actuarial analysis and the economic analysis. Optum submitted a separate report which formed the basis for the premium and total dollar cost estimates included in each of the individual mandate reviews by CPHHP. Optum's full report is attached to this report as Appendix IV.

Methodology

Center for Public Health and Health Policy

CPHHP staff conducted a search for published articles and other information related to the medical, social, economic and financial aspects of the required benefit. In addition, at the request of CPHHP staff, medical librarians at the Lyman Maynard Stowe Library at the University of Connecticut Health Center (UCHC) conducted searches using search terms particular to each proposed mandate. CPHHP staff consulted with clinical faculty and staff from the University of Connecticut School of Medicine and with outside medical providers on matters pertaining to medical standards of care, current and traditional practices, and evidence-based medicine related to the proposed benefit. Additional information was gathered through telephone and e-mail inquiries to appropriate state, federal, municipal, and non-profit entities and from internet sources such as the National Institutes of Health websites, the State of Connecticut website, Medicare website, other states' websites, and the websites of non-profit and community-based organizations.

CPHHP staff also surveyed six insurance companies and managed care organizations domiciled in Connecticut as to whether their fully insured group plans and individual policies currently included the proposed mandated benefit and for claims and enrollment data related to the proposed mandates.

Optum

CID contracted with Optum to provide actuarial and economic analyses of the proposed mandated benefit. Further details regarding the actuarial methods used to estimate the cost of the benefit and the economic methods used to estimate financial burden may be found in the Optum report (Appendix IV). We recommend that the mandate reports be read in conjunction with this actuarial report for a more in-depth discussion of the issues addressed in those reports.

State employee health benefit plan

The reviews provide an estimated cost to the State employee health benefit plan for each mandate, including a calculation for those members of the retiree plans who do not participate in Medicare. These costs are based on the assumption that the State plan will continue to include all of the Connecticut mandated benefits, even though the State plan are now self-funded and do not purchase insurance policies that are subject to state insurance mandates. It should be noted that the estimated cost to the State plan is calculated using the same cost calculations used for the fully insured population. The actual cost of the mandates to the State plan may be higher or lower, based on the actual benefit design of the State plan and the demographics of the covered lives (e.g., level of cost-sharing, average age of members, etc.).

Affordable Care Act[1]

Prior reports did not address the impact of the Affordable Care Act (Pub. L. 111-148 and Pub. L. 111-152) on the proposed mandate reviews. The Affordable Care Act (ACA) was not in effect at the time those reports were written and the regulations by which the act would be administered were still being developed. However, the ACA becomes effective on January 1, 2014, and will be in effect at the time any of these proposed mandates could be adopted by the Connecticut General Assembly. Therefore, this report includes a discussion of the interrelationship of the essential health benefits required in small group and individual health insurance policies after January 1, 2014 by the ACA and state-mandated insurance benefits.

The ACA and the final regulations promulgated under it[2] require all health insurance issuers that offer health insurance coverage in the small group and individual markets to include the "essential health benefits" package (EHB) as defined in the ACA.[3] This requirement applies to all individual and small group policies for plan years beginning on or after January 1, 2014, whether they are sold through the state's health insurance exchange or outside of it. For the plan years 2014 and 2015, EHB are determined in a given state by the selection of a benchmark plan in the state that reflects the scope of services provided by typical employer plans. For Connecticut, this is the ConnecticutCare HMO plan, with supplemental coverages for pediatric dental and vision care as required by ACA.

States are free to require policies issued through the exchange to cover benefits in addition to EHB, but the states are required to defray the cost of such additional state-required benefits either directly to the enrollee or to the plan issuer on behalf of the enrollee.[4] This applies only to policies issued through the exchange, whether or not they are subsidized plans. State-required benefits that were enacted on or before December 31, 2011 are deemed not to be in addition to EHB pursuant to HHS regulation. State-required benefits enacted after that date are deemed to be in addition to EHB.[5]

The definition of "state-required benefits" for the purpose of this regulation is narrower than P.A. 09-179's definition of "mandated benefit." "State-required benefit" is interpreted by HHS to include the care, treatment and services that an issuer must provide to its enrollees. It does not include requirements to cover specific types of providers or service delivery methods (these are included in P.A. 09-179's definition of

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[1] For an in-depth discussion of this topic, see California Health Benefits Review Program (CHBRP), (2013). *California state benefit mandates and the Affordable Care Act's essential health benefits.* Oakland, CA: CHBRP.

[2] Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value and Accreditation; Final Rule. Federal Register, 78 no. 37, p12834. Accessed December 22, 2013 from: http://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

[3] ACA Section 1302(a).

[4] ACA Section 1311(d)(3)(B).

[5] 45 CFR part 155, section 170.

mandated benefit). The state exchange is responsible for determining whether a state-required benefit is in excess of EHB, and the policy issuers are responsible for determining the cost attributable to an excess state-required benefit.

The definition of "small group plan" in the ACA also differs between the ACA and Connecticut law. Under the ACA, "small group" is 1-100 employees. Connecticut law defines a small group plan as 1-50 employees. For the 2014 and 2015 plan years, the ACA permits states to apply their own definitions of small group. However, for plan years beginning in 2016 and beyond the ACA definition must be applied. This may increase the potential liability of the state for defraying the costs of excess state-required benefits, because larger groups may become insured through the exchange. Additionally, for plan years beginning in 2017 the states may permit issuers to offer large group plans through their exchanges, with the potential to further increase the state's exposure under this section.

These provisions of the ACA should be kept in mind when considering proposed benefit mandates.

Chapter 1

Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcal Infections (PANDAS)

A Report to the Insurance and Real Estate Subcommittee
of the Connecticut General Assembly

Review of Senate Bill 956:

"An Act Concerning Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcal Infections."

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I. Overview

On July 19, 2013 the Chairs of the Insurance and Real Estate Committee of the Connecticut General Assembly directed the Connecticut Insurance Department (CID) to review Senate Bill No. 956 (S.B. 956) from the 2013 Regular Session, "An Act Concerning Pediatric Neuropsychiatric Disorder Associated with Streptococcal Infections." The CID contracted with the University of Connecticut Health Center for the services of the Center for Public Health and Health Policy (CPHHP) to conduct this review pursuant to the provisions of Public Act 09-179, "An Act Concerning Reviews of Health Insurance Benefits Mandated in this State."[6]

This review provides a background to pediatric autoimmune disorder associated with streptococcal infections (PANDAS), its diagnosis and treatment, and evaluates the potential financial and social impact of S.B. 956, as required by P.A. 09-179. The full text of S.B. 956 is located in Appendix III. Senate Bill 956 would require fully insured group and individual health insurance policies to:

> "*provide coverage for the diagnosis and treatment of pediatric autoimmune neuropsychiatric disorder associated with streptococcal infections.*"

PANDAS is a controversial diagnosis within the medical community that is sometimes given to a subset of children with obsessive compulsive disorder (OCD) or tic disorder symptoms. There are currently no professional guidelines describing PANDAS or prescribing a method for its diagnosis or treatment. This review relies upon PANDAS information provided by the National Institutes of Mental Health (NIMH) and other relevant sources to discuss the condition.

PANDAS criteria:

- Presence of OCD or tic disorder symptoms
- Pediatric onset of symptoms
- The abrupt onset of symptoms or dramatic symptom exacerbation, followed by an episodic or "sawtooth" course of symptom severity
- Temporal association with a strep infection
- Association with other neuropsychiatric symptoms, the appearance of which accompanies the OCD or tic symptoms

Treatments for PANDAS symptoms:

- Standard OCD and tic disorder treatments
- Standard course of antibiotics to treat active strep infection
- Immune-based therapies
  - Plasma exchange
  - Intravenous Immunoglobulin (IVIG)
- Prophylactic antimicrobial therapy to prevent the recurrence of PANDAS symptoms

Standard treatments for OCD and tic disorders are mandatorily covered by existing law. While they are mentioned in this review where appropriate, their cost is not included in the cost estimates of the proposed mandate.

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[6] Public Act 09-179 is codified at Connecticut General Statutes, Section 38a-21.

There is a split among professional guidelines over whether a patient meeting the PANDAS criteria other than a strep infection should be tested for such an infection. No professional guideline currently recommends treating PANDAS with plasma exchange, IVIG or prophylactic antimicrobial therapy, all of which may be considered experimental for treating PANDAS symptoms. The CID and the CPHHP interpret the proposed mandate to include strep tests as part of the PANDAS diagnosis, and to include the experimental PANDAS treatments, as well. This interpretation is due to the inclusion of this diagnostic tool and the experimental treatments in NIMH's PANDAS descriptions; and the practice of some clinicians in the state to diagnose children with, and treat them for, PANDAS using them.

The CPHHP invited six insurers and managed care organizations (carriers) domiciled in Connecticut to complete a survey and provide policy documents (whether the service is currently covered, utilization review processes, methods for determining medical necessity, etc.) and claims data and other information related to PANDAS diagnosis and treatment. The six carriers reported covering approximately 614,000 lives enrolled in fully insured group plans and 111,000 lives enrolled in individual health insurance policies in Connecticut in 2013. In addition, respondents provide administrative services only plans, stop gap insurance coverage and other services not considered fully-insured policies to self-funded plans.

The CID also contracted with the actuarial firm OptumInsight (Optum) to conduct an actuarial evaluation, individual cost burden analysis and five year projection of the cost of the mandate based on claims data and other sources. Optum's cost estimates do not include any costs from standard OCD or tic disorder treatments for children between the ages of 3 and 12 because fully insured policy coverage of these treatments are already governed by existing state law. Instead, the estimates include the coverage of strep tests, and the experimental PANDAS treatments of plasma exchange, IVIG, and prophylactic antimicrobial therapy.

Existing health insurance coverage

All of the carriers provide at least some coverage for standard OCD and tic disorder symptoms. Two of the carriers provide coverage for the diagnosis of PANDAS. Of these, one also provides coverage for the treatments of plasma exchange and prophylactic antimicrobial therapy. This carrier considers IVIG to be experimental for the treatment of PANDAS, and so reviews such claims on a case by case basis. The other carrier that covers the diagnosis of PANDAS considers both plasma exchange and IVIG to be experimental and does not provide routine coverage for either. The other three carriers responding to this question do not provide coverage for any specific PANDAS treatments. The carriers report that the self-funded plans for which they provide services cover PANDAS diagnoses and treatments to an extent similar to that of the carriers' fully insured policies.

Estimated 2014 premium

Group policies: Optum estimates the paid medical cost for S.B. 956 in 2014 for group policies would be $0.010 per member per month (PMPM). The premium impact when including medical cost, administrative fees, profit or surplus, and other costs is estimated to be $0.013 PMPM, which is 0.003 percent of the average premium for group policies.

Individual policies: Optum estimates the paid medical costs for S.B. 956 in 2014 for individual policies would be $0.011 PMPM. The premium impact when including paid medical cost, administrative costs, profit or surplus and other costs is estimated to be $0.014 PMPM, which is 0.005 percent of the average premium for individual policies.

This report is intended to be read in conjunction with the General Introduction to this volume and Optum's Actuarial Report which is included as Appendix IV.

II. Background

Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections, or PANDAS, is a term given to a combination of psychological and physical conditions in children that some researchers believe is linked to a recent infection with the streptococcal bacteria (strep) that causes strep throat.[7] The most common conditions associated with PANDAS are obsessive-compulsive disorder (OCD) and tic disorders. The relationship between these conditions, if any, is currently the subject of vigorous debate among medical researchers and practitioners. The basic causal theory, currently being tested, is that for some children a strep infection triggers an unhealthy immune response that results in several neuropsychiatric symptoms. These children are treated with generally accepted standard treatments for OCD and tic disorders and sometimes, controversially, with immune-based therapies and long-term administration of antibiotics.

PANDAS: Current extent of recognition of PANDAS among professional groups

No professional organization appears to have unequivocally accepted PANDAS as a distinct medical condition. The American Academy of Child and Adolescent Psychiatry (AACAP), however, comes close. Several other professional associations mention PANDAS in their most recent guidelines, but note that there is insufficient supporting evidence for its recognition as a separate condition. The American Heart Association (AHA) specifically recommends against recognizing the condition in its current guidelines for the treatment of rheumatic fever (which is caused by a strep infection).

The AACAP released guidelines for the diagnoses and treatment of children with OCD in January 2012. After noting that the diagnosis of PANDAS is controversial, it states that "[at] this time, the epidemiological evidence and expert clinical experience support the belief that a small subset of children with OCD and Tourette's Disorder have onsets and clinical exacerbations linked to [strep]."[8] In its guidelines for the assessment and treatment of tic disorders, published in December, 2013, the AACAP notes that "[i]ncreasingly, studies suggest that in some cases, a prior history of infections may increase risk for developing a tic disorder, although this remains controversial."[9] This later guideline does not, however, mention PANDAS specifically.

The American Psychiatric Association (APA) discusses PANDAS in its section on obsessive-compulsive and related disorders in the Diagnostic and Statistical Manual of Mental Disorders, the fifth edition of which was released in 2013 (DSM-5). While there is no separate PANDAS section, the relevant literature is reviewed when describing the criteria for the new diagnostic category "obsessive-compulsive disorder due to another medical condition."[10] The DSM-5 provides that "there is a body of evidence that supports the existence of

[7] There are other variants of the streptococcal bacteria that might, in other contexts, be shortened to the term "strep," but here, we use that term only to refer to Group A β-hemolytic streptococcus. The academic literature uses the acronyms GAS and GABHS interchangeably when discussing PANDAS-related strep infections.

[8] American Academy of Child and Adolescent Psychiatry (AACAP) (2012). AACAP Official Action: Practice parameter for the assessment and treatment of children and adolescents with obsessive-compulsive disorder. *Journal of the American Academy of Child & Adolescent Psychiatry*, 51(1):98-113, p. 99-100.

[9] American Academy of Child and Adolescent Psychiatry (AACAP) (2013). AACAP Official Action: Practice parameter for the assessment and treatment of children and adolescents with tic disorders. *Journal of the American Academy of Child & Adolescent Psychiatry*, 52(12):1341-1359.

[10] American Psychiatric Association (APA) (2013). "Obsessive-compulsive and related disorders" in Diagnostic and Statistical Manual of Mental Disorders (5th ed.) (DSM-5). Arlington, VA: American Psychiatric Publishing.

PANDAS" but that it "remains a controversial diagnosis" and "deserves further study."[11]

Other professional groups that have recently released guidelines mentioning PANDAS include: American Academy of Pediatrics (AAP) (strep throat);[12] American Academy of Allergy, Asthma & Immunology (AAAAI) (IVIG treatments);[13] American Academy of Neurology (AAN) (IVIG and plasma exchange);[14],[15] and AHA (strep infections related to rheumatic fever).[16] These groups all state that there is currently insufficient evidence to recognize PANDAS as a distinct condition. The AHA recommends against diagnosing or treating PANDAS.

The PANDAS Criteria

There is no universally accepted description of PANDAS. For the purpose of this review, we rely primarily on the description provided by two on-line documents produced by the National Institutes of Mental Health (NIMH), which we refer to as PANDAS Information and PANDAS FAQ, to provide the basic contours of the proposed condition.[17] There appears to be general agreement in the five primary PANDAS criteria.

The five PANDAS criteria can be stated as follows:

- Presence of OCD or tic disorder symptoms;
- Pediatric onset of symptoms;
- The abrupt onset of symptoms or dramatic symptom exacerbation, followed by an episodic, or "sawtooth" course of symptom severity;
- Temporal association with a strep infection; and,
- Association with other neuropsychiatric symptoms, the appearance of which accompanies the OCD or tic symptoms.[18]

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[11] APA (2013), "Obsessive-compulsive and related disorders."

[12] American Academy of Pediatricians (AAP) (2012). Section 3: Summaries of infectious Diseases "Group A Streptococcal infections, Clinical Manifestations," in The Red Book Online, available at http://aapredbook.aappublications.org/content/1/SEC131/SEC264.body (accessed December 27, 2013).

[13] American Academy of Allergy Asthma & Immunology (AAAAI) (2005). Position statement on the appropriate use of intravenously administered immunoglobulin (IGIV), p. 13; see Orange J, Hossny E, Weiler C, Ballow M, Berger M, Bonilla F, Buckley R, Chinen J, El-Gamal Y, Mazer B, Nelson R, Patel D, Secord E, Sorensen R, Wasserman R, Cunningham-Rundles C (2006). Use of intravenous immunoglobulin in human disease: A review of evidence by members of the primary immunodeficiency committee of the American Academy of Allergy, Asthma and Immunology. *Journal of Allergy and Clinical Immunology,* 117 (4):S525-S553.

[14] Cortese I, Chaudhry V, So Y, Cantor F, Cornblath D, Rae-Grant A (2011). Evidence-based guideline update: Plasmapheresis in neurologic disorders, report of the therapeutics and technology assessment subcommittee of the American Academy of Neurology. *Neurology* 76:294-300, p. 297.

[15] Patwa H, Chaudhry V, Katzberg H, Rae-Grant A, So Y (2012). Evidence-based guidelines: Intravenous immunoglobulin in the treatment of neuromuscular disorders, report of the therapeutics and technology assessment subcommittee of the American Academy of Neurology. *Neurology,* 78: 1009-1015.

[16] Gerber M, Baltimore R, Eaton C, Gewitz M, Rowley A, Shulman S, Taubert K (2009). Prevention of rheumatic fever and diagnosis and treatment of acute streptococcal pharyngitis: A scientific statement from the American Heart Association rheumatic fever, endocarditis, and Kawasaki disease committee of the council on cardiovascular disease in the young, the interdisciplinary council on functional genomics and translational biology, and the interdisciplinary council on quality of care and outcomes research: Endorsed by the American Academy of Pediatrics. *Circulation*, 119:1541-1551.

[17] Specifically, we rely upon a PANDAS information page created by the National Institute of Mental Health's Pediatrics and Developmental Neuroscience Branch of the Division of Intramural Research (PANDAS Information) (updated March 2012), accessed December 9, 2013 from: http://intramural.nimh.nih.gov/pdn/web.htm; and a "Frequently Asked Questions" (PANDAS FAQ) page providing summary information on PANDAS in a question and answer format, accessed August 28, 2013 from: http://www.nimh.nih.gov/health/publications/pandas/index.shtml. Between these two documents, NIMH makes, or appears to make, a number of suggestions regarding the diagnosis and treatment of PANDAS. Reference will also be made to an ongoing NIMH-sponsored PANDAS treatment trial and academic literature.

[18] NIMH PANDAS Information; NIMH PANDAS FAQ.

While the prescribed necessary age of onset to meet the PANDAS criteria varies somewhat between studies, generally PANDAS children experience initial symptoms between the age of three and approximately fourteen.[19]

There are primarily three established conditions that are associated with PANDAS: OCD, tic disorders, and strep infections.

Obsessive-Compulsive Disorder. The APA created a new chapter specifically for OCD and related disorders in the DSM-5 to highlight the clinical similarities of a number of conditions that feature obsessive thoughts and compulsive behavior.[20] OCD is characterized by obsessions, compulsions or (most often) both. An obsession is described as being "recurrent and persistent thoughts, urges or images that are experienced …as intrusive and unwanted…" A compulsion is "a repetitive behavior …or mental act …that the individual feels driven to perform in response to an obsession or according to rules that must be applied rigidly."[21] The cause of OCD is presently unknown. The average onset age for pediatric OCD is 11 years.[22]

NIMH states that OCD symptoms in PANDAS cases are virtually the same as symptoms in any other instance of pediatric OCD. The current PANDAS criteria require a "sudden onset" of the symptoms, however, rather than the gradual onset more common in other OCD patients.[23] NIMH describes a time period of 24 to 48 hours between no, or mild, symptoms and the onset of severe symptoms.

Tic Disorders. Tic disorders are described in the APA's DSM-5.[24] A tic is a "sudden, rapid, recurrent, non-rhythmic, motor movement or vocalization."[25] Almost any muscle can produce a tic, but common simple motor tics include eye blinking and shoulder shrugging. Common simple vocal tics include throat clearing, sniffing and short grunting sounds. Tics of longer duration may be classified as complex.[26] Tics that persist for more than a year are classified as chronic disorders. Tourette's Disorder is a chronic tic disorder that has both vocal and motor tics.

Tic disorder symptoms typically reach their peak severity between the ages of 10 and 12, and decline after that. Children who suffer from chronic tic disorders, particularly Tourette's Disorder, often have other co-occurring disorders. More than one in five of children who suffer from either OCD or Tourette's Disorder may suffer symptoms of the other condition.[27]

NIMH does not indicate that, other than sudden onset, tics experienced by children meeting the PANDAS criteria differ from tics experienced by other children.

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[19] Leckman J, King R, Gilbert D, Coffey B, Singer H, Dure L, Grantz H, Katsovich L, Lin H, Lombroso P, Kawikova I, Johnson D, Kurlan R, Kaplan E (2011). Streptococcal upper respiratory tract infections and exacerbations of tic and obsessive-compulsive symptoms: A prospective longitudinal study. *Journal of the American Academy of Child & Adolescent Psychiatry*, 50(2):108-118.

[20] American Psychiatric Association (2013). Highlights of Changes from DSM-IV-TR to DSM-5, American Psychiatric Publishing, p. 7, accessed November 19, 2013 from: http://www.dsm5.org/Documents/changes%20from%20dsm-iv-tr%20to%20dsm-5.pdf.

[21] APA (2013). "Obsessive-compulsive and related disorders."

[22] Taylor (2011). Early versus late onset obsessive-compulsive and related disorder: Evidence for distinct subtypes. *Clinical Psychology Review*, 31: 1083-1100, p. 1095. There is some debate in the literature over whether pediatric onset OCD should be considered a distinct condition from adult onset OCD. By definition, all PANDAS-related OCD is pediatric onset.

[23] NIMH, PANDAS Information.

[24] American Psychiatric Association (APA) (2013). "Tic disorders" in Diagnostic and Statistical Manual of Mental Disorders (5th ed.) (DSM-5). Arlington, VA: American Psychiatric Publishing.

[25] APA (2013). "Tic Disorders."

[26] APA (2013). "Tic Disorders."

[27] AACAP (2013), p.1345.

Strep Infections. The strep bacteria can cause several types of infections. The most common is acute pharyngitis,[28] that is, a sore throat. Strep is also the most common bacterial cause of acute pharyngitis, responsible for an estimated one third of all sore throat-inspired visits to the doctor, at least among children in school who are between the ages of 5 and 15.[29] Some children do not suffer any symptoms of the strep infection; these children are referred to as strep carriers. As much as twenty percent of children in school might be asymptomatic strep carriers.[30] Strep throat, particularly when untreated, may lead to another condition known as rheumatic fever. Rheumatic fever can result in heart problems and neurological problems. When rheumatic fever leads to involuntary movements, the resulting condition is referred to as Sydenham's Chorea, or St. Vitus' Dance.[31]

PANDAS Prevalence and Incidence

Neither the Connecticut Department of Public Health,[32] nor any other group that CPHHP identified has produced a reliable estimate of the number of children in the state who might meet the PANDAS criteria. The PANDAS Resource Network, in its report to the General Assembly's PANDAS/PANS Advisory Council, estimates the number of children nationwide who have PANDAS to be approximately 162,000.[33] CPHHP has not encountered this estimate in any peer-reviewed journal,[34] and a PANDAS researcher recently wrote that the number of children who might meet the PANDAS criteria is currently unknown.[35] The numbers of children suffering from any of the three PANDAS components, namely, OCD, tic disorder, and strep infection, are only somewhat better established.

OCD. Some researchers estimate that one to two percent of the United States population under 18 may have OCD, with a far greater number having at least occasional instances of obsessions or compulsions.[36]

Tic Disorder. Tics appear to be fairly common among children; as much as 20 percent of the population may experience at least transient tics at some point during childhood. Diagnosable tic disorders may affect 0.5 to 3 percent of the pediatric population.[37] The prevalence of Tourette's Disorder in children between the ages of 6 and 11 is estimated to be 1.9 per 1,000,[38] with greater prevalence among boys than girls.[39]

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[28] The AAP uses the more expansive term "*pharyngotonsillitis.*" See AAP (2012).

[29] Shulman S, Bisno A, Clegg H, Gerber M, Kaplan E, Lee G, Martin J, Van Beneden C. (2012). IDSA Guidelines: Clinical practice guideline for the diagnosis and management of group a streptococcal pharyngitis: 2012 update by the Infectious Diseases Society of America. Clinical Infectious Diseases, 55:e86-e102, p. e91; See also, Shaikh N, Leonard E, Martin J (2010). Prevalence of streptococcal pharyngitis and streptococcal carriage in children: A meta-analysis. *Pediatrics,* 126 (3): e557-e564, p. 561.

[30] AAP (2012), Red Book Online.

[31] Gerber et al. (2009), p. 1542.

[32] Confirmed through personal communication with DPH.

[33] Leisman G and Melilo R. A comprehensive analysis of research on the diagnoses and treatment for pediatric autoimmune neuropsychiatric disorder (PANDAS/PANS). F.R. Carrick Institute for Clinical Ergonomics, Rehabilitation and Applied Neurosciences. Garden City, New York: February 1, 2013, p. 6-7.

[34] The 162,000 estimate appears to have originated from another advocacy group, the PANDAS Network; see PANDAS Network Statistics Handout (2012), accessed November 21, 2013 from: http://pandasnetwork.org/wp-content/uploads/2012/08/Statistics.pdf).

[35] Murphy T and Toufexis M: Chapter 13 "PANDAS: Immune-related OCD," in Handbook of Treating Variants and Complications in Anxiety Disorders (Storch E and McKay D, Eds.). Springer Science and Business Media. New York: 2013.

[36] AACAP (2012),p. 99; see also Stewart S, Geller D, Jenike M, Pauls D, Shaw D, Mullin B, Faraone S (2004). Long-term outcome of pediatric obsessive-compulsive disorder: a meta-analysis and qualitative review of the literature. *Acta Psychiatrica Scandinavica*, 110:4-13.

[37] Murphy et al. (2013).

[38] Center for Disease Control and Prevention (2009). Prevalence of Diagnosed Tourette Disorder in Persons Aged 6 – 17 Years – United States, 2007. *Morbidity and Mortality Weekly Report*, 58 (21):581-585.

[39] CDC (2011). Bridging the Gap between Tourette Syndrome and Public Health. Knight et al. conducted a systematic review of studies estimating the prevalence of tic disorders, and found that most school-based studies reported a prevalence of Tourette's Disorder of 2 to 11 per 1,000. Knight T, Steeves T, Day L, Lowerison M, Jette N, Pringsheim T (2012). Prevalence of tic disorders: A systematic review and meta-analysis. *Pediatric Neurology,* 47:77-90.

Strep Throat. While it seems that most children experience some form of a strep infection, particularly strep throat, at some point,[40] CPHHP has not discovered any estimate of its yearly incidence or prevalence. According to one researcher, more than one-third of all children between the ages of 5 and 15 who seek treatment for a sore throat may have strep throat.[41]

Diagnosing PANDAS

PANDAS is diagnosed clinically and, in part, confirmed by laboratory tests. The clinician reviews the patient's symptoms and medical history to determine whether they meet the PANDAS criteria. The presence of a strep infection is confirmed through appropriate laboratory tests. PANDAS-related OCD and tic symptoms are diagnosed as with other children. Strep throat is generally diagnosed as with other children; NIMH does state, however, that patients meeting all of the PANDAS criteria except symptoms of an active strep infection should still be tested for it.

Diagnosing obsessive-compulsive disorder. OCD is diagnosed clinically. The APA produces guidelines for the diagnosis and treatment of OCD and related disorders.[42] The AACAP produces such guidelines tailored specifically to children.[43]

Diagnosing tic disorders. Tic disorders are also diagnosed clinically. The AACAP published guidelines for pediatric and adolescent tic disorders in December, 2013.[44] The American Academy of Family Physicians (AAFP) released a guide that focused on diagnosing and treating Tourette's Disorder in 2008.[45]

Diagnosing strep infections. Strep infections are diagnosed through a combination of clinical observation and laboratory confirmation. Practice guidelines for the diagnosis and treatment of strep throat have been published by the Infectious Disease Society of America (IDSA), most recently in 2012;[46] the American Academy of Pediatricians (AAP), also updated in 2012;[47] and the AHA as part of its guideline for the treatment and diagnosis of rheumatic fever, updated in 2009.[48] There is a great amount of agreement between these three guidelines. When a child is suspected to have strep throat, the three guides assert that laboratory confirmation is necessary, due to the broad overlap between the clinical symptoms of strep throat and throats that are sore from other causes.

NIMH suggests also testing an asymptomatic child for a strep infection if the child otherwise appears to meet the PANDAS criteria. The AACAP OCD guide states that "[i]nquiry of an infection with [strep] is indicated in acute and dramatic onsets or exacerbations in pre-adolescent patients or when a child in remission suddenly relapses…"[49] Its tic disorder guide provides that "for new sudden (overnight) onset or

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[40] Murphy T, Sajid M, Soto O, Shapira N, Edge P, Yang M, Lewis M, Goodmans W (2004). Detecting pediatric autoimmune neuropsychiatric disorders associated with streptococcus in children with obsessive-compulsive disorder and tics. *Journal of Biological Psychiatry*, 55(1):61-68, p. 61.

[41] Shaikh N, Leonard E, Martin J (2010). Prevalence of streptococcal phsaryngitis and streptococcal carriage in children: A meta-analysis. *Pediatrics*, 126(3):e557-e564, p. e561.

[42] APA (2013), "Obsessive-Compulsive and Related Disorders."

[43] AACAP (2012).

[44] AACAP (2013).

[45] Kenney C, Kuo S, Jimenez-Shahed J (2008). Tourette's Syndrome. *Journal of the American Family Physician,* 77(5): 652-658.

[46] Shulman et al. (2012).

[47] AAP (2012).

[48] Gerber et al. (2009).

[49] AACAP (2012), p. 104.

severe symptom exacerbations the provider may assess for co-occurring infection with diagnostic tests that indicate acute illness (e.g. culture, rapid viral tests, etc.).[50] The AHA, in contrast, recommends against testing asymptomatic children for a strep infection.[51]

If the initial test returns negative results, NIMH suggests measuring the child's anti-strep titers.[52] Children's titer levels rise as their immune systems fight off strep infections. These titer levels remain elevated for a time after the infection has cleared, so a raised level of titers is some evidence of a recent strep infection. The AACAP discusses the practice of using titer tests to confirm recent strep infections, though it does not explicitly recommend the test for PANDAS. The AHA warns that titers are difficult to interpret because each child's background titer level may be different.

Treating PANDAS

NIMH states that standard treatments for OCD, tics and strep throat may be administered to children meeting the PANDAS criteria in the same manner as they are to any other child with these conditions. More controversially, NIMH further suggests using the immune-based therapies of plasma exchange and IVIG to treat current OCD and tic disorder symptoms in some PANDAS patients; and also notes possible benefits of the long-term administration of antibiotics as a prophylactic measure to prevent the recurrence of PANDAS symptoms. These latter treatments are not recommended by any professional guideline, and, therefore, may be considered experimental for treating the symptoms of children meeting the PANDAS criteria.

Standard treatments for pediatric OCD. NIMH specifically mentions cognitive behavioral therapy (CBT);[53] and selective serotonin reuptake inhibitors medication (SSRIs), particularly, fluoxetine, fluvoxamine, sertraline and paroxetine to treat OCD symptoms among children meeting the PANDAS criteria.[54] The AACAP suggests treating OCD symptoms first with CBT alone, because some of the medications have adverse side-effects, particularly in children.[55] The AACAP recommends SSRIs for children who do not respond to CBT alone.

Standard treatments for tic disorders. NIMH states that the treatments for tics are the same for PANDAS patients as for any other child with similar symptoms.[56] There are a number of psychiatric and pharmacological treatments used to treat tic disorder symptoms, none of which have been demonstrated to reliably resolve tics completely.[57] The AACAP recommends initially treating tic disorder symptoms with habit reversal training (HRT), a type of behavioral intervention.[58] Only if HRT and other behavioral therapies fail, should pharmacological treatments be attempted. The most common medications used to treat tic disorders are clonidine, risperidone, and aripiprazol.[59] In addition the Food and Drug

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[50] AACAP (2013).

[51] Gerber et al. (2009), p. 1549.

[52] NIMH, PANDAS Information.

[53] For a fuller discussion of CBT see: Center for Public Health and Health Policy. Chapter 1: "Autism Spectrum Disorders," in Review and Evaluation of Certain Health Benefit Mandates in Connecticut. University of Connecticut: 2012, p. 15-17.

[54] NIMH, PANDAS Information.

[55] AACAP (2012), p. 104.

[56] NIMH, PANDAS FAQ.

[57] National Institute of Neurological Disorders and Stroke. Tourette Disorder Fact Sheet (updated October 19, 2012), accessed November 20, 2013 from: http://www.ninds.nih.gov/disorders/tourette/detail_tourette.htm.

[58] AACAP (2013).

[59] AACAP (2013).

Administration (FDA) has approved haloperidol and pimozide to treat Tourette's Disorder.[60]

Treatment of *"other neuropsychiatric symptoms."* While NIMH's PANDAS criteria require that the OCD or tic disorder symptoms be accompanied by other neuropsychiatric symptoms, it does not make any mention of how these other symptoms might be treated. This may be because the list of possible co-occurring conditions is large and somewhat undefined. Presumably, if the symptoms require treatments beyond those for OCD and tic disorder symptoms, the treatments would be the same as for any child with similar symptoms.

Standard treatments for strep throat. NIMH states that a PANDAS child with a strep infection should be treated in the same manner as any child with a strep infection. According to the IDSA, once the presence of strep throat is confirmed, the infection is typically treated with a ten-day regimen of antibiotics, most commonly penicillin or amoxicillin.[61]

NIMH does not suggest diagnosing PANDAS, or administering antibiotics, without laboratory confirmation of an associated strep infection. It notes, however, that "some clinicians have advocated using antibiotics to treat acute symptoms of PANDAS, even when no strep infection can be found."[62] There is currently a study at the University of South Florida examining whether antibiotics have any effect in directly treating OCD and tic disorder symptoms.[63]

Treating OCD and tic disorder symptoms with immune-based therapies. NIMH states that the administration of immune-based therapies may be useful to at least some PANDAS children. Specifically, it mentions plasma exchange and IVIG and notes that for both treatments there is evidence that the treatment "reduced symptoms significantly more than the placebo infusions."[64]

Plasma exchange and IVIG treatments both involve injecting plasma or plasma-based products into a patient's blood in order to improve the immune system. A plasma exchange removes some of the patient's blood, treats the blood so that the plasma separates from the other components, adds donor plasma, and then replaces the blood.[65] IVIG involves injecting a prepared solution into the patient. There are many different IVIG preparations, produced by several manufacturers, each having a slightly different range of antibody components.[66] The FDA recommends that IVIG contain plasma from between 15,000 and 60,000 individual donors.[67] Both plasma exchange and IVIG are used to treat a number of conditions. Some of these feature inherent defects in the immune system, called primary immunodeficiency, and require regular treatment for an indefinite and possibly-life long duration. Other conditions, such as the treatment of

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60 AACAP (2013).

61 Shulman et al. (2012).

62 NIMH, PANDAS Information page.

63 Antibiotic Treatment Trial for the PANDAS/PANS Phenotype, accessed December 5, 2013 from: http://clinicaltrials.gov/show/NCT01617083.

64 NIMH, PANDAS Information.

65 Cortese et al. (2011), p. 294.

66 Orange J, Hossny E, Weiler C, Ballow M, Berger M, Bonilla F, Buckley R, Chinen J, El-Gamal Y, Mazer B, Nelson R, Patel D, Secord E, Sorensen R, Wasserman R, Cunningham-Rundles C (2006). Use of intravenous immunoglobulin in human disease: A review of evidence by members of the primary immunodeficiency committee of the American Academy of Allergy, Asthma and Immunology. *Journal of Allergy and Clinical Immunology,* 117(4): S525-S553, p. S542; see also Ballow M, Berger N, Bonilla F, Buckley R, Cunningham-Rundles C, Fireman P, Kaliner M, Ochs H, Skoda-Smith S, Sweetser M, Taki H, Lathia C (2003). Pharmacokinetics and tolerability of a new intravenous immunoglobulin preparation, IGIV-C, 10% (Gamunex, 10%). *Vox Sanguinis*, 84: 202-210, p. 203.

67 Orange et al. (2006), p. S542.

inability to walk associated with Guillain-Barre's Syndrome, are the result of infections and typically require only a single or few treatments.[68]

The AAN[69] and the AAAAI[70] both maintain guidelines for the use of plasma exchange and IVIG. Neither organization recommends the use of either immune-based therapy for the treatment of patients meeting the PANDAS criteria. Thus, there are no established guidelines for the use of either plasma exchange or IVIG for the treatment of PANDAS and, therefore, these treatments may be considered experimental.

While there are no established guidelines for the administration of the immune-based treatments, some idea of how clinicians might administer these treatments can be had from the literature reporting the results of trials of these treatments.

Results from the primary PANDAS plasma exchange trial were published in 1999. For each child undergoing plasma exchange, one plasma volume (45 ml / kg of body weight) was exchanged during each plasma exchange procedure. The total treatment consisted of 5 procedures completed over the course of 12 days. Each procedure required 85 to 121 minutes to complete.[71]

The same study also administered IVIG to some children. These children were given 2g/kg of body weight IVIG over the course of two consecutive days.[72] The researchers did not report the duration of each IVIG infusion. Other researchers estimate that average administration times range from 2 to 4 hours.[73] NIMH's current IVIG trial uses the same IVIG dose as the earlier trial.[74]

Prophylactic use of antibiotics to prevent the recurrence of PANDAS OCD and tic disorder symptoms.

NIMH's PANDAS FAQ states that: "*[T]o avoid future episodes of PANDAS, it may be helpful to use antibiotics as prophylaxis (prevention) against strep infections….*"

NIMH directs those clinicians who choose to prescribe a prophylactic course of antibiotics to PANDAS patients to follow the AHA's rheumatic fever guidelines. For rheumatic fever patients who do not suffer from carditis or residual heart disease, the AHA recommends providing prophylactic antimicrobial treatments, specifically Benzathine Penicillin G, for five years or until the patient reaches the age of 21, whichever is longer.[75] It further recommends that the antibiotics should be administered by intramuscular injection every 4 weeks,[76] though it also notes that oral versions are available. The AHA itself specifically recommends against prophylactic administration of antibiotics to treat PANDAS symptoms. No professional guidelines recommend antimicrobial therapy for PANDAS patients, and therefore this treatment may be considered experimental.

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[68] Yuki N, Hans-Peter H (2012). Guillain-Barre Syndrome. *The New England Journal of Medicine*, 366 (24):2294-2304, p. 2301; See also Cortese et al. (2011), 295-296 (plasma exchange); Patwa et al. (2012), 1011 (IVIG).

[69] Cortese, et al. (2011), p. 298.

[70] Orange, et al. (2006), p. S540-41.

[71] Perlmutter S, Leitman S, Garvey M, Hamburger S, Feldman E, Leonard H, Swedo S (1999). Therapeutic plasma exchange and intravenous immunoglobulin for obsessive-compulsive disorder and tic disorders in childhood. *The Lancet*, 354:11153-1158, p. 1155.

[72] Perlmutter, et al. (1999), p. 1154.

[73] Stiehm E (2013). Adverse effects of human immunoglobulin therapy. *Transfusion Medicine Reviews,* 27:171-178.

[74] A Placebo-Controlled Trial of Intravenous Immunoglobulin (IVIG) for PANDAS. National Institutes of Health Clinical Center, information accessed November 20, 2013 from: http://clinicaltrials.gov/ct2/show/NCT01281969; see Ballow et al. (2003).

[75] Gerber et al. (2009), p. 1547, Table 3.

[76] Gerber et al. (2009), 1547.

Risks of PANDAS Treatments

All of the PANDAS treatments have at least some risk. The psychiatric therapies to treat OCD and tic disorders carry, perhaps, the least harmful risks. For these treatments the major risk may be potential ineffectiveness. No studies appear to test the efficacy of these treatments to improve OCD and tic disorder symptoms specifically among children meeting the PANDAS criteria.

Pharmacological treatments for pediatric OCD may cause adverse reactions. The APA notes that SSRIs may be less effective and have more severe side-effects among pediatric patients when compared to adult patients.[77] Further, there is some evidence that SSRIs are less effective in children who have both OCD and tic disorder symptoms, than in children who have OCD alone.[78] The AACAP cautions that there is little evidence of the long-term effects of SSRI administration on brain development.[79]

The AACAP notes that most studies of tic disorder medications involve adults, rather than children, and that adverse effects are common among children and may be severe, particularly for haloperidol. As much as 84 percent of patients taking this medication report adverse events and roughly one third experience involuntary movements called extrapyramidal movement.[80] Other pharmacological tic treatments for children may also cause adverse effects.[81]

Common side-effects of both types of immune-based therapies include headache, fever, chills, nausea and dizziness.[82] Uncommon but serious side-effects include seizures and heart failure. At least among IVIG recipients, side-effects are reported to be particularly common among those receiving the treatment for the first time, and those patients who have recently had a bacterial infection.[83,84]

Finally, the administration of antibiotics, whether to treat a strep infection or prevent its recurrence, presents some risks. IDSA warns against overuse of antibiotics primarily because research suggests over-use of antibiotics in children has contributed to the increasing incidence of antibiotic resistant bacteria.[85] The CDC's recent report on antibiotic resistance states that the "use of antibiotics is the single most important factor leading to antibiotic resistance" and found that at least two million people are infected with antibiotic resistant bacteria every year.[86]

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77 APA (2013).

78 APA (2013).

79 AACAP (2012), p. 108.

80 AACAP (2013).

81 De Nadai A, Storch E, McGuire J, Lewin A, Murphy T (2011). Evidence-based pharmacotherapy for pediatric obsessive-compulsive disorder and chronic tic disorders. *Journal of Central Nervous System Disease,* 3:125-142, p. 129.

82 Patwa et al. (2012), p. 1013.

83 Orange, et al. (2006), p. S544.

84 Perlmutter, et al. (1999), p. 1155-56.

85 Shulman et al. (2012).

86 Center for Disease Control and Prevention. Antibiotic Resistance Threats in the United States, 2013, accessed November 20, 2013 from: http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf.

III. Methods

The methods used to prepare this review of S.B. 956 included a literature review, web-based research, telephone inquiries, key informant interviews, surveys of insurers and managed care organizations (carriers), the Office of the State Comptroller, and local health departments; and findings from actuarial and economic analyses conducted by Optum.

CPHHP conducted a search for published articles and other information related to the medical, social, economic and financial aspects of the proposed benefit mandate. In addition, at the request of CPHHP, medical librarians at the Lyman Maynard Stowe Library at the University of Connecticut Health Center (UCHC) conducted searches using: PubMed, UptoDate, textbooks, and web-based searches. Keywords used included: Obsessive compulsive disorder, tics, movement disorders, pediatric autoimmune neuropsychiatric disorder associated with streptococcal infections, PANDAS, and PANS.

CPHHP also used telephone and e-mail inquiries to appropriate state, federal, municipal, and non-profit entities and reviewed internet sources such as the Centers for Medicare and Medicaid Services (CMS) website, other states' websites, the Connecticut Department of Public Health, the PANDAS / PANS Advisory Council, and non-profit and community-based organization websites. Additional sources of information included governmental reports (e.g., CDC, NIMH, AHRQ) and government-maintained data (e.g., Medical Expenditures Panel Survey, AHRQ) and relevant professional guidelines. CPHHP also consulted with faculty and staff from the University of Connecticut's School of Medicine on matters pertaining to medical standards of care, medical practices, and peer-reviewed evidence related to the diagnosis and treatment of PANDAS.

CPHHP fielded a survey to six carriers domiciled in Connecticut. The six carriers surveyed account for 90 percent of covered lives in the Connecticut-domiciled fully insured group market and 94 percent of covered lives in the Connecticut-domiciled individual market. CPHHP requested policy documents (e.g., service coverage, utilization review processes, parameters for defining medical necessity, etc.) and data for the proportion of members with policy exclusions, the extent of member coverage, and treatments approved, as specified by the mandate. All carriers responded; however, the completeness and quality of responses varied.

The CID contracted with Optum to provide actuarial and economic analyses of the mandated benefit. Optum's estimates of utilization and cost primarily relied on its in-house national and Connecticut-specific claims data from 2010-2011. Optum's full report is available in Appendix IV.

IV. Social Impact

1. The extent to which PANDAS treatments are utilized by a significant portion of the population.

It is unclear how many children in the state are currently being treating for PANDAS. The Connecticut PANDAS / PANS Advisory Council discussed the possibility of establishing a registry tracking PANDAS patients at its September, 2013, meeting,[87] so the size of this group may be more easily estimated in the future.

Estimates based on national samples suggest that one to two percent of children between the ages of five and fifteen might have OCD at any given time,[88] and 0.5 to 3 percent of the population younger than eighteen may have a diagnosed tic disorder.[89] There is some overlap in the above estimates, as some children have both OCD and a tic disorder.[90] Nearly everyone appears to suffer a strep infection at some point during childhood.[91] Optum reports that there were 114 children in the Connecticut portion of its internal database who received treatments for OCD or a tic disorder in 2010, and 88 in 2011. Fewer than five of them received a strep test either year. Optum did not have any instances in its database of a child receiving insurance coverage for either plasma exchange or IVIG treatments in Connecticut for any condition in 2010 or 2011. Seven children in Optum's database received long-term antibiotic treatments, though it is unclear how many of these children had OCD or a tic disorder. These figures do not include patients whose insurance claims may have been denied or who otherwise paid out-of-pocket. While Optum's database may not be representative of the larger state population, it does contain claims from policies that cover 135,000 lives less than 65 years old in the state, and so provides some evidence that the number of children currently receiving PANDAS treatments is low.

2. The extent to which PANDAS treatments are available to the population, including, but not limited to, coverage under Medicare, or through public programs administered by charities, public schools, the Department of Public Health, municipal health departments or health districts or the Department of Social Services.

A national PANDAS advocacy group, the PANDAS Network, maintains a list of PANDAS treatment providers in each state, though the inclusion criteria are not provided. The group lists four providers in Connecticut, all of whom practice in Fairfield County.[92] The recently created Connecticut PANDAS / PANS Advisory Council includes among its membership a private practitioner who treats PANDAS. This physician also practices in Fairfield County.[93] Evidence from the public testimony on S.B. 956 suggests that few medical providers diagnose or treat OCD or tic disorder symptoms as PANDAS in Connecticut.

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[87] September Minutes. Connecticut PANDAS / PANS Advisory Council, accessed November 20, 2013 from: http://www.ct.gov/dph/cwp/view.asp?a=3135&q=531036.

[88] AACAP (2012), p. 99; Stewart et al. (2004).

[89] Murphy T, Lewin A, Storch E, Stock S, and the American Academy of Child and Adolescent Psychiatry Committee on Quality Issues (2013). AACAP official action: Practice parameter for assessment and treatment of children and adolescents with tic disorders. *Journal of the American Academy of Child & Adolescent Psychiatry,* 52(12):1341-1359.

[90] Taylor (2011).

[91] Murphy et al. (2004), p. 61.

[92] PANDAS Network, Provider List, accessed November 12, 2013 from: http://pandasnetwork.org/resources/providers/provider-list/#CONNECTICUT.

[93] Connecticut PANDAS / PANS Advisory Council, Connecticut Department of Public Health, accessed November 12, 2013 from: http://www.ct.gov/dph/cwp/view.asp?a=3135&q=531036.

Medicare: Medicare does not provide specific coverage for PANDAS diagnosis or treatment.[94]

Public Programs Administered by Charities: No charity was discovered that provides funding for PANDAS treatments.

Public Programs Administered by Public Schools: While public schools provide a number of mental health services, a search of websites for the Connecticut State Department of Education, municipal and regional boards of education, and others found no information indicating public schools provide services or funding specifically for treating PANDAS.

The Department of Public Health (DPH): DPH does not fund or directly provide treatments for PANDAS.

Municipal Health Departments or Health Districts: None of the seven municipal health departments or sixteen local health districts responding to a phone and web-based inquiry reported providing funding or directly providing services related to diagnosis and treatment of PANDAS.

The Department of Social Services (DSS): Medicaid does not cover PANDAS treatments. Specifically, it considers plasma exchange, IVIG, and prophylactic antibiotic treatments experimental for children with OCD or tic disorders and Medicaid does not routinely cover experimental treatments.[95]

3. The extent to which insurance coverage is already available for the treatment of PANDAS.

Optum estimates that approximately thirty-five percent of Connecticut's population is covered under a fully insured policy.

All children meeting the PANDAS criteria have symptoms of OCD or a tic disorder. Standard treatments for these symptoms, and those of related mental health conditions described in the current edition of the DSM, are mandatorily covered in fully insured policies pursuant the provisions of §§ 38a-514 (group policies) and 38a-488a (individual policies).

Five carriers provided information on coverage for the specific diagnosis and treatment of PANDAS in fully insured policies. Two carriers cover diagnosis of the condition. Of these two, one carrier covers plasma exchange and prophylactic antibiotic treatments. It considers IVIG to be experimental and reviews such claims on a case by case basis. The other carrier that covers the diagnosis of PANDAS does not provide coverage for immune-based therapies or prophylactic use of antibiotics. The remaining three carriers do not provide specific coverage for either the diagnosis or treatment of PANDAS.

Optum reports that 42 percent of lives in Connecticut are covered by an employer-provided self-funded plan. Self-funded plans are not governed by state health benefit mandates. They are, however, subject to the requirements of the federal Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, the final regulations of which were released on November 13, 2013.[96] This act requires, among other things, that insurance plans that include mental health coverage provide parity between mental health benefits and other health benefits. The Connecticut carriers provide various services to self-funded plans in the state. The carriers report that these plans generally provide insurance coverage similar to that provided by the carriers' fully insured policies.

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[94] Personal Communication. Gwen Jenkins, Customer Service for Medicare & Medicaid Services. September 26, 2013.

[95] Personal Communication. Barbara Fletcher. DSS Medical Policy & Regulations Unit. September 27, 2013.

[96] Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008; Technical Amendment to External Review for Multi-state Plan Program. *Federal Register,* 78 (219); 68240-68296.

4. If the coverage is not generally available, the extent to which such lack of coverage results in persons being unable to obtain necessary health care treatment.

Anecdotal evidence from public testimony in support of S.B. 956, and the related S.B. 360, public testimony before the PANDAS/PANS Advisory Council, and stories featured on national PANDAS advocacy groups' webpages suggest that the most important hurdle to securing treatment for PANDAS is an inability to find a practitioner who will make a PANDAS diagnosis. Five parents testifying at the public hearing recounted the difficulty they faced finding a clinician who considered the possibility of a bacterial cause to their children's OCD or tic disorder symptoms.

To the extent that the evidence suggests that lack of insurance coverage is a barrier to receiving treatment for PANDAS, most of the focus is on IVIG.[97] Two parents at the public hearing on S.B. 956 stated that treatment for their children was delayed due to insurance disputes. A third testified that she was unable to obtain IVIG treatments for her child because they were not covered and the expense was too great.[98,99]

5. If the coverage is not generally available, the extent to which such a lack of coverage results in unreasonable financial hardships on those persons needing treatment.

Health care expenses can substantially affect other aspects of life. For example, an estimated half of all mortgage foreclosures are associated with unexpected health care expenses. Examining a sample of these foreclosures, researchers identified $2,000 in unreimbursed medical payments as a threshold for "significant medical distress."[100]

CPHHP has not discovered research in peer-reviewed literature estimating the cost of the experimental PANDAS treatments. Cost estimates for IVIG and plasma exchange to treat other disorders may provide some guidance, however. Guillain-Barre's Syndrome is an established immune deficiency condition that is treated with plasma exchange and IVIG in a manner similar to PANDAS. Based on prices from April, 2010, one study estimated that 5 plasma exchange procedures, of one plasma volume each, would cost an estimated $4,638. For IVIG, a dose of 2g/kg of body weight, administered over the course of five infusions, cost $10,325.[101] While the prices in the study were based on an adult weighing approximately 150 pounds, and are, presumably, somewhat higher than they would be for children, the cost of these treatments appears to be substantial. Anecdotal evidence from PANDAS advocacy groups suggests that the cost for an IVIG treatment for a 60-pound child may be as much as $6,000.[102] Optum estimates the average cost of prophylactic antimicrobial therapy to be $1,205 per year and the average cost for the diagnosis and treatment of PANDAS (other than by standard OCD and tic disorder treatments) to be $5,561. Thus, the costs of treating PANDAS may exceed a $2,000 significant medical distress threshold.

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[97] The efficacy of IVIG to treat OCD and tic disorder symptoms is controversial and CPHHP takes no position on whether it constitutes "necessary health care treatment" for children who are diagnosed with PANDAS.

[98] Public Hearing on S.B. 862. Connecticut Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Session, testimony submitted by James Carson, Paula J. Perna; accessed February 26, 2013 from: http://www.cga.ct.gov/2013/INSdata/chr/2013INS00226-R001300-CHR.htm.

[99] Public Hearing on S.B. 862. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by PANDAS Resource Network, Lisa Kilion, Unidentified Mother (Lily), Nancy Fleherty, Unidentified Mother (Campbell). Accessed February 26, 2013 from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013SB-00956-R000226-PANDAS%20Resource%20Network-TMY.PDF.

[100] Robertson C, Egelhof R, Hoke M (2008). Get sick, get out: The medical causes of home mortgage foreclosures. *Health Matrix,* 18: 65-104.

[101] Winters J, Brown D, Hazard E, Chainani A, Andrezejewski C (2011). Cost-minimization analysis of the direct costs of TPE and IVIG in the treatment of Guillain-Barre's Syndrome. *BMC Health Services Research*, 11:101-108, Tables 1-2.

[102] PANDAS Network, Treatment, accessed November 20, 2013 from: http://pandasnetwork.org/treatment.html.

6. The level of public demand and the level of demand from providers for PANDAS treatments.

Several parents and other caregivers spoke at the public hearing for S.B. 956. They recounted their frustration from having to bring their child to multiple physicians before finding one that considered a PANDAS diagnosis. Additionally, caregivers stated they perceived symptom improvement for their children when treated with PANDAS treatments, particularly antibiotics and IVIG. The proliferation of PANDAS advocacy and support groups on the Internet provides further evidence of public interest. One researcher estimated that, as of 2010, there were 100,000 web-pages with PANDAS discussions.[103] At least one advocacy group, the PANDAS Resource Network, is based in Connecticut.[104] A group of PANDAS advocates based in Massachusetts, the Northeast PANS / PANDAS Parent Association, organized a conference on November 9 and 10, 2013, for PANDAS advocates in the region.[105] The PANDAS Network[106] lists 17 states, including Connecticut, that proclaimed October 9, 2013 as PANDAS Awareness Day.[107] Discussion of PANDAS locally in traditional print media has been less extensive. CPHHP's informal review of 15 newspapers from across the state revealed one article on PANDAS published between January 2011 and November 2013.

The evidence on provider demand for PANDAS treatments is mixed. The AACAP's most recent guidelines for treating OCD suggest that practitioners should consider the possibility of PANDAS in some cases. Further, the APA discusses the PANDAS literature when describing its new diagnosis "obsessive-compulsive and related disorders due to another medical condition."[108] The state chapter of the American Academy of Pediatrics (AAP), however, submitted testimony against a related bill proposed in the General Assembly, S.B. 360, arguing that the condition remains unproven. Further, while many recent guidelines mention the PANDAS research and the NIMH criteria, no professional group has yet released guidelines specifically for the diagnosis and treatment of it.

7. The level of public demand and the level of demand from providers for insurance coverage for PANDAS treatments.

The PANDAS Resource Network and seven caregivers testified at the public hearing for S.B. 956 and described their struggles and dissatisfaction with insurance coverage for IVIG and prophylactic antibiotic treatments. They testified that carriers considered these treatments to be off-label and experimental, and so not qualified for coverage under health insurance policies. One caregiver testified that, while ultimately her insurance carrier did cover IVIG treatment, she had to undergo an extensive waiting period before the claim was cleared. The Connecticut Association of Health Plans and the Connecticut Business and Industry Association submitted testimony opposing health benefit mandates generally. There was no testimony submitted for consideration of S.B. 956 opposing insurance coverage specifically for PANDAS treatments.[109]

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[103] Murphy T, Kurlan R, Leckman J (2010). The immunobiology of Tourette's Disorder, pediatric autoimmune neuropsychiatric disorders associated with streptococcus, and related disorders: A way forward. *Journal of Child and Adolescent Psychopharmacology*, 20(4): 317-331.

[104] PANDAS Resource Network, accessed November 13, 2013 from: http://www.pandasresourcenetwork.org/.

[105] Northeast PANS / PANDAS Parent Association, accessed November 13, 2013 from: http://www.nepandasparents.com/home.html.

[106] The PANDAS Network does not appear to be directly connected to the Connecticut-based PANDAS Resource Network.

[107] PANDAS Network, Awareness Day, accessed November 13, 2013 from: http://pandasnetwork.org/resources/awarenessday/

[108] APA (2013),"Obsessive-compulsive and related disorders."

[109] DPH submitted neutral testimony regarding another part of S.B. 956 that is not part of the proposed health benefit mandate and not part of this review.

8. The likelihood of achieving the objectives of meeting a consumer need as evidenced by the experience of other states.

The National Association of Insurance Commissioners (NAIC) maintains a database of health benefit mandates and the states in which they were enacted. As of September 5, 2013, the NAIC database showed no states as having enacted a health benefit mandate requiring coverage of diagnosis or treatment of PANDAS.[110] A bill similar to S.B. 956 was considered in Massachusetts in the 2013 session, H. 984. This bill proposed specific provisions for the coverage of IVIG treatments for PANDAS patients.

9. The relevant findings of state agencies or other appropriate public organizations relating to the social impact of the mandated health benefit.

Twenty-nine states required a fiscal note or an additional review process for any newly required health insurance benefit prior to enactment in 2013.[111] In reviewing the online archives of the states with these processes, no analyses of a proposed or enacted health benefit mandate related to PANDAS were identified.

Connecticut's General Assembly (CGA) created the PANDAS/PANS Advisory Council in 2013 as part of Public Act 13-187. The Council began meeting in September, 2013. In a separate bill, the CGA commissioned the PANDAS Resource Network, an advocacy group, to draft a report summarizing the current research on PANDAS. The resulting report was subsequently presented to the PANDAS/PANS Advisory Council. No state agency appears to have prepared a review of the potential social impact of the mandated health benefit.

While not specific to PANDAS, there have been other task forces created recently to examine various aspects of mental health service provision in Connecticut. Public Act 13-178 created, among other things, the Children's Mental Health Task Force. In the same session, the General Assembly also created, in Public Act 13-3, the Task Force to Study the Provision of Behavioral Health Services for Young Adults. The later task force has considered many aspects of access to behavioral health services, including health insurance. Its focus population is somewhat older than the PANDAS population, however.

10. The alternatives to meeting the identified need, including but not limited to, other treatments, methods or procedures.

All children meeting the PANDAS criteria have OCD or tic disorder symptoms and may have an active strep infection. Regardless of whether PANDAS is recognized as a unique condition, or whether there is insurance coverage specifically to treat it, these conditions may be treated as they are for any patient with the same symptoms. Thus, the alternative to the experimental PANDAS treatments is an administration of standard treatments for OCD and tic disorders for an unknown duration, and a standard 10-day course of antibiotics for those children with a confirmed strep infection.

11. Whether the benefit is a medical or broader social need and whether it is consistent with the role of health insurance and the concept of managed care.

OCD and tic disorders, the primary conditions associated with PANDAS, are established in the professional literature and described in the current edition of the DSM. Mental health needs are recognized in

[110] National Association of Insurance Commissioners. Compendium of State Laws on Insurance Topics – Individual Chart. August, 2011.

[111] California Health Benefits Review Program. Other States' Health Benefit Review Programs, 2013 accessed November 13, 2013 from: http://chbrp.org/docs/Survey_and_Analysis_of_Other_States__Health_Benefit_Review_Programs_2013_FINAL_092013.pdf.

Connecticut as medical needs.[112,113] Thus, the diagnosis and treatment of OCD and tic disorder symptoms address a medical need. According to the CID, the goal of managed care is to, among other things, coordinate health care services and deliver appropriate treatments in an appropriate setting and in a cost–effective manner.[114]

PANDAS treatments are not currently accepted by the relevant medical communities and, therefore, may not be "appropriate treatments." Therefore, the proposed benefit may not be consistent with the concept of managed care. If the experimental PANDAS treatments prove to be effective at treating OCD and tic disorder symptoms, they will address a medical need. If PANDAS treatments become accepted by the relevant professional communities and, potentially, avoid the costs of long-term administrations of standard OCD and tic disorder treatments, they would then be consistent with the concept of managed care.

12. The potential social implications of the coverage with respect to the direct or specific creation of a comparable mandated benefit for similar diseases, illnesses, or conditions.

The proposed PANDAS mandate attempts to address a mental health need. Connecticut passed its first mental health parity law in 1997, initially limiting mandated insurance coverage to eight enumerated conditions covered by group plans. The mandate was soon extended to cover individual plans and the number of covered conditions increased during the years following.[115] The current version of the law; §§ 38a-488a (individual policies) and 38a-514 (group policies); mandates coverage of mental and nervous conditions described in the DSM, subject to some exclusions.[116] The DSM recognizes both OCD and tic disorders. If PANDAS becomes recognized as a subset of OCD or tic disorder,[117] its diagnosis might fall within the general ambit of the mental health parity law.

The basic causal theory of PANDAS is that a preceding bacterial infection causes an immunoregulatory response that triggers OCD, tic disorder, and other neuropsychiatric symptoms. Researchers at NIMH and elsewhere have recently suggested that other types of infections, including the virus that causes Lyme Disease,[118] may also trigger such an immunoregulatory response. In 2010, the term PANS (pediatric acute-onset neuropsychiatric syndrome) was proposed to refer collectively to all of these potential conditions that feature acute symptom onset.[119] If other particular conditions are established under the PANS framework, this may lead to a demand for future health benefit mandates addressing each particular condition. Alternatively, assuming the establishment of PANDAS and other PANS conditions, there may be a future demand for replacing the PANDAS mandate with a general PANS mandate, or amending the basic mental health parity law.

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[112] Center for Public Health and Health Policy. Chapter 2: "Diagnosis and Treatment of Mental or Nervous Conditions," in Review and Evaluation of Certain Health Benefit Mandates in Connecticut 2010, volume III, p. 47.; See also Legislative Program Review and Investigations Committee. Mental Health Parity: Insurance Coverage and Utilization. Legislative Program Review and Investigations Committee: 2009; Connecticut Office of the Health Care Advocate. Findings and Recommendations: Access to Mental Health and Substance Use Services (2013).

[113] Legislative Program Review and Investigations Committee. Mental Health Parity: Insurance Coverage and Utilization. Legislative Program Review and Investigations Committee: 2009; See also Connecticut Office of the Health Care Advocate. Findings and Recommendations: Access to Mental Health and Substance Use Services (2013).

[114] CID, What is Managed Care?; accessed November 20, 2013 from: http://www.ct.gov/cid/cwp/view.asp?a=1267&q=254490.

[115] PRI, Mental Health Parity: Insurance Coverage and Utilization (December 2005), pgs 8-10.

[116] CPHHP, Diagnosis and Treatment of Mental or Nervous Conditions (2010).

[117] See APA (2013) Obsessive compulsive and related disorders.

[118] Lyme Disease treatments are regulated by §§ 38a-492h (individual policies) and 38a-518h (group policies). CPHHP, Lyme Disease Treatments (2010).

[119] Swedo S, Leckman J, Rose N (2012). From research subgroup to clinical syndrome: Modifying the PANDAS criteria to describe PANS (pediatric acute-onset neuropsychiatric syndrome). *Pediatrics & Therapeutics,* 2(2).

13. The impact of the benefit on the availability of other benefits currently offered.

The mandate is estimated to add only a small amount to the average premium and, therefore, it might not, alone, impact the availability of other benefits. Optum estimates that a PANDAS mandate, if it is interpreted to follow the general description of diagnosis and treatment in the NIMH documents, might add an average of $0.013 PMPM, and constitute approximately 0.003 percent of the average group policy premium price.

14. The impact of the benefit as it relates to employers shifting to self-insured plans and the extent to which the benefit is currently being offered by employers with self-insured plans.

Some employers, particularly large employers, choose to insure their workers directly, rather than purchase an insurance policy from a carrier. Optum estimates that approximately 42 percent of Connecticut's population is covered by such a plan.

Employers appear to consider many factors when deciding whether to purchase a fully insured policy for their employees or to self-fund.[120] While research indicates that avoidance of compliance with state health benefit mandates is not a primary concern,[121] state regulation of these self-funded plans is preempted by the Federal Employee Retirement Income Security Act of 1974 (ERISA).[122]

The PANDAS mandate here would not likely cause many employers to switch to a self-funded plan. Most of the treatments associated with PANDAS are already regulated by other provisions of the general statutes. While the cost of the immune-based treatments and prophylactic antimicrobial therapy are high, there are not likely to be many patients who will need them, resulting in a low overall cost. Optum estimates that the increased cost arising from mandated coverage of the diagnosis and treatment of PANDAS would add $0.013 PMPM to the premiums of group policies.

15. The impact of making the benefit applicable to the state employee health insurance or health benefits plan.

According to the state Comptroller's Office, in 2012 there were 161,368 covered lives in the state employee health insurance plan under the age of 65. Connecticut transitioned to a self-funded plan on July 1, 2010. Therefore, it does not currently purchase a fully insured policy that is subject to state health insurance benefit mandate laws. Often, however, the state covers health insurance benefits similar to those described in the mandates. In the case of PANDAS, the state covers the diagnosis and some treatments, but it does not provide routine coverage for experimental treatments. Presumably, these include plasma exchange, IVIG and prophylactic antimicrobial therapy. If the state included coverage of these treatments to its employee plan, the increase in cost is estimated to be $1714 monthly or $20,568 annually. This estimate is a calculated estimate using the same weighted average integrating carrier response data and Optum's internal data that was used for the fully insured estimate. Further, it assumes the same rate of utilization for plasma exchange, IVIG, and prophylactic antibiotics as was assumed in the earlier estimate. Because of the number of children likely to be eligible for PANDAS treatments who are covered by the state benefit plan is very small, this estimate is highly unstable. In addition, the actual cost to the state plan will depend on the particular cost-share arrangements included in the plan.

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[120] Brien M, Panis C. Self-Insured Health benefit Plans. Deloitte; Advanced Analytical Consulting Group (2011), p. 6, accessed November 20, 2013 from: http://www.dol.gov/ebsa/pdf/ACASelfFundedHealthPlansReport032811.pdf.

[121] Jensen G, Cotter K, Morrisey M (1995). State insurance regulation and employers' decisions to self-insure. *The Journal of Risk and Insurance,* 62 (2), 185-213, p. 207.

[122] Office of Legislative Research (2005), Self-insured benefit plans and insurance mandates. 2005-R-9753; See also *Metropolitan Life Ins.* v. *Massachusetts*, 471 U.S. 724 (1985).

16. The extent to which credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community determines the treatment, service or equipment, supplies or drugs, as applicable, to be safe and effective.

The existence of PANDAS as a unique condition and the relationship, if any, between a strep infection and neuropsychiatric symptoms, is not generally recognized by professional guidelines and there is conflicting evidence in relevant peer-reviewed journals. Standard treatments for OCD and tic disorders, particularly CBT, SSRIs and other pharmacological treatments, are described in professional guidelines and supported by evidence published in relevant peer-reviewed literature. Some of these guidelines are referenced in the background, but the literature is not detailed here because existing law governs coverage of these treatments. Plasma exchange, IVIG and prophylactic antimicrobial therapy are not currently recognized by professional guidelines, though there is some supporting evidence in the literature and an ongoing study testing the efficacy of IVIG as a PANDAS treatment.

PANDAS as a unique medical condition. The children described in the foundational PANDAS paper by Swedo et al. (1998) had neuropsychiatric symptoms similar to an established condition that afflicts some children: Sydenham's Chorea.[123] The research into whether PANDAS is a unique condition, and, if so, the treatments that might be appropriate, has been greatly informed by research into this other condition. Sydenham's Chorea is a later development of rheumatic fever and is, thus, ultimately, caused by a strep infection.[124] Children who have Sydenham's Chorea are administered antibiotics to kill the underlying strep infection. Many are then given a long-term regimen of antibiotics to prevent a subsequent outbreak of rheumatic fever.[125] Experiments are ongoing that test whether there is an autoimmune deficiency associated with this condition,[126] and recently IVIG has been used experimentally to treat children suffering from it.[127]

Since PANDAS was first proposed, there has been research, at NIMH and elsewhere, aimed at determining whether PANDAS is a distinct condition and, if so, how it might best be treated.[128] The research has, however, thus far failed to demonstrate a causal link between a strep infection and OCD or tic disorder symptoms to the satisfaction of the relevant professional organizations. A 2010 review of PANDAS-related research found several peer-reviewed articles that support, and several that do not support, its existence.[129] Preliminary results from recent studies using animal models have produced some evidence supporting the existence of a causal link between a strep infection and neuropsychiatric symptoms.[130,131]

To some extent evidence for the existence, or not, of PANDAS as a condition will be revealed by research

[123] Swedo S, Leonard H, Garvey M, Mittleman B, Allen A, Perlmutter S, Lougee L, Dow S, Zamkoff J, Dubbert B (1998). Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections: Clinical description of the first 50 cases. *American Journal of Psychiatry,* 155(2):264-271.

[124] Bonthius D, Karacay B (2003). Sydenham's Chorea: Not Gone and Not Forgotten. *Seminars in Pediatric Neurology*, 10(1):11-19, p. 12.

[125] Walker K, Wilmshurst J (2010). An update on the treatment of Sydenham's chorea: The evidence for established and evolving interventions. *Therapeutic Advances in Neurological Disorders*, 3:301-309.

[126] Ben-Pazi H, Stoner J, Cunningham M (2013). Dopamine receptor autoantibodies correlate with symptoms in Sydenham's Chorea. *PLOS ONE*, 8(9):e73516.

[127] Walker K, Brink A, Lawrenson J, Mathiassen W, Wilmshurst J (2012). Treatment of Sydenham Chorea with intravenous immunoglobulin. *Journal of Child Neurology,* 27 (2): 147-155.

[128] Murphy, et al. (2010).

[129] Murphy, et al. (2010).

[130] Brimberg L, Benhar I, Mascaro-Blanco A, Alvarez K, Lotan D, Winter C, Klein J, Moses A, Somnier F, Leckman J, Swedo S, Cunningham M, Joel D (2013). Behavioral, pharmacological, and immunological abnormalities after streptococcal exposures: A novel rate model of Sydenham Chorea and related neuropsychiatric disorders. *Neuropsychopharmacology,* 37: 2076-2087, p. 2083.

[131] Hornig M, Lipkin W (2013). Immune-mediated animal models of Tourette syndrome. *Neuroscience and Biobehavioral Reviews*, 37:1120-1138.

attempting to determine whether the two controversial PANDAS treatments, that is, immunotherapy to treat PANDAS symptoms and prophylactic antimicrobial therapy to prevent the recurrence of them, are effective.

Effectiveness of immune-based therapy to treat PANDAS symptoms. Neither the AAAAI nor the AAN considers the current scientific evidence sufficient to recommend immunotherapy for the treatment of PANDAS. Perlmuter, et al. (1999), provides the main support in the academic literature for the efficacy of these treatments. These researchers divided a group of 30 children meeting the PANDAS criteria into three: one receiving plasma exchange, one IVIG and the third receiving a placebo injection.[132] They found significant improvement after one month in both of the experimental groups for OCD symptoms, and significant improvement in the plasma exchange group for tic disorder symptoms when compared to the placebo group.[133] A second small study produced some evidence that plasma exchange treatments are not effective in treating pediatric OCD patients who did not have a preceding strep infection.[134]

NIMH is currently conducting another experiment to determine the effectiveness of IVIG to treat children meeting the PANDAS criteria. The researchers will recruit about thirty children, half of whom will receive IVIG. NIMH predicts that the study will be completed by January of 2016. Interim results may be available in early 2014.

Effectiveness of the use of antimicrobial therapy to prevent recurrence of PANDAS symptoms.

Neither the IDSA nor the AHA finds the scientific evidence sufficient to recommend the use of prophylactic antimicrobial therapy for the prevention of PANDAS symptom recurrence. An early study of the efficacy of using antibiotics to prevent recurrence of neuropsychiatric symptoms in PANDAS patients failed to produce supporting evidence. The antibiotics also failed, however, to significantly reduce the recurrence of strep infections.[135] A second study produced some evidence that both penicillin and azithromycin treatments reduced the recurrence of OCD and tic disorder symptoms among PANDAS patients. This finding was based on a comparison of each child's prior year rates, however, and lacked a control group for comparison.[136]

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[132] Perlmutter, et al. (1999), p. 1154.

[133] Permutter, et al. (1999), p. 1156.

[134] Nicolson R, Swedo S, Lenane M, Bedwell J, Wudarsky M, Gochman P, Hamburger S, Rapoport J (2000). *The Journal of the American Academy of Child and Adolescent Psychiatry,* 39 (10): 1313-1315, p. 1314.

[135] Garvey M, Perlmutter S, Allen A, Hamburger S, Lougee L, Leonard H, Witowski M, Dubbert B, Swedo S (1999). A pilot study of penicillin prophylaxis for neuropsychiatric exacerbations triggered by streptococcal infections. *Biological Psychiatry*, 45: 1564-1571.

[136] Snider L, Lougee L, Slattery M, Grant P, Swedo S (2005). Antibiotic prophylaxis with azithromycin or penicillin for childhood-onset neuropsychiatric disorders. *Biological Psychiatry,* 57: 788-792.

V. Financial Impact

1. The extent to which the mandated health benefit may increase or decrease the cost of the treatment, service or equipment, supplies or drugs, as applicable, over the next five years.

Standard treatments for OCD and tic disorders are already mandatorily covered by statute; §§ 38a-488a (individual policies) and 38a-514 (group policies); the enactment of S.B. 956 would not likely have an effect on the prices for those treatments. Antibiotics are widely prescribed to treat a number of conditions; a PANDAS treatment benefit mandate would not likely have an effect on the price of antibiotics.

Recently, IVIG and plasma exchange have been experimentally used to treat many conditions, though they are recommended to treat only a few.[137,138] The supply of IVIG nearly doubled during the first decade of the 21st century. Still, there were some reports of local shortages.[139] These local shortages may have been a factor in the substantial price increase for IVIG from 1997 to 2010.[140] Because no reliable estimates of the number of children meeting the PANDAS criteria in Connecticut exist, and the efficacy of IVIG and plasma exchange to treat PANDAS symptoms has not yet been established, it is unclear whether passage of the proposed mandate would increase or decrease the utilization or cost of these treatments.

2. The extent to which the mandated health benefit may increase the appropriate or inappropriate use of the treatment, service or equipment, supplies or drugs, as applicable, over the next five years.

Adoption of S.B. 956 would not likely increase the appropriate or inappropriate use of standard OCD or tic disorder treatments because those treatments are already subject to a health benefit mandate. The mandate may decrease the utilization of the standard treatments among PANDAS patients if IVIG and plasma exchange prove effective at treating these symptoms, or prophylactic antimicrobial therapy successfully prevents the recurrence of them.

The provisions in S.B. 956 may encourage the use of IVIG and plasma exchange to treat those children with OCD or tics who meet the PANDAS criteria. It may also increase the number of children administered long-term regimens of antibiotics. Whether these are "*appropriate*" uses of the treatments will depend, in part, on whether these treatments prove to be effective.

The adoption of S.B. 956 may increase the inappropriate use of antibiotics. The IDSA warns generally that "*a substantial number of patients continue to receive inappropriate antimicrobial therapy*."[141] There is some evidence that the existence of the PANDAS hypothesis has encouraged further inappropriate use. Antibiotics are only considered appropriate when a strep infection has been confirmed by a laboratory test. One researcher reviewed the administration of antibiotics at a community clinic and found, however, that of the thirty-seven children who were diagnosed with having PANDAS, and prescribed antibiotics, twenty-two of them had not been tested for a strep infection.[142]

[137] AAAI (2005).

[138] Cortese et al. (2011).

[139] Eastern Research Group, Inc. "Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV). Prepared for the Office of the Assistant Secretary of Planning and Evaluation, U.S. Department of Health and Human Services: February, 2007.

[140] Winters, et al. (2011).

[141] Shulman, et al. (2012), p. e89.

[142] Gabbay V, Coffey B, Babb J, Meyer L, Wachtel C, Anam S, Rabinovitz B (2008). Pediatric autoimmune neuropsychiatric disorders associated with streptococcus: Comparison of diagnosis and treatment in the community and at a speciality clinic. *Pediatrics*, 122(2): 273-278.

3. The extent to which the mandated health benefit may serve as an alternative for more expensive or less expensive treatment, service or equipment, supplies or drugs, as applicable.

Children who meet the PANDAS criteria presumably receive some combination of OCD and tic disorder treatments, such as CBT, HRT, SSRIs, and various pharmacological treatments. If the proposed PANDAS treatments of plasma exchange and IVIG prove effective, they may become an alternative to the indefinite administration of standard OCD and tic disorder treatments. If prophylactic antimicrobial therapy proves to be effective, it may prevent the recurrence OCD and tic disorder symptoms in PANDAS patients and so render OCD and tic disorder treatments unnecessary in some instances.

4. The methods that will be implemented to manage the utilization and costs of the mandated health benefit.

Nothing on the face of the S.B. 956 limits insurance carriers from using their customary methods, such as prior authorization, to manage the utilization and cost of PANDAS treatments.[143] There is some ambiguity arising from the interaction of the language in S.B. 956 and the provisions governing "medical necessity" reviews, codified at §§38a-482a (individual policies) and 38a-513c (group policies), which may lead to a limitation on insurance carriers' ability to conduct usual medical necessity review.

For a service or treatment to satisfy the statutory definition of medical necessity, it must, among other things, be "*in accordance with generally accepted standards of medical practice.*" The statute further defines "*generally accepted standards of medical practice" to mean "standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community or otherwise consistent with the standards set forth in policy issues involving clinical judgment.*" If S.B. 956 requires coverage of IVIG, plasma exchange and long-term prophylactic administration of antibiotics, this may prevent carriers from denying coverage for these treatments on the basis that these treatments do not otherwise meet the statutory definition of medical necessity.

5. The extent to which insurance coverage for the treatment, service or equipment, supplies or drugs, as applicable, may be reasonably expected to increase or decrease the insurance premiums and administrative expenses for policyholders.

Optum estimates that adoption of the proposed PANDAS diagnosis and treatment mandate would add, on average, $0.013 PMPM for premiums of group policies and $0.014 to premiums of individual policies in 2014.

The three main components of the price of an insurance premium are health benefit payments, administrative costs and profit (or "contribution to surplus" for non-profit insurers).[144] Optum refers to administrative costs and profit as "*retention*" and health benefit costs as "*medical costs.*"

Standard treatments for OCD, tic disorder and other established neuropsychiatric disorders are already covered by mandate and, therefore, the adoption of S.B. 956 should not lead to an increase in premiums from these treatments.

Optum's PMPM estimate assumes that approximately 1 person per thousand covered individuals would be a child suffering from OCD or a tic disorder, that about 99 percent of them would receive a strep test, and

[143] For a discussion of those tools see, CPHHP, Autism Spectrum Disorder, (2012).

[144] Newson M and Fernandez B (2011). Private health insurance premiums and rate reviews. Congressional Research Service, available online through the Cornell University ILR School Digital Commons at: http://digitalcommons.ilr.cornell.edu/cgi/viewcontent.cgi?article=1793&context=key_workplace.

that 7.5 percent of these children would receive either plasma exchange, IVIG, prophylactic antimicrobial therapy or some combination thereof. In part because the actual prevalence rate of PANDAS is unknown, Optum also provides a lower estimate of 2.5 percent of children with OCD or tic disorders receiving PANDAS treatments and adding $0.005 PMPM, and a higher estimate of 12.5 percent of these children receiving PANDAS treatments, thereby adding $0.020 PMPM. Of the estimated $0.013 PMPM in premium increase, Optum calculates that $0.011 will be caused by increased paid medical costs and $0.002 will be attributable to increases in retention.

This estimate does not include any potential savings that might result from adoption of S.B. 956 because currently available evidence does not justify such an estimate.

6. The extent to which the treatment, service or equipment, supplies or drugs, as applicable, is more or less expensive than an existing treatment, service or equipment, supplies or drugs, as applicable, that is determined to be equally safe and effective by credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community.

The experimental PANDAS treatments of plasma exchange, IVIG, and prophylactic antimicrobial therapy have not been accepted by the relevant medical communities as being effective to treat OCD or tic disorder symptoms. If they become generally accepted, they may serve as alternatives to indefinite administrations of standard treatments for OCD and tic disorders. CPHHP has not discovered any studies estimating the average price of standard OCD or tic disorder treatments for children meeting the PANDAS criteria.

In 2010, an estimated national average price for five plasma exchanges for an adult was $4,638 and the administration of IVIG at the rate of 2g/kg of body weight for an adult over the course of five infusions was $10,325.[145] The number of plasma exchanges and the dose of the IVIG treatments are the same as described in the PANDAS treatment experiments discussed in the Background. The national estimates are based on adult patients, however, so the prices may be slightly higher than for children. Optum estimates that a year of antibiotics costs approximately $1,205.

7. The impact of insurance coverage for PANDAS treatments on the total cost of health care, including potential benefits or savings to insurers and employers resulting from prevention or early detection of disease or illness related to such coverage.

Optum estimates that S.B. 956 would add $15,604 per month or $$187,248 annually to the total cost of health care in 2014.

The total cost of health care, as understood here, includes all payments to health care providers, whether paid by the carrier or the policyholder. Collectively, these costs are referred to as "allowed costs." The portion of allowed costs paid by the carrier are called "paid medical costs," and the portion paid by the policyholder are called "cost-share." Cost-share includes copayments, deductibles, coinsurance payments and other means through which the policyholder pays the health care provider directly for the health care service.[146] Of the total health care cost estimate here, Optum calculates that $12,184 per month will be paid medical cost and $3,420 per month will be paid through cost-share.

This estimated cost includes coverage and utilization of strep tests for asymptomatic children to confirm a PANDAS diagnosis, the immune-based treatments of plasma exchange and IVIG and the prophylactic

[145] Winters et al. (2011).

[146] For further description, see Appendix IV.

use of antibiotics administered until the patient is aged 21. Because the actual size of the population who meet the PANDAS criteria and the percentage of them who will benefit from the expensive immune-based treatments are unknown, the true health care cost of S.B. 956 may vary from the estimate.

If the experimental PANDAS treatments prove effective at treating PANDAS symptoms and preventing their recurrence, these treatments may obviate the need for continued standard OCD and tic disorder treatments for some children. Thus, some cost savings to the cost of health care may result from S.B. 956 if the cost of the experimental treatments is less than the cost of the standard treatments that the patients would otherwise receive. No specific cost savings estimate is justified, however, because the effectiveness of the experimental PANDAS treatments and the duration for which children meeting the PANDAS criteria require standard treatments are unknown.

8. The impact of the mandated health care benefit on the cost of health care for small employers, as defined in section 38a-564, and for employers other than small employers.

Optum estimates that the average 2014 cost for the PANDAS mandate would be 0.003 percent of an average premium. Given the small percentage coverage of PANDAS diagnoses and treatments would have on the average premium, it may be that the effect of this mandate alone will be minimal on businesses of any size.

Small businesses are less likely to offer their employees health insurance benefits than are large businesses. This is particularly true for agricultural, retail, sanitation, and service firms. The Connecticut Office of Health Care Access (OHCA) found that a majority of small employers cited health insurance cost as a barrier to providing this benefit.[147]

Premiums generally may be higher for employees of small businesses than for employees of larger firms. While a recent study from the Kaiser Family Foundation found that, in the northeast, premiums were statistically indistinguishable between large and small firms, it defined "small" as 199 or fewer employees.[148] Using Connecticut's current definition of "small employer," fewer than 50 employees, Optum found that small businesses face premiums that were nearly $500 more per year for employee-only coverage than large firms.

In addition to possibly paying higher premiums, small employers may secure fewer benefits for their employees than large employers. This may be due to small firms having less bargaining power than large firms, or fewer resources to invest in selecting insurance policies. The ACA attempts to address this to some extent with the Small Business Health Options Program (SHOP),[149] the national launch of which was announced on September 26, 2013.[150] If small businesses offer fewer benefits than large firms, health benefit

[147] The OHCA's definition of "small business" does not exactly track the statutory definition provided in §38a-565 (4). It only includes businesses up to 20 employees, and it may include some non-profit and other organizations that are excluded from the statutory definition. Still, it is illustrative of the fact that there are many small businesses in Connecticut. Office of Health Care Access, The Connecticut Office of Health Care Access 2004 Small Employer Health Insurance Survey – Focus on Results. November, 2004, accessed December 11, 2013 from: http://www.ct.gov/dph/lib/dph/ohca/publications/2004_employer_survey_brief11-1_with_banner.pdf.

[148] Panchal N, Rae M, Claxton G. Snapshot: A Comparison of the availability and cost of coverage for workers in small firms and large firms, the Kaiser Family Foundation, December 5, 2012, accessed December 11, 2013 from: http://kff.org/private-insurance/issue-brief/snapshots-a-comparison-of-the-availability-and-cost-of-coverage-for-workers-in-small-firms-and-large-firms/.

[149] Exchange Functions: Small Business Health Options Program (SHOP), §§ 45 C.F.R. 155.700 et seq. HHS announced the opening of the SHOPs on September 26, 2013. "Launching the Small Business Health Option Program Marketplace," HHS News, accessed December 12, 2013 from: http://www.hhs.gov/news/press/2013pres/09/20130926b.html.

[150] "Launching the Small Business Health Option Program Marketplace," HHS News, accessed December 12, 2013 from: http://www.hhs.gov/news/press/2013pres/09/20130926b.html.

mandates would have a relatively larger effect on them.

Employers of small businesses may pay a smaller share of their employees' premiums. For all fully insured plans in Connecticut, a typical employer pays from 70 to 79 percent of the premium.[151]

9. The impact of the mandated health benefit on cost-shifting between private and public payers of health care coverage and on the overall cost of the health care delivery system in the state.

S.B. 956 would not likely lead to an immediate shift in cost between public and private payers for health care coverage. If the PANDAS treatments prove effective, however, it may contribute to a potential shift from public to private payers, or at least savings to public payers, for health care and other services in the long term. Because, by definition, these disruptive PANDAS symptoms manifest during important, formative years, it may be that some of these children will require publically funded health care and other public services when adults. If PANDAS treatments prove effective, it may be that some of these future public payments might be avoided.

The overall cost of the health delivery system in the state includes total insurance premiums and cost-sharing. The 2014 projection for the overall cost to the health care delivery system for the coverage of PANDAS diagnosis and treatment for the population covered by fully insured group and individual health policies is $17,754 per month or $213,048 annually. Of this, $14,334 per month are attributed to increase in premium and $3,420 per month to cost-share.

[151] Percentages calculated from the Medical Expenditure Panel Survey (MEPS). Private-Sector Data Premium, Contribution and Cost distributions, 2012, accessed December 12, 2013 from: http://meps.ahrq.gov/data_stats/quick_tables_results.jsp?component=2&subcomponent=2&year=-1&tableSeries=10&searchText=&SearchMethod=1&Action=Search.

Chapter 2

Lung Cancer Screenings

A Report to the Insurance and Real Estate Subcommittee
of the Connecticut General Assembly

Review of Senate Bill 862:

"An Act Requiring Health Insurance Coverage for Lung Cancer Screening."

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Table of Contents

I. Overview

On July 19, 2013 the Chairs of the Insurance and Real Estate Committee of the Connecticut General Assembly directed the Connecticut Insurance Department (CID) to review Senate Bill No. 862 (S.B. 862) from the 2013 Regular Session, "An Act Requiring Health Insurance Coverage for Lung Cancer Screening." The CID contracted with the University of Connecticut Health Center for the services of the Center for Public Health and Health Policy (CPHHP) to conduct this review pursuant to the provisions of Public Act 09-179, "*An Act Concerning Reviews of Health Insurance Benefits Mandated in this State*."[152]

This review provides a background to lung cancer screening and evaluates the potential financial and social impact of S.B. 862, as required by P.A. 09-179. The full text of S.B. 862 is located in Appendix III. S.B. 862 would require fully insured group and individual health insurance policies to:

> "*provide coverage for lung cancer screening tests, in accordance with the recommendations established by the American Lung Association, after consultation with the American Cancer Society, based on age, family history and frequency provided by such recommendations*."

The ALA and the ACS currently recommend[153] lung cancer screening by low-dose computed tomography (LDCT) scan:

- For high-risk individuals
  - Current or former smokers (quit within the past 15 years)
  - With a 30 pack-year history of smoking
  - Who are aged 55 to 74
- At facilities with multidisciplinary teams with expertise conducting LDCT scans and skilled in the evaluation, diagnosis, and treatment of abnormal lung lesions.

Under federal law, fully insured and self-funded insurance plans must cover, without cost-sharing, preventive services recommended by the United States Preventive Services Task Force (USPSTF) in most instances. The USPSTF does not currently recommend, and federal law does not require, the coverage of lung cancer screening. The USPSTF proposed in 2013, however, to update its recommendations to support lung cancer screening in a manner similar to the ALA and ACS recommendations, only extending the eligible age to seventy-nine years. If the USPSTF finalizes this proposed recommendation, then fully insured and self-funded plans will be required by federal law to provide coverage for the service without cost-sharing. In that case, a state mandate would only directly operate on fully insured policies to the extent that it required more extensive benefit coverage than that required by federal law. Potential interaction of federal law with state law will be noted in the analysis.

The CPHHP invited six insurers and managed care organizations (carriers) domiciled in Connecticut to complete a survey and provide policy documents (current service coverage, utilization review processes, methods for determining medical necessity, etc.) and claims data and other information related to lung cancer screening. The six carriers reported covering approximately 614,000 lives enrolled in fully insured group plans and 111,000 lives enrolled in individual health insurance policies in Connecticut in 2013. In addition, respondents provide administrative services only plans, stop gap insurance coverage and other services not regulated as fully insured policies to self-funded plans.

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[152] Codified at Connecticut General Statutes § 38a-21.

[153] Minor variations in the recommendations of these two groups and professional groups are discussed in the background.

The CID also contracted with the actuarial firm OptumInsight (Optum) to conduct an actuarial evaluation, individual cost burden analysis and five year projection of the cost of the mandate based on claims data and other sources.

Following the guidelines of the ALA and ACS, this proposed mandate would cover annual LDCT lung cancer screenings for some specified individuals at high risk for developing lung cancer in facilities with multidisciplinary teams with expertise conducting LDCT scans and skilled in the evaluation, diagnosis, and treatment of abnormal lung lesions.

Existing health insurance coverage

Three of the carriers responding to the carrier survey stated that they provided coverage for lung cancer screening in 2013 to an extent similar to what S.B. 862 would mandate. Two carriers stated that they did not provide such coverage in new policies in 2013, and one carrier did not respond to this question. Additionally, the state employee health benefits plan covers lung cancer screening, according to the state Comptroller's Office.

The respondent carriers report that the self-funded plans for which they provide services cover lung cancer screening at levels similar to that provided by the carriers' fully insured plans.

Estimated 2014 premium

Group policies: Optum estimates the paid medical cost for S.B. 862 in 2014 for group policies would be $0.226 per member per month (PMPM). The total premium impact when including medical cost, administrative costs, profit or surplus, and other costs is estimated to be $0.266 PMPM, which is 0.055 percent of the estimated premium for group policies.

Individual policies: Optum estimates the paid medical costs for S.B. 862 in 2014 for individual policies would be $0.202 PMPM. The total premium impact when including paid medical cost, administrative costs, profit or surplus and other costs is estimated to be $0.247 PMPM, which is 0.081 percent of the estimated premium for individual policies.

This review is intended to be read in conjunction with the General Introduction to this volume and Optum's Actuarial Report which is included as Appendix IV.

II. Background

The present review is of a proposed health insurance benefit mandate that would require insurance coverage of annual lung cancer screening for certain individuals. The review focuses on lung cancer screening using low-dose computed tomography (LDCT) scans, which is currently the only method of lung cancer screening recommended by professional groups. Recent studies suggest that lung cancer-related mortality is 20 percent lower among high-risk patients who receive such screening, compared with patients who do not.[154] Still, questions persist about the service, particularly with regard to interpretation of screening results and the dangers of increased exposure to medical radiation.

Lung Cancer

Cancer refers to a condition in which cells divide uncontrollably, disrupting the usual balance of cell division, growth and death, to the detriment of nearby healthy cells.[155] Lung cancer is cancerous cell growth on the tissues of the lung, usually in cells lining the air passages.[156] It is the second most common cancer for both men (behind prostate cancer[157]) and women (behind breast cancer[158]).[159] Nationally, the median age for initial diagnosis of lung cancer is 70 years; the median age for lung cancer-related death is 72 years.[160] Approximately half of these cases occur in people aged 55 to 74.[161] Nearly ninety percent of all patients diagnosed with lung cancer will die of the disease.[162] Overall, the five-year survival rate following a lung cancer diagnosis is less than seventeen percent. When the cancer is detected while still in an early stage, the five-year survival rate increases to 52 percent.[163] Currently, however, only fifteen percent of lung cancer is diagnosed while in an early stage.[164]

The age-adjusted incidence rate for lung cancer in Connecticut in 2010 was 66.1 per 100,000.[165] The incidence rate among 55 to 64 year-olds in the state was approximately 121 per 100,000 and for those aged 65 to 74 it was 300 per 100,000 in 2010. Between 2006 and 2010, inclusive, there were 6,595 newly

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[154] The National Lung Screening Trial Research Team (2011). Reduced lung-cancer mortality with low-dose computed tomographic screening. *The New England Journal of Medicine,* 365(5):395-409.

[155] National Cancer Institute, Defining Cancer (updated February, 2013), accessed November 14, 2013 from: http://www.cancer.gov/cancertopics/cancerlibrary/what-is-cancer.

[156] National Cancer Institute: A Snapshot of Lung Cancer (updated March 23, 2013) accessed November 14, 2013 from: http://www.cancer.gov/researchandfunding/snapshots/lung.

[157] Center for Public Health and Health Policy. Chapter 2: "Coverage for Prostate Cancer Screening," in Connecticut Mandated Health Insurance Benefits Reviews 2010, Volume I. University of Connecticut: 2011, p 24.

[158] Center for Public Health and Health Policy. Chapter 1: "Mammography and Breast Ultrasound" in Connecticut Mandated Health Insurance Benefits Reviews 2010, Volume II. University of Connecticut: 2011, p. 10.

[159] Cancer Facts and Figures 2013, American Cancer Society: 2013, p. 10, accessed November 14, 2013 from: http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-036845.pdf.

[160] "SEER Stat Fact Sheets: Cancer of the Lung and Bronchus," Surveillance, Epidemiology, and End Results (SEER) Program. National Cancer Institute, accessed November 14, 2013 from: http://seer.cancer.gov/statfacts/html/lungb.html.

[161] Ibid.

[162] Draft Recommendation Statement, United States Preventive Services Task Force (USPSTF): July 30, 2013, p.2, accessed November 14, 2013 from: http://www.uspreventiveservicestaskforce.org/uspstf/uspslung.htm.

[163] Draft Recommendation Statement, USPSTF, p. 5.

[164] Ibid.

[165] Howlader N, Noon A, Krapcho M, Garshell J, Neyman N, Altekruse S, Kosary C, Yu M, Ruhl J, Tatalovich Z, Cho H, Mariotto A, Lewis D, Chen H, Feuer E, Cronin K (Eds.). SEER Cancer Statistics Review, 1975-2010, National Cancer Institute (2013) (updated June 14, 2013), table 15.22, accessed October 15, 2013 from: http://seer.cancer.gov/csr/1975_2010/.

diagnosed cases of lung cancer among state residents aged 55 to 74.[166] While the difference in incidence between males and females is narrowing, along with a narrowing of the difference in smoking rates, men's rates are still somewhat higher. The overall age-adjusted death rate from lung cancer in 2010 in Connecticut for all ages was 44.2 per 100,000[167] and it is the leading cause of cancer-related death for both men and women in the state.[168] The primary exposure-based risk factors that have been associated with lung cancer include exposure to cigarette smoke, radon and other household and workplace toxins (such as asbestos), and radiation from radiation therapy administered to the chest.[169]

The major risk factor for lung cancer is cigarette smoking. As much as 85 percent of lung cancer cases may be associated with this activity.[170] While most of these cancers occur in smokers, three thousand deaths per year nationwide may be caused by exposure to second-hand smoke.[171] In 2008, there may have been as many as seven million individuals nation-wide between the ages of 55 and 74 who had smoked the equivalent of one pack of cigarettes per day, every day, for at least 30 years (referred to as a 30 pack-year history).[172] Connecticut's Department of Public Health estimates that, in 2010, approximately 16.7 percent of adults in the state smoked cigarettes and that 44 percent of them smoked a pack or more per day.[173] The percentage of 50-64 year-olds who report smoking daily is 11.6. Of these, 43.2 percent (or roughly 5 percent of the population this age) report smoking at least a pack of cigarettes every day.[174]

The second most common risk factor, and the first among non-smokers, is exposure to radon. The CDC estimates that, nationally, there are 20,000 radon-related lung cancer cases each year.[175] An estimated seven million housing units nationwide exceeded the U.S. Environmental Protection Agency's recommended radon level in 2008.[176,177] The ongoing Environment and Genetics in Lung Cancer Etiology (EAGLE) trial, sponsored in part by the National Institutes of Health, is currently investigating the risk of lung cancer from genetics and environmental exposures.[178]

The risk of lung cancer death from radiation exposure from low-dose lung cancer screening may be 1 in

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[166] Surveillance, Epidemiology, and End Results (SEER) Program, SEER*Stat Database: Incidence, 2006-2010, available from the Connecticut Tumor Registry at the Connecticut Department of Public Health. The Tumor Registry provides aggregate counts for five years, here 2006 to 2010. The estimate used in the text is the result of calculating the average yearly cancer incidence for the population in the target age range and dividing that by the relevant age group's population from the 2010 census.

[167] Howlader et al. (2013), table 15.23.

[168] Cancer in Connecticut 2005 with a Focus on Tobacco-Related Cancer. Connecticut Department of Public Health (2009), p. 11- 12.

[169] Center for Disease Control and Prevention. Basic Information about Lung Cancer, What are the Risk Factors? (updated November 21, 2013) accessed December 27, 2013 from: http://www.cdc.gov/cancer/lung/basic_info/risk_factors.htm.

[170] Draft Recommendation Statement, USPSTF, p. 2.

[171] Basic Information about Lung Cancer, CDC.

[172] Draft Recommendation Statement, USPSTF.

[173] Fact Sheet: 2010 Adult Cigarette Smoking in Connecticut. Connecticut Department of Public Health: (n.d.).

[174] Connecticut Adult Tobacco Survey, 2010, unpublished data, available from the Tobacco Use Prevention and Control Program, Connecticut Department of Public Health.

[175] Lung Cancer Risk Factors. Centers for Disease Control and Prevention (updated August 6, 2013), accessed November 14, 2013 from: http://www.cdc.gov/cancer/lung/basic_info/risk_factors.htm.

[176] Angell W (2008). The US radon problem, policy, programming and industry: Achievements, challenges and strategies. *Radiation Protection Dosimetry,* 130 (1), p. 8-13.

[177] The Environmental Protection Agency maintains a radon page at the following address: http://www.epa.gov/radon/. The Connecticut Department of Public Health also maintains a webpage on radon, which may be accessed here: http://www.ct.gov/dph/cwp/view.asp?a=3140&q=387592&dphNav_GID=1828&dphPNavCtr=%7C

[178] De Matteis S, Consonni D, Lubin J, Tucker M, Peters S, Vermeulen R, Kromhout H, Bertazzi P, Caporaso N, Pesatori A, Wacholder S, Landi M (2012). Impact of occupational carcinogens on lung cancer risk in a general population. *International Journal of Epidemiology*, 41: 711-721, p. 712.

2,500 persons screened.[179] More on the risks of medical imaging-based radiation exposure appears in the risk section below.

Screening Methods

There are primarily three potential lung cancer screening mechanisms discussed in the literature: chest x-ray; sputum cytology; and LDCT scanning, only the last of which is currently recommended by professional guidelines.[180]

A chest x-ray, or chest radiography, can produce a two-dimensional picture of the inside of the chest by sending ionized radiation through the target area by way of electromagnetic waves. X-rays are used to examine a number of areas, though chest applications are the most common.

Sputum cytology is the systematic analysis of cells found in sputum, a substance that is coughed up from the lungs. The bulk of these cells are mucus, but sputum may contain other types of cells that suggest pulmonary lesions or other abnormalities in the lungs.

Similar to traditional chest x-rays, LDCT scans can produce images of the interior of the chest using ionized radiation. Unlike traditional x-ray, LDCT scans produce images of slices of the lung or other target that can then be combined to form three dimensional pictures. LDCT scans are able to detect much smaller nodules on the lungs than can traditional x-rays, as small as 1 mm in diameter.[181]

Professional and Other Guidelines

S.B. 862 references recommendations from the American Lung Association (ALA) and the American Cancer Society (ACS). Both groups have recently released guidelines for lung cancer screening. These guidelines provide recommendations on who should be screened and where the screening should take place. The United States Preventive Services Task Force (USPSTF) has also recently produced a draft in which it proposes to recommend lung cancer screening by LDCT. Other professional organizations have also issued guidelines, which are largely similar, though a few recommend considering additional factors for determining who has a "high-risk" of getting lung cancer. These recent guidelines are primarily based upon the results of two large random controlled trials, the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) and the National Lung Screening Trial (NLST).

The ALA released its lung cancer screening guidelines in April, 2012.[182] It recommends LDCT lung cancer screening for current or former smokers (those who quit within the last 15 years), who are aged 55 to 74 years, and have a smoking history of at least 30 pack-years.[183] Further, the ALA recommends that such screening should occur in facilities that have experience conducting LDCT scans and that have multidisciplinary teams that can provide comprehensive follow-up. The ALA does not appear to have made

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[179] Bach P, Mirkin J, Oliver T, Azzoli C, Berry D, Brawley O, Byers T, Colditz G, Jett J, Sabichi A, Smith-Bindman R, Wood D, Qaseem A, Detterbeck F (2012). Benefits and harms of CT screening for lung cancer: A systematic review. *Journal of the American Medical Association,* 307 (22): 2418-2429, p. 2425.

[180] See, e.g., The PLCO Project Team (2011). Screening by chest radiograph and lung cancer mortality: the prostate, lung, colorectal, and ovarian randomized trial. *Journal of the American Medical Association*, 306 (17): 1865-1873, p. 1865.

[181] McWilliams A, Tammemagi M, Mayo J, Roberts H, Liu G, Soghrati K, Yasufuku K, Martel S, Laberge F, Gingras M, Atkar-Khattra S, Berg C, Evans J, Finley R, Yee J, English J, Nasute P, Goffin J, Puska S, Stewart L, Tsai S, Johnston M, Manos D, Nicholas G, Goss G, Seely J, Amjadi K, Tremblay A, Burrowes P, MacEchern P, Bhatia R, Tsao M, Lam S (2013). Probability of cancer in pulmonary nodules detected on first screening CT. *The New England Journal of Medicine,* 369 (10): 910-919, p. 911.

[182] American Lung Association (ALA) (April 23, 2013). Providing Guidance on Lung Cancer Screening to Patients and Physicians, accessed November 14, 2013 from: http://www.lung.org/lung-disease/lung-cancer/lung-cancer-screening-guidelines/.

[183] ALA, 21.

any recommendation regarding the frequency with which eligible patients should be screened.

The ACS released its current version of lung cancer screening guidelines in April, 2013.[184] In most respects, the ACS recommendations are the same as those of the ALA.[185] Its facility recommendations are somewhat more detailed, providing that "wherever possible" screening should be conducted at an institution that has experience with LDCT and has a multidisciplinary team skilled in the evaluation, diagnosis, and treatment of lung abnormalities. Absent that, the patient should be directed to a facility with experience conducting LDCT scans, diagnostic tests and lung cancer surgeries. If such settings are unavailable, the ACS does not recommend screening.[186] The ACS also recommends that eligible patients should be screened annually.[187]

Other organizations that have recently issued guidelines for lung cancer screening include the American Society for Clinical Oncology (ASCO),[188] the recommendations of which have been adopted by the American Thoracic Society; the American College of Chest Physicians (ACCP);[189] the National Comprehensive Cancer Network (NCCN) (which recommends two screening groups);[190] and the American Association for Thoracic Surgery (AATS) (which recommends three screening groups).[191] The USPSTF has proposed revising its current guidelines to recommend certain populations for lung cancer screening using LDCT.[192] The recommendations of all of these groups are largely similar to those by the ALA and ACS. Their provisions are included in the summary of high-risk population recommendations in Table 2.1, and facility recommendations in Table 2.2. The American College of Radiology (ACR) has indicated an intent to release technical guidelines for lung cancer screening using LDCT by spring of 2014.

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[184] Wender R, Fontham E, Barrera E, Colditz G, Church T, Ettinger D, Etzioni R, Flowers C, Gazelle G, Kelsey D, LaMonte S, Michaelson J, Oeffinger K, Shih Y, Sullivan D, Travis W, Walter L, Wolf A, Brawley O, Smith R (2013), American Cancer Society Lung Cancer Screening Guidelines. CA: *A Cancer Journal for Clinicians*, 63 (2): 106-117.

[185] Wender, et al. (2013), 114.

[186] Wender, et al. (2013), 114.

[187] Wender, et al. (2013), 114.

[188] Bach P, Mirkin J, Oliver T, Azzoli C, Berry D, Brawley O, Byers T, Colditz G, Gould M, Jett J, Sabichi A, Smith-Bindman R, Wood D, Qaseem A, Detterbeck F. (2012). The role of CT screening for lung cancer in clinical practice. The evidence based practice guideline of the American college of chest Physicians and the American society for clinical oncology, accessed December 4, 2013 from: http://www.asco.org/quality-guidelines/role-ct-screening-lung-cancer-clinical-practice-evidence-based-practice-guideline.

[189] Detterbeck F, Mazzone P, Naidich D, Bach P (2013). Screening for lung cancer. *Chest*, 154 (5): e78S-e92S (supplement, diagnosis and management of lung cancer, 3rd ed.: ACCP Guidelines).

[190] Wood, D, Eapen G, Ettinger D, Hou L, Jackman D, Kazerooni E, Klippenstein D, Lackner R, Leard L, Leung A, Massion P, Meyers B, Munden R, Patterson G, Peairs K, Pipavath S, Pratt-Pozo C, Reddy C, Reid M, Roter A, Schabath M, Sequist L, Tong B, Travis W, Unger M, Yang S (2012). Lung Cancer Screening: Clinical Practice Guidelines in Oncology. *Journal of the National Comprehensive Cancer Network* (NCCN),10: 240-265, p. 250.

[191] Jaklitsch M, Jacobson F, Austin J, Field J, Jett J, Keshavjee S, MacMahon H, Mulshine J, Munden R, Salgia R, Strauss G, Swanson S, Travis W, Sugarbaker D (2012). The American Association for Thoracic Surgery guidelines for lung cancer screening using low-dose computed tomography scans for lung cancer survivors and other high-risk groups. *The Journal of Thoracic and Cardiovascular Surgery*, 144 (1): 33-39, p. 35-36.

[192] The ALA notes in its own guidelines that its recommendations are to provide guidance until the USPSTF issues recommendations. ALA, 5. See also, "American Lung Association Applauds New Lung Cancer Screening Recommendations" (July 29, 2013), accessed November 14, 2013 from: http://www.lung.org/press-room/press-releases/new-cancer-screening-recommendations.html.

Table 2.1: Recommendations for who should be screened.

Source	Date	Min. Age	Max. Age	Pack-Year history	Smoking Status	Screen Frequency
ALA	April, 2012	55	74	30	Current and quit within 15 years	None specified
ACS	March, 2013	55	74	30	Current and quit within 15 years	Annual
USPSTF	Draft for public comment July 30, 2013	55	79	30	Current and quit within 15 years	Annual
ASCO	July, 2012	55	74	30	Current or quit within 15 years	Annual
ACCP	May, 2013	55	74	30	Current or quit within 15 years	Annual
ATS	July, 2012	55	74	30	Current or quit within 15 years	Annual
NCCN (I)	February, 2012	55	74	30	Current or quit within 15 years	Annual
NCCN (II)	February, 2012	50	None	20 (and one additional risk factor)	Any	Annual
AATS (I)	July, 2012	55	79	30	Any	Annual
AATS (II)	July, 2012	None	None	None, based on lung cancer history	Any	Annual
AATS (III)	July, 2012	50	79	20, and other factors	Any	Annual

Table 2.2: Recommendations for screening facilities.

ALA	"[S]creening [should] be linked to access to 'best practices' multidisciplinary teams that can provide the needed follow-up for evaluation of nodules."
ACS	"[P]referably should enter an organized screening program at an institution with expertise in LDCT screening, with access to a multidisciplinary team skilled in the evaluation, diagnosis, and treatment of abnormal lung lesions." Absent that "they should be referred to a center that performs a reasonably high volume of lung CT scans, diagnostic tests, and lung cancer surgeries."
USPSTF	None, but notes: "Clinical settings that have high rates of diagnostic accuracy using LDCT, appropriate followup protocols for positive results, and clear criteria for performing invasive procedures are more likely to duplicate the results found in trials."
ACSO	"Screening should be conducted in a center similar to those where the NLST was conducted, with multidisciplinary coordinated care and a comprehensive process for screening, image interpretation, management of findings, and evaluation and treatment of potential cancers."
ACCP	"[S]ettings that can deliver the comprehensive care provided to NLST participants."
ATS	Same as ASCO.
NCCN	"Lung cancer screening with CT should be part of a program of care and should not be performed in isolation as a free-standing test… It is recommended that institutions performing lung cancer screening use a multidisciplinary approach that may include specialties such as radiology, pulmonary medicine, internal medicine, thoracic oncology, and thoracic surgery."
AATS	"[T]hose considering screening should do so in environments where multidisciplinary teams are available for the management of indeterminate and positive screening scans. Furthermore, the provisions of care by an interdisciplinary team of thoracic surgeons working with radiologists, pulmonologists, and oncologists is required to ensure decreased mortality from lung cancer…"

Most of the recent guidelines adopt the criteria used in the NLST for determining who is at high-risk. The ALA notes, however, that "it would be useful to have tools that identify those smokers at highest risk,"[193] suggesting that its adoption of the NLST eligibility criteria is provisional. Scholars have recently proposed various other factors that might be considered, including the patient's age, racial group, education, body mass index, history of chronic obstructive pulmonary disease, personal history of cancer, and family history of lung cancer.[194] The ALA also notes that "the NLST …did not include other subgroups at high risk for lung cancer"[195] and CPHHP has discovered no other group that has investigated whether lung cancer screening might be effective among non-smoking populations.

[193] ALA, 17.

[194] Tammemagi M, Katki H, Hocking W, Church T, Caporaso N, Kvale P, Chaturvedi A, Silvestri G, Riley T, Commins J, Berg C (2013). Selection Criteria for lung-cancer screening. *New England Journal of Medicine*, 368 (8): 728-736, Table 2.

[195] ALA,12.

Risks of Screening

The most commonly identified risks stemming from the use of LDCT lung cancer screening are unnecessary follow-up procedures arising from false-positive results; overdiagnosis of lung cancer; and patient exposure to radiation. A recent review of screening trials led Heleno et al. (2013) to conclude that harms arising from cancer screenings are often "poorly reported."[196]

False positives. False-positive screening results, that is, the rate of nodules identified as suspicious for cancer that do not ultimately cause cancer, may lead to unnecessary follow-up procedures. The LDCT scan reveals nodules and other abnormalities in the lungs; it does not determine which of these the treating clinician should consider suspicious and worthy of follow-up. The rate of "false positives" is thus closely linked to the clinical definition of a "positive" result. There is no consensus yet on what this definition might be. The ACCP provides some guidance in its recently released guidelines for the diagnosis of lung cancer, but notes that this is an area that has been "incompletely studied"[197] and that the recommendations are "based on evidence that is relatively low in quality."[198] Further, initial, or baseline, scans typically yield more "positive" results because some detected nodules can be ruled non-cancerous in subsequent scans based on observed growth rate. The NLST researchers defined a detected non-calcified nodule of more than 4 mm as a "positive" finding, but refrained from making any suggestions regarding follow-up procedures. They reported a positive rate of 27.3 percent and a false-positive rate of 96.2 percent for baseline scans.[199] Other researchers, employing different criteria, report substantially different positive and false-positive rates.[200,201,202]

Overdiagnosis. Overdiagnosis of cancer is a potential problem of lung cancer screening. Overdiagnosis occurs when cancer is detected and treated even though that cancer would not have produced important symptoms during the life of the patient. While the existence of overdiagnosis from lung cancer screening has not been determined, researchers from the NLST reported that 119 more cancers were detected in the experimental group than in the control group,[203] suggesting its possibility. Further, overdiagnosis of other ailments may also follow if LDCT scans incidentally detect abnormalities suggesting conditions other than lung cancer.[204]

Exposure to radiation. Patients who receive LDCT screening will be subject to ionized radiation, itself a cause of lung cancer. Medical radiation exposure is often measured in a unit called Sieverts, and expressed in units of one thousandth of a Sievert, called millisieverts (mSv). The National Cancer Institute estimates

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[196] Heleno B, Thomsen M, Rodrigues D, Jorgensen K, Brodersen J (2013). Quantification of harms in cancer screening trials: Literature review. *British Medical Journal* 2013; 347:f5334, p. 5.

[197] Gould M, Donington J, Lynch W, Mazzone P, Midthun D, Naidich D, Wiener R (2013). Evaluation of individuals with pulmonary nodules: When is it lung cancer? *Chest*, 143 (5) supp.: e93S-e120S, e109S.

[198] Ibid, e97S.

[199] USPSTF, 7.

[200] Henschke C, McCauley D, Yankelevitz D, Naidich D, McGuinness G, Miettinen O, Libby D, Pasmantier M, Koizumi J, Altorki N, Smith J (1999). Early Lung Cancer Action Project: Overall design and findings from baseline screening. *Lancet*, 354: 99-105.

[201] Henschke C, Yip R, Yankelevitz D, Smith J (2013). Definition of a positive test result in computed tomography screening for lung cancer. *Annals of Internal Medicine*, 158 (4): 246-252, p. 247.

[202] Horeweg N, van der Aalst C, Vliegenthart R, Zhao Y, Xie X, Scholten E, Mali W, Thunnissen E, Weenink C, Groen H, Lammers J, Nackaerts K, Rosmalen J, Oudkerk M, Koning H (2013). Volumetric computer tomography screening for lung cancer: Three rounds of the NELSON trial. *European Respiratory Journal Express* (available online, not in print as of November 14, 2013).

[203] The National Lung Screening Trial Research Team (2011). Reduced lung-cancer mortality with low-dose computed tomographic screening. *The New England Journal of Medicine,* 365 (5): 395-409.

[204] Ding A, Eisenberg J, Pandharipande (2011). The economic burden of incidentally detected findings. *Radiological Clinics of North America*, 49:257-265.

that, on average, patients can expect to be exposed to 1.5 mSv of radiation per LDCT scan.[205] Newer scanners administer lower doses of radiation. A recent review of one suggested that it delivered, on average, 0.93 mSv per scan.[206]

The risk of increased cancer caused by annual LDCT scans has not been fully assessed.[207] One researcher suggests that annual administration of LDCT chest scans to the identified population might cause 1 cancer for every 2500 individuals screened,[208] though this estimate rests primarily on the exposure resulting from the three scans in the NLST. It is unclear whether annual scans for up to 20 years increases this risk.[209] The ALA notes that radiation-caused cancer may not manifest for 20 years following initial exposure.[210] CT scans are today the largest source of radiation exposure from medical devices. Overall, exposure has been increasing. In 2006 the annual dose of radiation from medical procedures to the population of the United States was 7.1 times that which it had been in 1980.[211]

Preventive Screening Services and the Affordable Care Act

While this review focuses on state law, some of the provisions of the Affordable Care Act (ACA) will be applied to areas traditionally under the regulation of the states, and thus may affect the operation of state law to some extent. One such provision is the preventive services mandate, § 42 USC 300gg-13.[212] The ACA, among other things, amended § 2713 of the Public Health Services Act to require that health insurance plans include coverage of specified preventive services, without cost-sharing in most instances. The preventive services mandate applies both to fully insured policies and to ERISA-regulated self-funded plans.[213] Such insurance must provide preventive services that are recommended by: the USPSTF (A and B grade recommendations); the Advisory Committee on Immunization Practices at the Centers for Disease Control and Prevention (CDC); the Health Resources and Services Administration (HRSA)'s comprehensive guidelines for the health of infants, children and adolescents; and the HRSA's guidelines for women's preventive care.[214] The Centers for Medicare & Medicaid Services maintains a web page listing the current

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[205] National Cancer Institute. Computed tomography (CT) scans and cancer fact sheet (updated July, 2013), accessed November 14, 2013 from: http://www.cancer.gov/cancertopics/factsheet/detection/CT.

[206] Young S. CT scanner delivers less radiation: Faster, more sensitive scans and better image processing may reduce the risk of x-ray-related cancers. *MIT Technology Review*, February 7, 2013.

[207] Draft Recommendation Statement, USPSTF.

[208] Bach, et al. (2012), 2425.

[209] Gill R, Jaklitsch M, Jacobson F (2013). Controversies in lung cancer screening. *Journal of the American College of Radiology,* 10(12): 391-396.

[210] ALA, 20.

[211] Hendee W, Becker G, Borgstede J, Bosma J, Casarella W, Erickson B, Maynard C, Thrall J, Wallner P (2010). Addressing overutilization in medical imaging. *Radiology*, 257 (1):240-245, p. 241. In order to better understand and help reduce the danger posed by medical exposure to radiation, the Federal Food and Drug Administration created a Center for Devices and Radiological Health in 2010. About the Center for Devices and Radiological Health, U.S. Food and Drug Administration (updated August 15, 2013) accessed November 14, 2013 from: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/default.htm.

[212] 42 USC 300gg-13 provides, in relevant part: "A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost-sharing requirements for [recommended preventive services]…"

[213] "Coverage of Preventive Health Services," 45 CFR § 147.130. See also, "Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 41726 (July 19, 2010).

[214] 45 CFR 147.130. The Department of Health and Human Services has created a limited "religious exception" for the provision of certain recommended preventive services, most notably contraceptives. The United States Supreme Court has recently decided to review a legal challenge to that provision. The case is Sebelius v. Hobby Lobby Stores, Inc., which has been consolidated with Conestoga Wood Specialties v. Sebelius, et al. See Order List: Certiorari Granted, November 26, 2013, 571 U.S. ___, accessed December 2, 2013 from: http://www.supremecourt.gov/orders/courtorders/112613zr_ed9g.pdf.

recommended preventive services covered by the federal mandate.[215] The preventive services mandate provision preempts state laws only to the extent that such laws would act to prevent the application of it. States may require more extensive benefits than mandated by federal law.[216]

The USPSTF's current lung cancer screening guideline, issued in 2004, recommends against screening and so this service is not currently a recommended preventive service for purposes of federal law. After reviewing the results of the NLST, the PLCO, and other recently produced evidence, however, the task force proposed a new guideline recommending for screening using LDCT. The proposed language was released for public comment on July 30, 2013 and closed on August 26, 2013. At the time of this review, the USPSTF is considering the public comments. If the USPSTF ultimately adopts its draft proposal, presumably lung cancer screening by LDCT will be included as a mandatorily covered preventive service without cost-sharing under the provisions of the federal preventive services mandate. The proposed state mandate, S.B. 862, would only operate to the extent that it required more extensive benefits than federal law.

III. Methods

The methods used to prepare this review of S.B. 862 included a literature review, web-based research, telephone inquiries, key informant interviews, surveys of insurers and managed care organizations (carriers), the Office of the State Comptroller, and local health departments; and findings from actuarial and economic analyses conducted by Optum.

CPHHP conducted a search for published articles and other information related to the medical, social, economic and financial aspects of the proposed benefit mandate. In addition, at the request of CPHHP, medical librarians at the Lyman Maynard Stowe Library at the UConn Health Center (UCHC) conducted searches using: PubMed, UptoDate, textbooks, and web-based searches. Keywords used included: lung cancer; lung neoplasms; lung / radiography; and tomography, x-ray computed.

CPHHP also used telephone and e-mail inquiries to appropriate state, federal, municipal, and non-profit entities and reviewed internet sources such as the Centers for Medicare and Medicaid Services (CMS) website, other states' websites, the Connecticut Department of Public Health, and non-profit and community-based organization websites. Additional sources of information included governmental reports (e.g., CDC, NIH, AHRQ) and government maintained data (e.g., Connecticut Tumor Registry and Connecticut Adult Tobacco Survey results, Department of Public Health; Medical Expenditures Panel Survey, AHRQ) and professional guidelines appearing in the National Guidelines Clearinghouse and elsewhere.

CPHHP fielded a survey to six carriers domiciled in Connecticut. The six carriers surveyed account for 90 percent of covered lives in the Connecticut-domiciled fully insured group market and 94 percent of covered lives in the Connecticut-domiciled individual market. CPHHP requested policy documents (e.g., service coverage, utilization review processes, parameters for defining medical necessity, etc.) and data for the proportion of members with policy exclusions, the extent of member coverage, treatments approved, as covered by the mandate. All carriers responded; however, the completeness and quality of responses varied. The CID contracted with Optum to provide actuarial and economic analyses of the mandated benefit.

[215] "What are my preventive care benefits?" Centers for Medicare & Medicaid Services, accessed December 2, 2013 from: https://www.healthcare.gov/what-are-my-preventive-care-benefits/.

[216] HHS discusses the interaction between federal and state preventive services mandates in the preamble to "Interim final rules for group health plans and health insurance issuers relating to coverage of preventive services under the patient protection and affordable care act, 75 *Federal Register*, 41,726, p. 41739.

Optum's estimates of utilization and cost primarily relied on its in-house national and Connecticut-specific claims data from 2010-2011. Optum's full report is available in Appendix IV.

IV. Social Impact

1. The extent to which lung cancer screening is utilized by a significant portion of the population.

There have been no systematic attempts to determine the number of Connecticut residents who have been screened for lung cancer. Until recently no major professional organization recommended lung cancer screening and there were no broadly accepted guidelines for such a service. Despite this, however, there is evidence, both national and state-based, that some patients may already have been screened. According to one estimate, as many as 4.1 million Americans were screened for lung cancer in 2010, with approximately 1 million of them receiving an LDCT scan.[217] Further, a national survey of physicians revealed that nearly one quarter of them had ordered an LDCT scan to screen for lung cancer in 2005-2006.[218] Optum reports that 14 individuals from Connecticut in its internal database received lung cancer screening by LDCT in 2010. This number does not include individuals whose claims may have been rejected or who otherwise paid for the screening out-of-pocket. Finally, a lung cancer survivor's advocacy group, the Lung Cancer Alliance, lists five lung cancer screening centers in the state. While it is unclear whether these centers all (or are the only centers that) satisfy the ACS recommendations, their existence suggest that at least some Connecticut residents have been screened for lung cancer.[219]

2. The extent to which lung cancer screening is currently available to the population, including, but not limited to, coverage under Medicare, or through public programs administered by charities, public schools, the Department of Public Health, municipal health departments or health districts or the Department of Social Services.

The national advocacy group Lung Cancer Alliance lists five hospitals across the state that it deems to be lung cancer screening centers.[220] Of these, three are located in Fairfield County, one in New Haven County and one in Middlesex County. Additionally, the University of Connecticut Health Center announced the opening of a lung cancer screening program in late October, 2013[221] at its Farmington campus in Hartford County.[222]

Medicare: Medicare does not currently provide coverage for lung cancer screening.[223, 224] The USPSTF

[217] Doria-Rose V, White M, Klabunde C, Nadel M, Richards T, McNeel T, Rodriguez J, Marcus P (2012). Use of lung cancer screening test in the United States: Results from the 2010 national health interview survey. Cancer Epidemiology, Biomarkers, and Prevention, 21 (7), 1049-1059, p. 1056. The authors note, however, that this number may include patients who were already experiencing lung cancer symptoms at the time of the procedure, as the survey asked whether they had had an x-ray or CT scan to "check" for lung cancer.

[218] Klabunde C, Marcus P, Han P, Richards T, Vernon S, Yuan G, Silvestri G (2012). Lung cancer screening practices of primary care physicians: Results from a national survey. *Annals of Family Medicine,* 10 (2): 102-110.

[219] Lung Cancer Alliance, Lung Cancer Screening Centers in Connecticut, accessed November 14, 2013 from: http://www.lungcanceralliance.org/get-information/am-i-at-risk/where-should-i-be-screened/lung-cancer-screening-centers/connecticut.html.

[220] Ibid.

[221] Kaminski C (October 28, 2013). Health Center Introduces Lung Cancer Screening Program, UConn Today: Health Center News. Accessed October 29, 2013 from: http://today.uconn.edu/blog/2013/10/health-center-introduces-lung-cancer-screening-program/.

[222] UCHC Lung Cancer Screening Program, accessed October 29, 2013 from: http://www.uchc.edu/patients/services/lung_cancer/index.html.

[223] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, What Medicare Covers, Preventative and Screening Services, accessed October 15, 2013 from: http://medicare.gov/coverage/preventive-and-screening-services.html.

[224] Personal Communication. Gwen Jenkins. Customer Service for Medicare. Centers for Medicare and Medicaid Services. September 26, 2013.

has recently issued a draft proposal to recommend lung cancer screening using LDCT. If the draft recommendation becomes final, then the Centers for Medicare and Medicaid Services (CMS) may amend Medicare insurance coverage to include this service.[225] In November, 2013, the ACR announced that it had entered into talks with CMS's Coverage and Analysis Group to develop a Medicare coverage policy for lung cancer screening by LDCT.[226]

Public Programs Administered by Charities: No charities were discovered that provide funding for lung cancer screening in Connecticut. Many hospitals in the state, however, provide financial assistance generally to low income, under- and uninsured patients. Recently, some Connecticut hospitals have been providing lung cancer screening at reduced or no cost. For example, Middlesex Hospital's Lung Cancer Screening Program advertises a cost of $125.[227] It also offered free screening to veterans on certain days in November, 2013. The University of Connecticut Health Center lists a price of $100 for the service. In October, 2013, Norwalk Hospital's Radiology and Mammography Center began offering a free screening to anyone who met the NCCN guidelines.[228] Stamford Hospital's Lung Cancer Screening Program also advertised free screening in the months of November and December, 2013.

Public Programs Administered by Public Schools: An investigation of the Connecticut Department of Education, municipal and regional boards of education, web pages and other web-based inquiries found no evidence suggesting that public schools provide funding for, or the provision of, lung cancer screening.

Municipal Health Departments or Health Districts: None of the seven municipal health departments and sixteen local health districts responding to a phone and web-based inquiry reported providing funding or directly providing lung cancer screening.

The Department of Public Health (DPH): DPH neither funds nor provides lung cancer screening.

The Department of Social Services (DSS): CPHHP contacted DSS to determine whether insurance coverage of lung cancer screening using an LDCT scan was available through Medicaid. Personnel from DSS stated that "if the [CPT] code is on our fee schedule we would cover it when ordered by a doctor" and that there would be "no eligibility restrictions."[229] The code for Computerized Tomography Thorax-Without Contrast Material (CPT code 71250) is included in the Medicaid Provider Fee Schedule;[230] therefore, DSS appears to cover lung cancer screening using an LDCT scan through the Medicaid program.

3. The extent to which insurance coverage is already available for lung cancer screening.

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[225] Centers for Medicare and Medicaid Services, Medicare Quick Reference Information: Preventive Services, accessed October 29, 2013 from: http://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/Downloads/MPS_QuickReferenceChart_1.pdf. Section 4105 of PL 111-148, the Patient Protection and Affordable Care Act, states in relevant part: "[T]he Secretary may…modify…the coverage of any preventive service…to the extent that such modification is consistent with the recommendations of the United States Preventive Services Task Force…"

[226] American College of Radiation (November 1, 2013). ACR seeks comprehensive CT lung cancer screening Policy for Medicare. ACR Advocacy in Action eNews, accessed November 5, 2013 from: http://www.acr.org/Advocacy/eNews/20131101-Issue/ACR-Seeks-Comprehensive-CT-Lung-Cancer-Screening-Policy-for-Medicare.

[227] Middlesex Hospital, Cancer Center, Lung Cancer Screening Program. Available at: http://middlesexhospital.org/our-services/hospital-services/cancer-center/cancer-programs-and-services/total-lung-care-center/lung-cancer-screening-program (accessed September 18, 2013).

[228] Sesny R (October 4, 2013). Norwalk Hospital Offers Free Lung Cancer Screenings. Norwalk Daily Voice, accessed October 29, 2013 from: http://norwalk.dailyvoice.com/lifestyle/norwalk-hospital-offers-free-lung-cancer-screenings.

[229] Personal Communication. Barbara Fletcher, DSS Medical Policy & Regulations Unit. September 27, 2013.

[230] DSS Provider Fee Schedule: Physician Radiology, 2013. The provider fee schedule is available through DSS's Connecticut Medical Assistance Program webpage, accessed October 31, 2013 from: https://www.ctdssmap.com/CTPortal/Home/tabId/36/Default.aspx.

Five carriers provided information about coverage for lung cancer screening under their current policies. Three of them stated that they provide coverage consistent with the proposed mandate, with one exceeding the mandate and covering members up to age 79, consistent with USPSTF's proposed recommendations. One carrier does not provide coverage for lung cancer screening, and one carrier provides coverage in some policies issued before March 12, 2009, but not in policies issued subsequently. Optum reports that fourteen individuals in its database received coverage for lung cancer screening in 2010 and seven in 2011. This was out of a population of 17,594 covered Connecticut lives between the ages of 55 and 64 in its internal database.

The above policies and data only include individuals in fully insured policies. Optum estimates that slightly more than one third of Connecticut's population is insured under this type of plan. It reports that another 42 percent of the population is insured as part of an employer-provided self-funded plan.

4. If the coverage is not generally available, the extent to which such lack of coverage results in persons being unable to obtain necessary health care treatment.

While there was some testimony at the public hearing about individuals having trouble receiving an LDCT scan to screen for lung cancer, these instances appear to arise from unavailability of service rather than cost. One member of the public, for example, testified that she had been screened for lung cancer with chest x-ray, but that the x-ray did not detect her cancer.[231] Another speaker recounted difficulties due to her physician's unfamiliarity with this type of screening.[232]

As a general matter, however, there is evidence that utilization of preventive services increases when the service recipient does not have to pay up-front costs out-of-pocket.[233] As such, even when services are not "unobtainable" due to price, they may remain "unobtained" by much of the target population.

5. If the coverage is not generally available, the extent to which such a lack of coverage results in unreasonable financial hardships on those persons needing treatment.

According to estimates derived from the American Community Survey, administered by the U.S. Census Bureau, the median family income in Connecticut in 2012 was $85,254. Twelve percent of state families had incomes of less than $25,000; another twelve percent had incomes more than $200,000.

Table 2.3: Family Income in Connecticut in 2012

Income	Percent of Connecticut Families
Less than $25,000	11.6%
$25,000 to $50,000	15.7%
$50,000 to $100,000	30.9%
$100,000 to $200,000	30.3%
More than $200,000	11.5%

Based on data from the American Community Survey 2012 one-year estimate.

[231] Public Hearing on S.B. 862. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by Daria G. Thompson. February 19, 2013, accessed October 29, 2013 from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013SB-00862-R000219-Daria%20G.%20Thompson-TMY.PDF.

[232] Public Hearing on S.B. 862. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by Joan Liska. February 19, 2013, accessed October 29, 2013 from: http://www.cga.ct.gov/2013/INSdata/chr/2013INS00219-R001300-CHR.htm.

[233] Jonnalagadda S, Bergamo C, Lin J, Lurslurchachai L, Diefenbach M, Smith C, Nelson J, Wisnivesky J (2012). Beliefs and attitudes about lung cancer screening among smokers. *Lung Cancer*, 77: 526-531.

According to Optum's internal data, the average allowed cost for a lung cancer screening in Connecticut was $205 in 2010 with a maximum cost of $501. The allowed cost includes all payments to the service provider, whether made by the carrier or the policyholder. A commercial, online medical services price comparison guide estimates that the "*fair price*" for a CT scan without contrast in the Hartford area is $381.[234] Hospitals identified by CPHHP in the state that charge for LDCT lung cancer screening currently advertise prices ranging from $100[235] to approximately $450.[236] The estimated "fair price" of $381 is 0.8 percent of a gross family income of $50,000 per year. Nearly three quarters of Connecticut families in 2012 had an income of $50,000 or more. For the average Connecticut family income of $85,000, the cost represents 0.4 percent. Spreading the cost over the course of one year yields a weekly cost of approximately $7.33 per week. By comparison, the estimated average cost of a pack of cigarettes is about $8.00 in Connecticut.[237]

6. The level of public demand and the level of demand from providers for lung cancer screening.

Providers and prospective patients testified at the public hearing in support of S.B. 862. Several members of the public spoke in support of screening generally, and the importance of early detection of lung cancer. One patient[238] and one provider[239] described their dissatisfaction with the ineffectiveness of chest x-rays as a form of screening, and favorably compared the results of LDCT scans. The Radiological Society of Connecticut, a professional association of radiologists practicing in the state, submitted testimony in favor of the bill.[240] An informal review of fifteen newspapers from across the state revealed a dozen articles on lung cancer screening printed over the past few years, another indication of interest in the procedure.

At the national level, the rapidity with which relevant national professional organizations have updated, or have begun the process of updating, their recommendations regarding lung cancer screening suggests that medical professionals have taken an interest in providing the service.

7. The level of public demand and the level of demand from providers for insurance coverage for lung cancer screening.

The Permanent Commission on the Status of Women (PCSW), three providers, and three recipients of lung cancer screenings provided testimony in favor of an insurance mandate for the service.[241] The Radiological Society of Connecticut suggested that "the language should specify that coverage would be as a preventative

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[234] Healthcare Blue Book, Medical Services, Chest CT (no contrast), accessed November 14, 2013 from: https://www.healthcarebluebook.com/page_Results.aspx?id=138&dataset=MD&g=Chest+CT+-+(no+contrast).

[235] UCHC Lung Cancer Screening Program, accessed October 29, 2013 from: http://www.uchc.edu/patients/services/lung_cancer/index.html.

[236] Smilow Cancer Hospital, Yale Cancer Center, Lung Screening and Nodule Program, accessed September 18, 2013 from: http://yalecancercenter.org/top/specialties/screening/index.aspx. Personal Communication. Danielle B, Lung Screening and Nodule Program. Yale Cancer Center. October 15, 2013.

[237] Connecticut Department of Public Health, Tobacco. Costs & Consequences (updated November, 2011), accessed November 14, 2013 from: http://www.ct.gov/dph/cwp/view.asp?a=3137&q=388056.

[238] Public Hearing on S.B. 862. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Session, testimony submitted by Kirk Davis. February 19, 2013; accessed November 14, 2013 from: http://www.cga.ct.gov/2013/INSdata/chr/2013INS00219-R001300-CHR.htm.

[239] Public Hearing on S.B. 862. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Session, testimony submitted by Raymond Schoonmaker, MD. February 19, 2013, accessed November 14, 2013 from: http://www.cga.ct.gov/2013/INSdata/chr/2013INS00219-R001300-CHR.htm.

[240] Public Hearing on S.B. 862. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Session, testimony submitted by the Radiological Society of Connecticut. February 19, 2013, accessed October 15, 2013 from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013SB-00862-R000219-Radiological%20Society%20of%20CT-TMY.PDF.

[241] Public Hearing on S.B. 862. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Session, testimony submitted by Kirk Davis. Joan Liska, Daria G. Thompson, the Radiological Society of Connecticut, and Middlesex Hospital. February 19, 2013, accessed November 14, 2013 from: http://www.cga.ct.gov/2013/INSdata/chr/2013INS00219-R001300-CHR.htm.

service, and thus not subject to co-pay or co-insurance, as are the cases with other screening tests for cancer."[242] The Connecticut Conference of Municipalities submitted neutral testimony, requesting that the general assembly conduct fiscal analyses of all of the health benefit mandates proposed in 2013 session before deciding whether to adopt any of them.[243] The Connecticut Business and Industry Association and the Connecticut Association of Health Plans submitted testimony opposing all of the health benefit mandates proposed in 2013 and opposing health benefit mandates generally.[244, 245] There was no submitted testimony arguing against mandating insurance coverage specifically for lung cancer screening.

8. The likelihood of achieving the objectives of meeting a consumer need as evidenced by the experience of other states.

The National Association of Insurance Commissioners (NAIC) maintains a database of health benefit mandates and the states in which they were enacted. As of September 5, 2013, the NAIC database showed no states as having enacted a lung cancer screening health benefit mandate.

While no state has yet adopted a lung cancer screening health benefit mandate, and, therefore, the effect of such a mandate has not yet been systematically examined, a small preliminary study suggests that the provision of insurance coverage generally may increase the percentage of the high-risk population who opt to get screened for lung cancer. Survey respondents who met the ALA definition of "high-risk" were twice as likely to express a willingness to be screened if the test were covered by insurance compared to if they had to pay for the service out-of-pocket.[246] Further, studies on utilization rates for other cancer screening procedures suggest a positive correlation between insurance coverage mandates and preventive service utilization. Researchers at the ACS found a positive association between state colorectal screening health benefit mandates and utilization of that service. The effect was only modest, but the researchers noted that they were unable to disaggregate members of fully insured health care plans, which were subject to the mandate, and those in self-funded plans, which were not.[247]

9. The relevant findings of state agencies or other appropriate public organizations relating to the social impact of the mandated health benefit.

Twenty-nine states require a fiscal note or an additional review process in 2013 for any newly required health insurance benefit prior to enactment.[248] After reviewing the on-line archives of the states with these

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[242] Public Hearing on S.B. 862. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by the Radiological Society of Connecticut. February 19, 2013, accessed November 14, 2013 from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013SB-00862-R000219-Radiological%20Society%20of%20CT-TMY.PDF.

[243] Public Hearing on S.B. 862. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by the Connecticut Conference of Municipalities. February 19, 2013, available at: Public Hearing on S.B. 862. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by the Connecticut Association of Health Plans. February 19, 2013, accessed November 14, 2013 from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013SB-00862-R000219-The%20Connecticut%20Conference%20of%20Municipalities-TMY.PDF.

[244] Public Hearing on S.B. 862. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by the Connecticut Business and Industry Association. February 19, 2013, accessed November 14, 2013 from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013SB-00862-R000219-Jennifer%20Herz,%20CBIA-TMY.PDF.

[245] Public Hearing on S.B. 862. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by the Connecticut Association of Health Plans. February 19, 2013, accessed November 14, 2013 from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013SB-00862-R000219-Connecticut%20Association%20of%20Health%20Plans-TMY.PDF.

[246] Jonnalagadda et al. (2012).

[247] Cokkinides V, Bandi P, Shah M, Virgo K, Ward E (2011). The association between state mandates of colorectal cancer screening coverage and colorectal cancer screening utilization among US adults aged 50 to 64 years with health insurance. *BMC Health Services Research*, 11(19).

[248] California Health Benefits Review Program (Sept. 20, 2013). Other States' Health Benefit Review Programs, 2013 accessed October 30, 2013 from: http://chbrp.org/docs/Survey_and_Analysis_of_Other_States__Health_Benefit_Review_Programs_2013_FINAL_092013.pdf.

processes, CPHHP was unable to identify any analysis of a proposed or enacted lung cancer screening health benefit mandate.

No Connecticut executive branch agency submitted testimony supporting or opposing S.B. 862 and CPHHP is unaware of any state agency studies on the social effect of mandating insurance coverage for lung cancer screening. The PCSW, an agency of the General Assembly, submitted testimony in favor of S.B. 862. The PCSW does not appear to have conducted a full investigation of the results of lung cancer screening. Based on an earlier study conducted by DPH, PCSW estimated that 1,335 women are diagnosed with lung cancer annually in Connecticut in its 2013 annual report to the legislature.[249]

The USPSTF, as part of its reconsideration of its current lung cancer screening recommendations, has conducted a review of current lung cancer screening research. The USPSTF's review concludes that lung cancer screening is beneficial for certain individuals at high-risk for developing lung cancer who are between the ages of 55 and 79.[250]

10. The alternatives to meeting the identified need, including but not limited to, other treatments, methods or procedures.

Chest x-ray is perhaps the most commonly used alternative lung cancer screening method, and until recently may have been the most common method. No professional organization currently recommends lung cancer screening by chest x-ray, and CPHHP is unaware of any reliable estimate for the number of individuals who have been screened by this means in Connecticut. Sputum cytology is another cited alternative means of screening for lung cancer, but, when employed, it is typically used with, and not instead of, chest x-ray. Recently, investigations have begun in breath analysis, blood analysis, and non-ionized-radiation based imaging methods to detect lung cancer.[251]

11. Whether the benefit is a medical or broader social need and whether it is consistent with the role of health insurance and the concept of managed care.

The proposed benefit meets a medical need. Lung cancer is a well-established medical condition.[252] The main purpose of lung cancer screening is to detect lung cancer at an early stage when it is most treatable. According to the CID, the goal of managed care is to, among other things, deliver appropriate treatments in an appropriate setting and in a cost-effective manner.[253] By providing a better picture of a patient's lungs than a physician would otherwise have, lung cancer screening assists the physician to determine an appropriate treatment. The ALA and ACS guidelines recommend the appropriate settings for the service. Further, treatment of lung cancer in early stages may be more effective and less expensive than treatment in later stages,[254] and so cost-effective, consistent with the concept of managed care.

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[249] Permanent Commission on the Status of Women (June 2013). Legislative Report, accessed November 4, 2013 from: http://ctpcsw.files.wordpress.com/2010/07/2013-pcsw-legislative-report-final-for-web.pdf.

[250] Humphrey L, Deffebach M, Pappaas M, Baumann C, Artis K, Mitchell J, Zakher B, Rongwei F, Slatiore C (2013). Review: Screening for lung cancer with low-dose computed tomography: A systematic review to update the U.S. Preventive Services Task Force Recommendation. Annals of Internal Medicine. pre-publication draft accessed December 17, 2013 from: http://www.uspreventiveservicestaskforce.org/uspstf/uspslung.htm.

[251] Sanchez R, Tanner N, Siddiqi N, Silvestri G (2013). Lung Cancer Screening: Adjuncts and Alternative to Low-dose CT Scans. *Current Surgery Reports*, 1 (4): 249-256.

[252] Witschi H (2001). Profiles in toxicology: A short history of lung cancer. *Toxicological Sciences*, 64: 4-6.

[253] CID, What is Managed Care? (updated August, 2008), accessed December 11, 2013 from: http://www.ct.gov/cid/cwp/view.asp?a=1267&q=254490 (a)

[254] Cipriano L, Romanus D, Earle C, Neville B, Halpern E, Gazelle S, McMahon P (2011). Lung cancer treatment costs, including patient responsibility, by disease stage and treatment modality, 1992-2003. *Value in Health*, 14:41-52.

12. The potential social implications of the coverage with respect to the direct or specific creation of a comparable mandated benefit for similar diseases, illnesses, or conditions.

The proposed mandate governs screening, rather than the diagnosis or treatment of a condition. As such, it is similar to other screening mandates, most of which screen for cancer. These include screening for breast cancer,[255] prostate cancer,[256] and colorectal cancer.[257] Because, currently, the only lung cancer screening method recognized by the relevant professional literature involves the use of LDCT imaging, it may be that the proposed mandate would interact with the mandate regarding imaging services copayments, §§38a-511 (individual policies) and 38a-550 (group policies). The imaging services mandate requires insurance carriers that provide coverage for any LDCT or other enumerated imaging services to limit co-pays to $75 per session with a total annual co-pay limitation of $375 for all services.[258]

While LDCT imaging is increasingly accepted by professional guidelines as a tool for screening for lung cancer for some populations at high-risk for developing lung cancer, the procedure itself presents the patient with some risk, including increased risk of developing lung cancer from radiation exposure. Because of this, other methods continue to be investigated to screen for cancer, including sputum cytology, chest x-ray, blood analysis and non-ionized-radiation based imaging. If these, or other, screening procedures are found to be as effective at detecting cancer, they may be adopted in the future by the ALA and ACS and would, presumably, thereafter be covered by the proposed mandate. Further, as researchers continue to investigate the types of exposures that put a person at a comparably high risk for developing lung cancer as heavy smoking, the eligible "high-risk" population may expand to include these other groups. Additionally, as the technology for LDCT scanning develops, increasingly sharper images will likely be available using lower doses of radiation. Scanning may become relatively more effective for patients with lower risks of developing lung cancer. On the other hand, according to industry reports and other sources, per capita cigarette consumption has been steadily declining,[259] suggesting that the number of eligible patients in this group may decrease.

Treatment of lung cancer has a higher success rate the earlier the cancer is treated. This same dynamic is present in other cancers as well. As more methods for early detection of cancer are discovered, demand for those services is likely to follow. To the extent that the screening services require high up-front payments, demand for insurance coverage will also likely follow.

13. The impact of the benefit on the availability of other benefits currently offered.

Optum estimates that the addition of a lung cancer screening health benefit mandate might add $0.266 PMPM to an average group policy premium. This increase includes costs arising from the lung cancer screen itself, as well as likely foreseeable costs arising from additional follow-up. It does not, however, include any possible savings from treating lung cancer at earlier stages, and so may be an overestimate. The estimated PMPM increase is similar to the estimated PMPM cost arising from the prostate cancer screening

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[255] Center for Public Health and Health Policy. Chapter 1: "Mammography and Breast Ultrasound," in Connecticut Mandated Health Insurance Benefits Reviews 2010, Volume II. University of Connecticut: 2011.

[256] Center for Public Health and Health Policy. Chapter 2: "Coverage for Prostate Cancer Screening," in Connecticut Mandated Health Insurance Benefits Reviews 2010, Volume I. University of Connecticut: 2011.

[257] Center for Public Health and Health Policy. Chapter 10: "Colorectal Cancer Screening," in Connecticut Mandated Health Insurance Benefits Reviews 2010, Volume I. University of Connecticut: 2011.

[258] Center for Public Health and Health Policy. Chapter 9: "Co-payments regarding in-network imaging services," in Connecticut Mandated Health Insurance Benefits Reviews 2010, Volume IV. University of Connecticut: 2011.

[259] Orzechowski and Walker (2011). The Tax Burden on Tobacco: Historical Compilation, 2011, p.3, accessed November 4, 2013 from: http://www.taxadmin.org/fta/tobacco/papers/Tax_Burden_2011.pdf.

mandate,[260] and less than the estimated PMPM cost associated with breast cancer screening[261] or colorectal screening,[262] the latter of which both exceed $2.00 PMPM. Due to the low expected increase in PMPM, this benefit may not greatly affect the availability of other offered benefits. To the extent that it does, the magnitude of this should be less than that of existing cancer screening mandates.

14. The impact of the benefit as it relates to employers shifting to self-insured plans and the extent to which the benefit is currently being offered by employers with self-insured plans.

Some employers provide their employees with health coverage directly, rather than purchase fully insured policies from insurance carriers. Optum estimates that in Connecticut approximately 42 percent of the population is covered by a self-funded plan. State regulation of self-funded plans is preempted by the Federal Employee Retirement Income Security Act of 1974 (ERISA).[263] There are many possible reasons why employers might choose to self-fund, and research suggests that state health benefit mandates may not play a primary role.[264] To the extent that mandates are a consideration, this may arise from increased premiums associated with the administrative, medical, and other expenses of mandate compliance.

Carriers report that the self-funded plans for which they provide administrative and other services tend to cover lung cancer screening to the same extent as the fully insured plans. Optum estimates the increased premium PMPM for the proposed lung cancer screening mandate will be $0.266 PMPM. Because the self-funded plans appear to be following the carriers' lung cancer screening coverage policies and because the added cost to premiums from mandated coverage of the service is predicted to be low, enactment of the proposed mandate may not have an important effect on the decision to self-fund.

If the USPSTF recommends lung cancer screening, the coverage of the service will then be mandated by federal law for both fully insured policies and ERISA regulated self-funded plans. In that case, the state mandate would only have an effect on fully insured policies to the extent that it mandated more extensive benefits than federal law. This would likely substantially reduce any effect the proposed mandate might have on the decision to self-fund.

15. The impact of making the benefit applicable to the state employee health insurance or health benefits plan.

According to the state Comptroller, in 2012 there were 161,368 covered lives in the state employee health benefits plan under the age of 65. The State of Connecticut employee health benefits plan transitioned to a self-insured plans on July 1, 2010. Therefore, it does not currently purchase a fully insured policy that is subject to state health insurance benefit mandate laws. The state often, however, covers health insurance benefits similar to those described in the mandates. In the case of lung cancer screening by LDCT, the Comptroller's Office reports that the state already provides coverage for LDCT lung cancer screening for those identified as being at "high-risk" to develop lung cancer. Therefore, the adoption of this proposed mandate is not expected to affect the state employee benefits plan.

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[260] CPHHP (2010), "Coverage for prostate cancer screening."

[261] CPHHP (2010), "Mammography and Breast Ultrasound."

[262] CPHHP (2010), "Colorectal Cancer Screening."

[263] Office of Legislative Research (2005), Self-Insured Benefit Plans and Insurance Mandates. 2005-R-9753; *Metropolitan Life Ins.* vs. *Massachusetts,* 471 U.S. 724 (1985).

[264] Jensen G, Cotter K, Morrisey M (1995). State insurance regulation and employers' decisions to self-insure. *Journal of Risk and Insurance*, 62 (2): 185-213.

16. The extent to which credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community determines lung cancer screening to be safe and effective.

Investigations into the possibility of screening for lung cancer stretch back at least as far as the 1950s.[265] The recent guideline revisions have been primarily inspired by two large, randomized controlled trials, the Prostate, Lung, Colorectal and Ovarian (PLCO) cancer screening trial and the National Lung Screening Trial (NLST). The PLCO enrolled 154,934 smokers and non-smokers between 1993 and 2001. Approximately half of the study group was randomly assigned to receive regular lung cancer screenings, and the other half to be given usual care. The experimental group received three annual chest x-rays.[266] The NLST enrolled 53,454 study participants between 2002 and 2004. One group received three annual LDCT scans and the other received three annual chest x-rays.

The NLST produced evidence that administering LDCT screening reduces lung cancer mortality by at least 20 percent compared with chest x-ray screening among the high-risk population included in the study.[267] In light of this finding, a subgroup of the PLCO who met the NLST participant criteria was studied to determine whether mortality decreased for those who received annual chest x-rays compared to those who received no screening. No difference in the mortality rate was found.[268]

A full account of recent and ongoing lung cancer screening trials is available in a systematic review conducted by the Cochrane Collaboration in 2013.[269] A large ongoing trial being conducted in the Netherlands and Belgium, referred to as NELSON, involves 15,822 participants, half of whom will receive three annual LDCT lung cancer screens. The study group will be followed for 10 years.[270]

CPHHP has not discovered a study systematically examining the increased risk of developing cancer from annual LDCT scans administered over the course of a 20 year period. Medical researchers have also noted the paucity of such studies.[271]

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[265] Boucot K, Horie U, Sokoloff M (1959). Lung cancer detected by survey methods. American Journal of Public Health, 49 (6): 793-799.

[266] Hocking, et al. (2010). Lung cancer screening in the Randomized prostate, lung, colorectal, and ovarian (PLCO) cancer screening trial; Oken et al. (2011). Screening by chest radiograph and lung cancer mortality, the prostate, lung, colorectal, and ovarian (PLCO) randomized trial.

[267] The National Lung Screening Trial Research Team (2011). Reduced lung-cancer mortality with low-dose computed tomographic screening. *New England Journal of Medicine,* 365 (5): 395-409, p. 398.

[268] Oken, et al. (2011), 1872.

[269] Manser R, Lethaby A, Irving B, Stone C, Byrnes G, Abramson M, Campbell D (2013). Screening for lung cancer (Review). *The Cochrane Collaboration* 2013 (6).

[270] Horeweg et al. (2013), p. 6.

[271] Heleno et al. (2013).

V. Financial Impact

1. The extent to which the mandated health benefit may increase or decrease the cost of lung cancer screening over the next five years.

Adoption of a lung cancer screening health benefit mandate, as in S.B. 862, may not substantially influence the price of the service. Lung cancer screening is likely to increase even in the absence of a state benefit mandate, lung cancer screening services will be only one of many factors that influence the cost to purchase and maintain LDCT scanners, and the labor supply of radiologists appears to be keeping up with increased demand for all imaging services.

Lung cancer screening is likely to increase in the near future. The recent recommendations by several professional groups favoring lung cancer screening by LDCT will likely encourage increased use of the service. Three of the major insurance carriers in Connecticut responded that they already provide coverage for it and also report similar coverage in the self-funded plans for which they provide services. Further, the USPSTF has issued a draft recommending LDCT lung cancer screening for high-risk individuals. If adopted, this recommendation would likely lead to Medicare and private insurance carriers covering the services without cost-sharing.

Additionally, the use of LDCT scans for other purposes[272] has been increasing over the past 20 years[273] and LDCT technology appears to be rapidly developing, leading to substantial price variation. While lung cancer screening will contribute to the future increase in use, it will be only one application among many. Anecdotal evidence available on the internet suggests that in 2012 prices for commonly used CT scanners ranged from $400,000 to $2 million.[274]

Further, the provisions of the proposed mandate are not likely to cause an increase in price arising from a shortage in labor. A recent study by the ACR suggests that, while there was a mild radiologist shortage nationally in the early 2000s, the market had mostly adjusted by 2010 and was keeping up with increased demand.[275]

2. The extent to which the mandated health benefit may increase the appropriate or inappropriate use of lung cancer screening over the next five years.

Insurance coverage will likely increase the utilization of lung cancer screening among the population identified as high risk by the ALA and ACS. It may also increase utilization, or at least increase demand for the service, by other individuals at high risk for developing lung cancer. It is unclear whether it will have an effect on utilization by individuals who are not at high risk for lung cancer.

A recent study produced some evidence that high-risk individuals were nearly twice as likely to report an interest in being screened when insurance covered the upfront costs compared to paying costs out-

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[272] The International Commission on Radiation Units and Measurements (2012). Radiation dose and image-quality assessment in computed tomography, ICRU Report no. 87. Journal of the ICRU 12 (1), accessed November 5, 2013 from: http://jicru.oxfordjournals.org/content/12/1/NP.full.pdf.

[273] Hendee et al. (2010).

[274] Herman B (April 45, 2012). Twelve Statistics on CT Scanner Costs. Becker's Hospital Review, accessed November 5, 2013 from: http://www.beckershospitalreview.com/hospital-key-specialties/12-statistics-on-ct-scanner-costs.html.

[275] Bhargavan M, Kaye A, Forman H, Sunshine J (2009). Workload of Radiologists in United States in 2006-2007 and Trends since 1991-1992. *Radiology,* 252 (2): 458-467.

of-pocket.[276] Further, another study based on data collected in 2001-2002, a decade before the results of the NLST or accompanying guidelines, suggested that even then patients generally believed that lung cancer screening tests were highly effective. The authors noted that when the general public believes in the efficacy of a medical procedure, demand is higher than otherwise.[277] There is also evidence from a study of mandated health benefits for colorectal cancer screening that mandates have an independent, though modest, association with the increase of appropriate use of cancer screening.[278] In the case of lung cancer screening in Connecticut, however, Optum predicts the magnitude of this increase will be low, due to the resistance that some in the high-risk group may have to health initiatives.

The definition of "inappropriate" is somewhat ambiguous with regard to the current recommendations for the appropriate population to screen for lung cancer. The NLST limited its study to persons aged 55 to 74 with a 30 pack-year history of smoking. Therefore, this is the only group for which there is high-level evidence on the efficacy of lung cancer screening. Other groups might also have a high risk of getting lung cancer. Such groups may include workers chronically exposed to asbestos and other carcinogens;[279] and persons living for extended periods in housing with elevated radon levels.[280] Widespread lung cancer screening of those who meet the ALA or ACS criteria may lead to a greater demand for the service, and perhaps greater utilization, among these other groups.

It is less clear whether utilization among non-high-risk populations will increase. Some researchers suggest that the dangers of medical radiation are not well studied[281] and that, generally, inappropriate use of imaging services may already be a problem.[282]

3. The extent to which the mandated health benefit may serve as an alternative for more expensive or less expensive treatment, service or equipment, supplies or drugs, as applicable.

While a number of other lung cancer screening methods are currently under investigation, none are recommended at this time. In practice, some physicians appear to be screening their patients with traditional chest x-ray. In some cases this may be in conjunction with an analysis of samples of the patient's sputum. Presumably, now that professional guidelines recommend LDCT scanning and not chest x-ray or sputum cytology to screen for lung cancer, physicians will increasingly adopt this method.

4. The methods that will be implemented to manage the utilization and costs of the mandated health benefit.

Nothing on the face of S.B. 862 limits insurance carriers from employing their customary utilization review methods, such as prior authorization and medical necessity review, to manage the utilization and cost of lung cancer screening.[283] Carriers' ability to charge co-payments for the scans, however, may be limited somewhat by §§38a-511 (individual policies) and 38a-550 (group policies), which prescribes limits to co-

[276] Jonnalagadda et al. (2012).

[277] Sinicrope P, Rabe K, Brockman T, Patten C, Petersen W, Slusser J, Yang P, Swensen S, Edell E, de Andrade M, Petersen G. (2010). Perceptions of lung cancer risk and beliefs in screening accuracy of spiral computed tomography among high-risk lung cancer family members. *Academic Radiology*, 17 (8): 1012-1025.

[278] Cokkinides et al. (2011).

[279] De Matteis et al. (2012).

[280] Angell, W (2008).

[281] Heleno et al. (2013).

[282] Hendee et al. (2010).

[283] While carriers are not required to perform utilization reviews, when they do, the reviews are governed by § 38a-591b. A discussion of utilization review generally is found in CPHHP, Autism Spectrum Disorders, accessed November 4, 2013 from: http://www.publichealth.uconn.edu/assets/2012-health_benefit_review_of_proposed_mandates.pdf.

payments for imaging services. Section 38a-511 provides, in relevant part, that no insurance carrier "that provides coverage under an individual health insurance policy or contract for magnetic resonance imaging or computed axial tomography may … require total copayments in excess of three hundred seventy-five dollars for all such in –network imaging services combined annually, or … require a co-payment in excess of seventy-five dollars for each in-network" imaging service. Section 38a-550 provides a similar limit to group policies.

The ALA and, particularly, the ACS both have issued recommendations describing the facilities in which the screening should take place. The intent of recommending particular settings for the lung cancer screens is to reduce the incidence of unnecessary follow-up procedures performed on the patient. If successful, the facility recommendations might also contribute to cost management.

If the USPSTF finalizes its proposed recommendation in support of lung cancer screening, federal law may preclude carriers from imposing cost-sharing arrangements currently permitted by state law. If such a recommendation lacks a setting requirement similar to that of the ACS, it is unclear whether state law or individual carriers may limit coverage to those facilities that meet the ACS's facility recommendations.

5. The extent to which insurance coverage for lung cancer screening may be reasonably expected to increase or decrease the insurance premiums and administrative expenses for policyholders.

Optum estimates that the adoption of S.B. 862 would add, on average, $0.266 PMPM to premiums in group policies and $0.247 PMPM to premiums of individual policies in Connecticut.

Insurance premiums incorporate three large cost components as well as a collection of miscellaneous costs. The three main cost components are sometimes called health benefit costs, administrative costs and profit (or "contribution to surplus" for non-profit insurers).[284] Optum refers to administrative costs and profit as "retention" and health benefit costs as "medical costs."

Optums's estimate assumes that 22 percent of the target population will avail themselves of the service. It also incorporates the potential costs arising from procedures following the screening results, based on observed rates of follow-up in USPSTF's review of the NLST and other studies. It does not, however, account for any potential savings that may accrue from treatment of lung cancer in earlier stages and the current state of the research does not justify a particular numerical estimate. Optum also provides a low estimate, based on a 10 percent uptake rate, of $0.180 PMPM and a high estimate, based on a 40% uptake rate, of $0.350 PMPM. Optum further estimates that the medium estimate of $0.266 PMPM will constitute approximately 0.055 percent of the price of an average group policy premium.

If the USPSTF finalizes its draft recommendation supporting lung cancer screening, and coverage of the service is mandated by federal law, the proposed state mandate would only affect premiums to the extent that it required coverage more extensive than the federal mandate.

[284] Newson M and Fernandez B (2011). Private health insurance premiums and rate reviews. Congressional Research Service, available through the Cornell University ILR School Digital Commons, accessed November 11, 2013 from: http://digitalcommons.ilr.cornell.edu/cgi/viewcontent.cgi?article=1793&context=key_workplace.

6. The extent to which lung cancer screening is more or less expensive than an existing treatment, service or equipment, supplies or drugs, as applicable, that is determined to be equally safe and effective by credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community.

There are no alternatives to an LDCT scan for lung cancer screening that are recommended by relevant guidelines or that have been demonstrated to be equally safe and effective by evidence published in peer-reviewed medical literature.
In practice, the main alternatives to LDCT scanning for lung cancer screening are chest x-ray and sputum cytology. The Health Care Blue Book, an online price comparison guide cited by Consumer Reports,[285] states that a "fair price" cost of a chest x-ray in the Hartford area is $51.[286] Cost estimates for a sputum culture are not readily available.

A recent large trial examining whether chest x-ray used as a screening device is effective at reducing lung cancer mortality failed to produce positive evidence.[287, 288] The ACR, which promulgates guidelines for the general application of x-rays[289] and the particular application of x-rays administered to the chest,[290] does not recommend chest x-rays for lung cancer screening.

Smaller trials examining sputum cytology, either alone or in combination with chest x-ray, have also failed to produce evidence that this means of screening is effective.[291, 292] The Papanicolaou Society of Cytopathology promulgates guidelines for administering sputum tests.[293] It does not recommend the procedure for screening for lung cancer.

7. The impact of insurance coverage for lung cancer screening on the total cost of health care, including potential benefits or savings to insurers and employers resulting from prevention or early detection of disease or illness related to such coverage.

Optum estimates that S.B. 862 would add $298,597 per month or $3,583,164 annually to the total cost of health care in 2014.

The total cost of health care, as understood here, includes all payments to health care providers, whether paid by the carrier or the policyholder. Collectively, these costs are referred to as "allowed costs." The portion of allowed costs paid by the carrier are called "paid medical costs," and the portion paid by the

[285] Consumer Reports Magazine (2012). That CT scan costs how much? Health-care prices are all over the map, even within your plan's network, accessed October 17, 2013 from: http://www.consumerreports.org/cro/magazine/2012/07/that-ct-scan-costs-how-much/index.htm#.

[286] Health Care Blue Book, accessed November 14, 2013 from: http://healthcarebluebook.com/page_Default.aspx.

[287] Oken M, Hocking W, Kvale P, Andriole G, Buys S, Church T, Crawford E, Fouad M, Isaacs C, Reding D, Weissfeld J, Yokochi L, O'Brien B, Ragard L, Rathmell J, Riley T, Wright P, Caparaso N, Hu P, Izmirlian G, Pinsky P, Prorok P, Kramer B, Miller A, Gohagan J, Berg C (2011). Screening by chest radiograph and lung cancer mortality: The prostate, lung, colorectal, and ovarian (PLCO) randomized trial. *Journal of the American Medical Association*, 306 (17), 1865 – 1873.

[288] Hocking W, Hu P, Oken M, Winslow S, Kvale P, Prorok P, Ragard L, Commins J, Lynch D, Andriole G, Buys S, Fouad M, Fuhrman C, Isaacs C, Yokochi L, Riley T, Pinsky P, Gohagan J, Berg C (2010). Lung Cancer Screening in the Randomized Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial. *Journal of the National Cancer Institute*, 102 (10): 722-731.

[289] American College of Radiology Practice Guideline for General Radiography (2013).

[290] American College of Radiology Practice Guideline for the Performance of Chest Radiography (2011).

[291] Manser et al. (2013).

[292] Bach, et al. (2012). Benefits and harms of CT screening for lung cancer: A systematic review, 2418.

[293] Guidelines of the Papanicolaou Society of Cytopathology for the Examination of Cytologic Specimens Obtained from the Respiratory Tract. (1999).

policyholder are called "cost-share." Cost-share includes copayments, deductibles, coinsurance payments and other means through which the policyholder pays the health care provider directly for the health care service.[294] Of the total health care cost estimate here, Optum calculates that $259,560 per month will be paid medical cost and $39,035 per month will be paid through a cost-share.

In addition to the costs associated with the LDCT lung cancer screening itself, this estimate includes expenses arising from follow-up procedures addressing the results of the screen. While these follow-up procedures are not directly mandated by the proposed language of S.B. 862, the costs will likely occur as a result of its passage. The cost of follow-up procedures is a large cost component to the overall estimated price of lung cancer screening. Optum bases its assumptions for calculating these costs on the observed follow-up to screening in the NLST. At the time of the NLST, LDCT technology was new and clinicians had little experience interpreting the risk associated with very small lung nodules. As a result, they may have prescribed more invasive (and expensive) follow-up procedures than necessary. As lung cancer screening becomes more common, and guidelines for the interpretation of lung nodules improve, costs associated with follow-up procedures may decrease.

The current state of the literature does not justify a numerical estimate of possible health care savings associated with earlier detection of lung cancer in the target population. There is, however, some evidence that there may be such savings. A recent analysis of Medicare payments and other national data sources suggests that the cost of treatments for lung cancer are twenty-five percent higher when the cancer is treated at stage III or IV, as compared to when it is treated earlier, at stage I or II, among a population older than 65.[295] While these results may not be reflective of costs of lung cancer patients younger than 65, the researchers also found that, at least for those older than 65, the age of the patient did not significantly affect the overall price of treatment.

8. The impact of the mandated health care benefit on the cost of health care for small employers, as defined in section 38a-564,[296] and for employers other than small employers.

Optum estimates that the average 2014 cost for a lung cancer screening mandate would be 0.06 percent of an average group premium. Given the small percentage lung cancer screening would have on the average premium, it may be that the effect of this mandate alone will be minimal on businesses of any size.

Small businesses are less likely to offer their employees health insurance benefits than are large businesses. This is particularly true for agricultural, retail, sanitation, and service firms. The Connecticut Office of Health Care Access found that a majority of small employers cited health insurance cost as a barrier to providing this benefit.[297]

Premiums generally may be higher for employees of small businesses than for employees of larger firms.

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[294] For further description, see Appendix IV.

[295] Cipriano L, Romanus D, Earle C, Neville B, Halpern E, Gazelle S, McMahon P (2011). Lung cancer treatment costs, including patient responsibility, by disease stage and treatment modality, 1992-2003. *Value in Health*, 14:41-52.

[296] Section 38a-564 (4) defines "small employee," as relevant here, as "any person …who …employed no more than fifty eligible employees, the majority of whom were employed within the state of Connecticut" with various exceptions.

[297] The OHCA definition of "small business" does not exactly track the statutory definition provided in §38a-565 (4). It only includes businesses up to 20 employees, and it may include some non-profit and other organizations that are excluded from the statutory definition. Still, it is illustrative of the fact that there are many small businesses in Connecticut. Office of Health Care Access, The Connecticut Office of Health Care Access 2004 Small Employer Health Insurance Survey – Focus on Results. November, 2004, accessed December 11, 2013 from: http://www.ct.gov/dph/lib/dph/ohca/publications/2004_employer_survey_brief11-1_with_banner.pdf.

While a recent study from the Kaiser Family Foundation found that, in the northeast, premiums were statistically indistinguishable between large and small firms, it defined "small" as 199 or fewer employees.[298] Using Connecticut's current definition of "small employer," fewer than 50 employees, found that small businesses face premiums that were nearly $500 more per year for employee-only coverage than large firms.

For all fully-insured policies in Connecticut, a typical employer pays from 70 to 79 percent of the premium.[299] Optum reports that small employers covered a smaller percentage of the premium than larger firms. Further, it reports that employees of small business pay more in cost-sharing. As an example, Optum states employee-only policyholders at small businesses pay approximately $1,000 more per year in deductibles than employees at large firms.

In addition to possibly paying higher premiums, small employers may secure fewer benefits for their employees than large employers. This may be due to small firms having less bargaining power than large firms, or fewer resources to invest in selecting insurance policies. The ACA attempts to address this to some extent with the Small Business Health Options Program,[300] the national launch of which was announced on September 26, 2013.[301] If small businesses offer fewer benefits than large firms, health benefit mandates would have a relatively larger effect on them.

If lung cancer screening coverage becomes federally mandated for fully insured and self-insured plans, the proposed mandate would only affect large and small businesses to the extent that it required more extensive coverage than federal law.

9. The impact of the mandated health benefit on cost-shifting between private and public payors of health care coverage and on the overall cost of the health care delivery system in the state.

It is unclear whether S.B. 862 will lead to a substantial shift in cost between public and private health care payers. Widespread adoption of lung cancer screening among high-risk patients will lead to the detection of more cancer in earlier stages, which means that patients will be somewhat younger when the cancer is first detected than would otherwise be the case. Some patients who would not be diagnosed with lung cancer until they are eligible for Medicare, therefore, may receive the diagnosis while still covered by private insurance.

The overall cost of the health delivery system in the state includes insurance premiums and cost-sharing. Optum projects the premium cost of the proposed coverage of lung cancer screening would be approximately $305,365 per year, and the overall cost, including premium and cost-share, would be $344,401.

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[298] Panchal N, Rae M, Claxton G. Snapshot: A Comparison of the Availability and Cost of Coverage for Workers in small firms and large firms, the Kaiser Family Foundation, December 5, 2012, accessed December 11, 2013 from: http://kff.org/private-insurance/issue-brief/snapshots-a-comparison-of-the-availability-and-cost-of-coverage-for-workers-in-small-firms-and-large-firms/.

[299] Percentages calculated from the Medical Expenditure Panel Survey (MEPS). Private-Sector Data Premium, Contribution and Cost distributions, 2012, accessed December 12, 2013 from: http://meps.ahrq.gov/data_stats/quick_tables_results.jsp?component=2&subcomponent=2&year=-1&tableSeries=10&searchText=&SearchMethod=1&Action=Search.

[300] Exchange Functions: Small Business Health Options Program (SHOP), §§ 45 C.F.R. 155.700 et seq. HHS announced the opening of the SHOPs on September 26, 2013. "Launching the Small Business Health Option Program Marketplace," HHS News, accessed December 12, 2013 from: http://www.hhs.gov/news/press/2013pres/09/20130926b.html.

[301] "Launching the Small Business Health Option Program Marketplace," HHS News, accessed December 12, 2013 from: http://www.hhs.gov/news/press/2013pres/09/20130926b.html.

Chapter 3
Fertility Preservation

A Report to the Insurance and Real Estate Subcommittee
of the Connecticut General Assembly

Analysis of House Bill 5644:

"An Act Requiring Health Insurance Coverage for Fertility Preservation."

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Table of Contents

I. Overview

On July 19, 2013, the Chairs of the Insurance and Real Estate Committee of the Connecticut General Assembly (the Committee) directed the Connecticut Insurance Department (CID) to review the proposed House Bill (H.B.) number 5644 from the 2013 Regular Session, "An Act Requiring Health Insurance Coverage of Fertility Preservation." This report follows the requirements stipulated under Public Act 09-179, An Act Concerning Reviews of Health Insurance Benefits Mandated in this State.[302] Reviews of required health insurance benefits are a collaborative effort of CID and the University of Connecticut Health Center, Center for Public Health and Health Policy (CPHHP). The CID also contracts with the actuarial firm OptumInsight (Optum) to conduct an analysis of claims data related to the mandate.

This report evaluates the financial and social impact of H.B. 5644, a bill that would:

> "*require health insurance coverage of fertility preservation for insureds facing likely infertility as a result of a necessary medical procedure for insured with cancer and other medical conditions.*"

The full text of H.B. 5644 is located in Appendix III. This review considers the implications if coverage were mandated for both fully insured group plans and individual health insurance policies. CPHHP received only this language from which to conduct a review. Therefore, several additional assumptions regarding the coverage parameters were made based on an interpretation provided by CID and public hearing testimony.

The CID interpretation takes into account Connecticut's existing infertility mandates which define infertility as "the condition of a presumably healthy individual who is unable to conceive or produce conception or sustain a successful pregnancy during a one-year period" and allows carriers to limit coverage until the individual's fortieth birthday. [303]

Analysis of the proposed mandate is limited to benefits to cover the cost of fertility preservation, not infertility treatment. Fertility preservation, for this evaluation, is defined as cryopreservation of sperm, oocytes and embryos plus the associated medically necessary expenses. Eligibility is considered for individuals of reproductive ages from ten to thirty-eight years old. The age ten threshold is set due to the lack of accepted fertility preservation methods for pre-pubertal children. It is assumed that the patient would need to be finished with treatment for the underlying medical condition no later than age 38 to meet the one year infertile period and avoid the fortieth birthday cutoff for eligibility under the infertility mandate.

The methods used to evaluate the financial and social impact of implementing H.B. 5644 included a literature review, web-based research, telephone inquiries, key informant interviews, a survey of Connecticut-domiciled insurers and managed care organizations (carriers), a survey of the Office of the State Comptroller, and findings from analyses of claims data and projections developed by the actuarial firm, Optum. Respondents to the carrier survey included six carriers domiciled in Connecticut. Fully insured plans issued by Connecticut-domiciled carriers are subject to state health benefit mandates. The six carriers reported covering approximately 614,000 lives enrolled in fully insured group plans and 111,000 lives enrolled in individual health insurance policies in Connecticut in 2013. Including self-funded plans, respondents reported providing services for about 51 percent (1.55 million lives) of the Connecticut population under age 65.

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[302] Codified at Connecticut General Statutes § 38a-21.

[303] Codified at Connecticut General Statutes § 38a-509 and 38a-536.

The Optum analysis estimates the 2014 per member per month (PMPM) cost of including coverage for fertility preservation under fully insured group plans and individual policies. Analysis of the potential financial and social impact of fertility preservation coverage "as a result of a necessary medical procedure" was limited to those receiving cytotoxic treatments. Cytotoxic treatments such as chemotherapy and radiation therapy are known to be likely causes of infertility and are common treatments for cancers, as well as lupus and other autoimmune disorders.

Existing health insurance coverage

Carrier responses to the CPHHP survey suggest variation as to whether fertility preservation is a covered or excluded benefit. According to one carrier, "cryopreservation of oocytes or embryos is considered medically necessary in women facing infertility due to chemotherapy, pelvic radiotherapy, or other gonadotoxic therapies." Another carrier indicated "sperm and embryo cryopreservation is covered when meeting medical necessity criteria" but did not define the threshold for medical necessity. Conversely, three other carriers reported cryopreservation as excluded from coverage.

Estimated 2014 premium

Group plans: Optum projected the average premium impact for 2014 when including medical cost, administrative fees, risk factor, and profit or surplus would be $0.059 PMPM, which is 0.012 percent of the average total premium for group plans. Medical cost accounts for $0.05 of the PMPM.

Individual policies: Optum projected the average premium impact for 2014 would be $0.062 PMPM, which is 0.021 percent of the average total premium for individual policies. Medical cost accounts for $0.051 of the PMPM.

Further implications exist if the proposed language "insureds facing likely infertility as a result of a necessary medical procedure" is enacted without further clarification. If enacted in this form, there would likely be a greater impact on utilization and cost than presented, using the assumptions in this report.

- "As a result of a necessary medical procedure" could be interpreted to include pharmaceuticals, surgical procedures or other treatments for medical conditions.
- Infertility may be interpreted as a permanent or temporary condition. This could include treatments, such as pharmaceuticals, where the infertility symptoms subside if the medication is discontinued.
- "Likely infertility" is a distinction that may be difficult to make, even for chemotherapy and radiation therapy. At what threshold will a medical procedure be considered likely to cause infertility? In many cases, existing evidence may make such a distinction difficult.
- The proposed language also lacks a definition of any age limits, whether any time limits would exist for storage, whether there is a need to establish infertility following the medical procedure, and the extent to which this mandate is intended to complement the infertility mandate.

This report is intended to be read in conjunction with the General Introduction to this volume and the OptumInsight Actuarial Report which is included as Appendix IV.

II. Background

Fertility Preservation

Fertility preservation is an evolving field of reproductive medicine through which surgical, medical, or laboratory procedures are used to preserve the potential for genetic parenthood.[304] The field is primarily described in reference to cancer patients and other patients for whom chemotherapy or radiation therapy is the recommended treatment. "Oncofertility" is the emerging medical subfield that bridges the gap between reproductive medicine and oncology, focusing on preserving the reproductive future of cancer patients without compromising overall care. Scientific articles and treatment guidelines seldom describe the application of preservation methods for individuals who may be at risk of losing fertility from other medical conditions or other medical procedures. One guideline suggests that early diagnosis of genetic disorders associated with premature ovarian failure, such as Turner Syndrome or Fragile X, "may raise the possibility of fertility preservation in these populations."[305]

Chemotherapy and radiation therapy, both of which are frequently used to treat cancer, sometimes cause infertility. These treatments are also used successfully for patients with non-malignant autoimmune diseases, such as rheumatoid diseases, systemic lupus erythematosus, steroid-resistant glomerulonephritis, inflammatory bowel disease, pemphigus vulgaris, and hematological diseases.[306, 307] Medical professionals commonly refer to these treatments that damage the gonads, the organs that makes sperm and egg cells, as "gonadotoxic" and those that damage cells as "cytotoxic." The risk of infertility from chemotherapy and radiation therapy depends on the age of the patient, agent used, dosage, frequency, and site of treatment.[308,309] Some treatment regimens have a high risk, greater than 80 percent, whereas others have a minimal risk of less than 20 percent.[310, 311] On the other hand, data on common chemotherapeutic regimens is inconclusive for firmly establishing infertility risks.[312] In addition to chemotherapy and radiation therapy, surgical procedures used on the reproductive organs for treatment of cancer and other conditions can lead to infertility.

Incidence

Cancers are the primary condition resulting in the use of cytotoxic or gonadotoxic treatments for which fertility preservation is pursued. On a national basis, 8.5 percent of the 1.6 million new cancer cases estimated for 2013 are among the population under age 45. Of cases among persons younger than 45,

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[304] Gosden R. Fertility preservation: definition, history, and prospect. *Seminars in Reproductive Medicine*. 2009; 27(6): 433-437.

[305] The Practice Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. Mature oocyte cryopreservation: a guideline. *Fertility and Sterility*® 2013; 99: 37-43.

[306] Sommezer M, Oktay K. Fertility preservation in patients undergoing gonadotoxic treatment or gonadal resection. Literature review current through Jul 2013. Last updated Apr 24, 2013. *UpToDate.*®

[307] Coyne KD, Kader A, Agarwal A. Creating a standard of care for fertility preservation. *Current Women's Health Reviews*. 2010; 6(3): 261-266.

[308] Maltaris T, Seufert R, Fischl F, Schaffrath M, Pollow K, Koelbl H, Dittrich R. The effect of cancer treatment on female fertility and strategies for preserving fertility. *European Journal of Obstetrics & Gynecology and Reproductive Biology*. 2007; 130: 148-155.

[309] Clowse M, Stone J. General toxicity of cyclophosphamide and chlorambucil in inflammatory diseases. *UpToDate*®. Literature review current through Jul 2013. Topic last updated : Mar 7, 2013.

[310] Rodriguez-Macias Wallberg K, Keros V, Hovatta O. Review Clinical Aspects of Fertility Preservation in Female Patients. P*ediatric Blood & Cancer*. 2009; 53: 254-260.

[311] Salama M, Winkler K, Murach K, Seeber B, Ziehr S, Wildt L. Female fertility loss and preservation: threats and opportunities. *Annals of Oncology.* 2013; 24; 598-608.

[312] Loren AW et al. Fertility preservation for patients with cancer: American society of clinical oncology clinical practice guideline update. *Journal of Clinical Oncology.* 2013; 31(19):2500-10.

about 62 percent are females.[313] In Connecticut, there were 4,286 newly diagnosed cases of cancer in the population aged 10 to 39 from 2006-2010.[314] Roughly, this is an average of 857 new cancer cases diagnosed annually among the reproductive age population. Females accounted for more than three out of five of the newly diagnosed cancers. These new cancer cases, some of which are diagnosed to the same individual, represent less than one-tenth of one percent (0.03) of the overall Connecticut population under age 65. About half of these new cancer cases likely require gonadotropic or cytotoxic treatments.[315]

Other conditions, such as systemic lupus erythematosus (SLE) and rheumatoid arthritis may also be treated with cytotoxic agents. A large European study attributed these and other non-malignant diseases (e.g, Turner Syndrome, immunological disorders, auto-immune disorders) to nine percent of those who received fertility preservation procedures.[316] Estimates of SLE incidence range substantially, from 1.8 to 7.6 per 100,000 for the general population.[317] Rheumatoid arthritis incidence among the reproductive age population is also relatively low, with 8.7 cases per 100,000 among individuals ages 18-34.[318]

Intervention Strategies

Cryopreservation of sperm, oocytes (eggs), or embryos is the established method for fertility preservation for adolescent and reproductive age adults. No clinically proven methods for preserving fertility exist for pre-pubertal males or females.[319]

Cryopreservation allows for maintaining tissues and organs in a viable state for future use by freezing them at extremely low, sub-zero temperatures stopping all biologic activity.[320] This can be done using slow-freeze techniques or vitrification, a process using high concentrations of cryoprotectant followed by ultra-rapid cooling. The development of vitrification technology in recent years has led to the recognition of oocyte cryopreservation as an accepted fertility preservation option for females,[321] due in part to improved post-thaw survival rates.[322]

Both sperm cryopreservation and embryo cryopreservation processes have been well-developed as part of infertility or reproductive medicine. Cryopreservation of testicular tissue or ovarian tissue, both classified as reproductive tissue, is considered investigational. Females have the option of embryo cryopreservation or oocyte cryopreservation. Considerations for preservation include the age of the patient, treatment type, the type and site of cancer, the timeline for commencing chemotherapy or radiation therapy, and whether a male

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[313] American Cancer Society. Estimated new cancer cases by sex and age (years). Atlanta: American Cancer Society, 2013. Accessed December 17, 2013 from: http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-037114.pdf.

[314] Personal communication December 9, 2012 with Lou Gonsalves, PhD, Epidemiologist CT Tumor Registry, Connecticut Department of Public Health. Reported data is from the Surveillance, Epidemiology, and End Results (SEER) Program, SEER*Stat Database: Incidence, 2006-2010, available from the Connecticut Tumor Registry at the Connecticut Department of Public Health.

[315] Salama M, Winkler K, Murach K, Seeber B, Ziehr S, Wildt L. Female fertility loss and preservation: threats and opportunities. *Annals of Oncology*. 2013; 24; 598-608.

[316] Lawrenz B, Jauckus J, Kupka M, Strowitzki T, von Wolff M. Fertility preservation in >1,000: patient characteristics, spectrum, efficacy and risks of applied preservation techniques. *Archives of Gynecology and Obstetrics*. 2011; 293: 651-656.

[317] U.S. Centers for Disease Control and Prevention. Systemic lupus erythematosus. Last updated: April 20, 2012. Accessed December 23, 2013 from: http://www.cdc.gov/arthritis/basics/lupus.htm.

[318] U.S. Centers for Disease Control and Prevention. Rheumatoid arthritis. Last updated: November 19, 2012. Accessed December 23, 2013 from: http://www.cdc.gov/arthritis/basics/rheumatoid.htm.

[319] Trost L, Brannigan. Oncofertility and the male cancer patient. *Current Treatment Options in Oncology.* 2012; 13:146-160.

[320] Mosby's Medical Dictionary. American Heritage Medical Dictionary. SART, 2013.

[321] Loren AW et al. Fertility preservation for patients with cancer: American society of clinical oncology clinical practice guideline update. *Journal of Clinical Oncology*. 2013; 31(19):2500-10.

[322] Salama M, Winkler K, Murach K, Seeber B, Ziehr S, Wildt L. Female fertility loss and preservation: threats and opportunities. *Annals of Oncology.* 2013; 24; 598-608.

partner or donor sperm is needed.[323] To minimize potential DNA damage, specimens should be collected prior to chemotherapy or radiation therapy. For some, cryopreservation is not an appropriate option.

Embryo cryopreservation follows the procedures used for in vitro fertilization (IVF), with the exception that once the embryo is created it is cryopreserved for implantation in the future. The transfer of frozen/thawed embryos is a clinical routine for IVF programs. Embryo cryopreservation requires ovarian stimulation and a surgical procedure to retrieve a mature oocyte from the female patient. IVF is then used to combine the oocyte and sperm from a male partner or sperm donor to create an embryo. The need to stimulate the ovaries can be a barrier for those with highly aggressive malignancies and estrogen sensitive tumors since conventional methods can take two to three weeks. For individuals with highly aggressive malignancies, such as leukemia, some lymphoma and sarcomas, the lag time before starting cancer treatment would be too long. Since embryo cryopreservation requires sperm from a male partner or donor, adolescent girls and single women may also have ethical or other hesitations toward embryo cryopreservation.[324]

Oocyte cryopreservation requires ovarian stimulation and a surgical procedure to retrieve mature oocytes but does not require sperm from a male partner or donor. In the future, the preserved oocyte can be thawed, fertilized with sperm from a donor or male partner, and implanted.[325]

Sperm cryopreservation is a minimally invasive procedure for males. Most patients can readily produce the necessary sample through natural ejaculation, the preferred method of sperm procurement. Less commonly, sperm aspiration, surgical sperm extraction, sperm retrieval or vibrastimulatory methods may be used. Cryopreserved sperm can later be thawed and prepared for use using artificial insemination procedures [intracervical insemination (ICI), intrauterine insemination (IUI)] or assisted reproductive technologies [intra-cytoplasmic sperm injection (ICSI) or IVF].

Table 3.1: Cryopreservation for Fertility Preservation and Future Use.

Embryo Cryopreservation	Oocyte Cryopreservation	Sperm Cryopreservation
Fertility Preservation		
→ Ovarian stimulation → Oocyte retrieval → Donor/Male Partner Sperm Collected → IVF used to create embryo(s) → Cryopreservation	→ Ovarian stimulation → Oocyte retrieval → Cryopreservation	→ Sperm procurement → Cryopreservation
Future Use		
→Thaw embryo(s) →Implantation	→Thaw oocytes →Donor/Male Partner Sperm Collected →IVF used to create embryo(s) →Implantation	→Thaw sperm →Artificial insemination or →Donor or partner oocyte(s) collected →IVF used to create embryo →Implantation

[323] Salama M, Winkler K, Murach K, Seeber B, Ziehr S, Wildt L. Female fertility loss and preservation: threats and opportunities. *Annals of Oncology.* 2013; 24; 598-608.

[324] Ibid.

[325] Ibid.

Reproductive tissue cryopreservation and reimplantation. Cryopreservation of reproductive tissue is considered experimental or investigational. However, if cryopreservation of reproductive tissues is deemed safe and effective, this would introduce a preservation option for prepubertal boys and girls, women with estrogen-sensitive cancers, and women needing rapid initiation of cancer treatment for highly aggressive malignancies. [326] Ovarian tissue cryopreservation and reimplantation involves a partial removal (one half to two-thirds) of the ovarian cortex in most cases, with the goal of preserving primordial follicles. Post cancer-recovery, cryopreserved tissue can be thawed and reimplanted.[327] Testicular tissue cryopreservation and transplantation process involves freezing testicular tissue or germ cells, cryopreservation and reimplantation after cancer treatment. This method has not been successfully tested in humans.[328]

Ovarian and testicular protection techniques. When surgical removal of reproductive organs is required to treat cancer, less-invasive surgeries that minimize damage to the reproductive organs are sometimes recommended. (See Table 3.2). For example, unilateral removal of the affected ovary (oophorectomy) or testis (orchiectomy) may be substituted for bilateral removal if appropriate. Cryopreservation of sperm, oocytes or embryos is sometimes done in addition to the less-invasive surgical method.[329] Individuals undergoing surgical procedures may also require chemotherapy or radiation therapy.

In addition to the above techniques, pelvic shielding is sometimes used to shield the abdomen during pelvic irradiation therapy. For women, this may or may not be combined with a method called ovarian transposition or oophoropexy, where the ovaries are surgically relocated to a field outside of the irradiation field. Due to radiation scatter, ovaries are not always protected by transposition and this method is not always successful for preserving female fertility.

Table 3.2: Less Invasive Surgical Procedures

Less-Invasive Surgical Procedures	What it is	When it is used
Unilateral oophorectomy	Surgical removal of one ovary, rather than both	Reduce possibility of developing ovarian cancer or in cases where hormones produced by the ovaries are making a disease such as breast cancer worse
Unilateral orchiectomy	Surgical removal of one testical, rather than both	A common treatment for testicular cancer; may also be used for prostate cancer
Radical trachelectomy	Surgical removal of the cervix leaves the uterus intact, rather than radical hysterectomy	Stage IA2-IB cervical cancer with diameter <2 cm and invasion <10 mm
Ovarian cystectomy	Surgical removal of ovarian cyst, rather than entire ovary	Early-stage ovarian cancer
Oophoropexy	Transposition of the ovaries outside of the radiation field	Female cancer patients receiving pelvic irradiation

[326] Salama M, Winkler K, Murach K, Seeber B, Ziehr S, Wildt L. Female fertility loss and preservation: threats and opportunities. *Annals of Oncology*. 2013; 24; 598-608.

[327] Meirow D. Fertility preservation in cancer patients using stored ovarian tissue: clinical aspects. *Curr Opin Endocrinol Diabetes Obes.* 2008; 15: 536-547.

[328] Lee S, Schover L, Partridge A, Patrizio P, Wallace W.H., Hagerty K, Beck L, Brennan L, Oktay K. American Society of Clinical Oncology Recommendations on fertility preservation in cancer patients. *Journal of Clinical Oncology* 2006; 24: 2917-2931.

[329] Rodriguez-Macias Wallberg K, Keros V, Hovatta O. Review Clinical Aspects of Fertility Preservation in Female Patients. *Pediatric Blood & Cancer.* 2009; 53: 254-260.

Hormone suppression therapy is recommended against for males and is not considered a reliable method for females.

Treatment/Practice Guidelines

Major professional organizations for oncology and reproductive medicine first established guidelines for medical providers addressing the issue of potential infertility after cancer treatments in 2005[330] and 2006.[331] In addition, the American Academy of Pediatrics Section on Hematology/Oncology issued guidance for counseling pediatric patients and their parents about fertility options in 2008.[332] Initial and updated recommendations encourage physicians to discuss the potential impact of cancer and cancer treatments on fertility, make early referrals of interested patients to reproductive specialists, and address fertility preservation options when appropriate. Documentation of discussions is recommended. In 2013, both the American Society of Clinical Oncology (ASCO) and the American Society for Reproductive Medicine (ASRM), in conjunction with the Society for Assisted Reproductive Technology (SART),[333] issued updates to their original guidelines for fertility preservation.

The updated guidelines continue to affirm sperm and embryo cryopreservation as standard, widely available medical procedures for use with patients facing infertility due to chemotherapy or radiation therapy. The 2013 guidelines add oocyte cryopreservation as recommended with appropriate counseling. However, ASRM/SART suggests against using oocyte cryopreservation "routinely in lieu of embryo cryopreservation," and does not recommend use for the "sole purpose of circumventing reproductive aging in healthy women" or use of universal donor oocyte banking based on insufficient data.[334] Similarly, ASCO states: "cryopreservation of unfertilized oocytes is an option, particular for patients who do not have a male partner, do not wish to use donor sperm, or have religious or ethical objections to embryo freezing." ASCO also provides recommendations for the use of ovarian transposition and conservative gynecologic surgery.[335]

Other preservation methods are not currently recommended. Cryopreservation of reproductive tissue and reimplantation is considered investigational and should only be carried out by providers with the necessary expertise as part of a clinical trial under the guidance of an appropriate Institutional Review Board.[336] Little has been published or proven about methods of preparation and use of tissue or the capability to yield fertilizable oocytes and viable offspring.[337] Concerns also exist about the risk of reintroducing malignant cells when reimplanting tissue.[338]

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[330] Fertility preservation and reproduction in cancer patients. *Fertility and Sterility*®. 2005; 83: 1622.

[331] Lee S, Schover L, Partridge A, et al. American Society of Clinical Oncology recommendations on fertility preservation in cancer patients. *Journal of Clinical Oncology:* Official Journal of the American Society of Clinical Oncology. 2006; 24: 2917.

[332] Fallat ME, Hutter J, American Academy of Pediatrics Committee on Bioethics, American Academy of Pediatrics Section on Hematology/Oncology, American Academy of Pediatrics Section on Surgery. Preservation of fertility in pediatric and adolescent patients with cancer. *Pediatrics*. 2008; 121(5):e1461-9.

[333] The Practice Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. Mature oocyte cryopreservation: a guideline. *Fertility and Sterility*® 2013; 99: 37-43.

[334] Ibid.

[335] Loren AW et al. Fertility preservation for patients with cancer: American society of clinical oncology clinical practice guideline update. *Journal of Clinical Oncology.* 2013; 31(19):2500-10.

[336] Ibid.

[337] Jungheim E, Carson K, Brown D. Counseling and consenting women with cancer on their oncofertility options: a clinical perspective. *Cancer Treat Res.* 2010; 156: 403-412.

[338] Rosendahl M, Greve T, Andersen C. The safety of transplanting cryopreserved ovarian tissue in cancer patients: a review of the literature. *J Assist Reprod Genet.* 201; 30: 11-24.

Hormone therapy is considered not successful for men and insufficient evidence exists for use of gonadotropin-releasing hormone agonist and antagonist (GnRHa) or other methods for women; therefore, it is not a recommended method.[339] ASCO recommends against gonadal suppression for males and suggests that for females GnRHa "should not be relied upon as a fertility preservation method." However, the ASCO Update Panel "encourages participation in clinical trials that meet these criteria as long as the patients also consider alternative and effective methods of fertility preservation."[340]

Treatment Risk

Cryopreservation of sperm, oocytes and embryos is considered to be safe and effective by the medical community. However, there is a low level of risk associated with procedures used for oocyte or embryo cryopreservation. These procedures include ovarian stimulation and the surgical removal of the oocyte.

- Ovarian stimulation may cause ovarian hyperstimulation syndrome in fewer than five percent of patients.[341] A debate also exists around the appropriateness and risks of using conventional ovarian stimulation for estrogen sensitive cancers, such as breast, endometrial or gynecological cancers. The concern lies in observed tumor growth in animal studies.[342, 343]
- Surgical complications, most of which occur during fewer than 0.1 percent of procedures, include vaginal bleeding, intra-abdominal bleeding, intestinal injuries, inflammation of the lining of the abdominal cavity, and ovarian torsion.[344]

In addition, the future use of cryopreserved sperm, oocytes or embryos requires the use of artificial insemination or assisted reproductive technology (ART). Use of ART elevates the risk for multiple gestations, congenital anomalies, preterm delivery, low birth weight, and the complications associated with these outcomes.[345]

III. Methods

The methods used to evaluates the financial and social impact of implementing H.B. 5644 included a literature review, web-based research, telephone inquiries, key informant interviews, surveys of Connecticut-domiciled carriers, the Office of the State Comptroller, local health departments, and Connecticut fertility clinics; and findings from actuarial and economic analyses conducted by Optum.

The CPHHP staff conducted a search for published articles and other information related to the medical, social, economic and financial aspects of the required benefit. In addition, at the request of CPHHP, medical librarians at the Lyman Maynard Stowe Library at the University of Connecticut Health Center (UCHC) conducted searches using: PubMed, UptoDate, textbooks, and Web Search-Google. Keywords

[339] Loren AW et al. Fertility preservation for patients with cancer: American society of clinical oncology clinical practice guideline update. *Journal of Clinical Oncology*. 2013; 31(19):2500-10.

[340] Ibid.

[341] Institute of Medicine (IOM) and National Research Council (NRC). Assessing the medical risks of human oocyte donation for stem cell research: Workshop Report. 2007. Washington, DC: The National Academies Press.

[342] Loren AW et al. Fertility preservation for patients with cancer: American society of clinical oncology clinical practice guideline update. *Journal of Clinical Oncology*. 2013; 31(19):2500-10.

[343] Kim S, Klemp J, Fabian C. Breast cancer and fertility preservation. *Fertility and Sterility*®. 2011. 95(5): 1535-43.

[344] Institute of Medicine (IOM) and National Research Council (NRC). Assessing the medical risks of human oocyte donation for stem cell research: Workshop Report. 2007. Washington, DC: The National Academies Press.

[345] Paulson R. Pregnancy outcome after assisted reproductive technology. *UpToDate*.® Eds. Lockwood C, Barbieri R, Barss V. Literature review current through Nov. 2013. Topic last updated Nov 15, 2013.

used included: fertility, infertility, fertility management, fertility preservation, pregnancy complications, neoplastic, tissue preservation, family planning services, trachelectomy/cervicectomy, subfertility, gonadotoxic, oncofertility, and fertility sparing.

CPHHP staff also used telephone and e-mail inquiries to appropriate state, federal, municipal, and non-profit entities and from internet sources such as the Centers for Medicare and Medicaid Services (CMS) website, other states' websites, the Connecticut Department of Public Health, and non-profit and community-based organization websites. Also, the CPHHP research team consulted with faculty and staff from the University of Connecticut's School of Medicine and Center for Advanced Reproductive Services on matters pertaining to medical standards of care, traditional, current and emerging practices, evidence-based medicine related to the benefit, treatment cost and utilization.

CPHHP staff fielded a survey to six carriers domiciled in Connecticut. The six carriers surveyed account for 90 percent of covered lives in the Connecticut-domiciled fully insured group market and 94 percent of covered lives in the Connecticut-domiciled individual market. The survey requested policy documents (e.g., utilization review processes, parameters for defining medical necessity, etc.) and data for the proportion of members with policy exclusions, the extent of member coverage, treatments requested and approved, and claims related to fertility preservation, as specified by the mandate. All carriers responded; however, the completeness and quality of responses varied.

The CID contracted with the actuarial firm Optum to provide actuarial and economic analyses of the mandated benefit. Optum's estimates of utilization and cost primarily relied on Optum's in-house national and Connecticut-specific claims data from 2010-2011. The full Optum report is available in Appendix IV.

IV. Social Impact

1. The extent to which fertility preservation is utilized by a significant portion of the population.

Reproductive age males and females with a newly diagnosed cancer are the primary consumers of fertility preservation. This population, combined with others needing chemotherapy or radiation therapy, accounts for a small portion of the overall population. Those who use fertility preservation comprise an even smaller percentage of the reproductive age population with cancer. There is a lack of high quality estimates on use of fertility preservation procedures in general and for the population that would be eligible under the proposed mandate. The CPHHP team generated rough estimates based on Connecticut cancer incidence and a range of use-rates identified in the literature. In addition, this response includes data on utilization at one Connecticut clinic.

In Connecticut, there were 4,286 newly diagnosed cases of cancer in the population aged 10 to 39 from 2006-2010.[346] Roughly, this is an average of 857 new cancer cases diagnosed annually among the reproductive age population. More than three out of five new cancers were diagnosed in females. These new cancer cases, some of which are diagnosed to the same individual, represent less than one-tenth of one percent (0.03) of the overall population under age 65. Roughly half of these new cancer cases likely require cytotoxic treatments.[347]

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[346] Personal communication with Lou Gonsalves, PhD, Epidemiologist Connecticut Tumor Registry, Connecticut Department of Public Health. December 9, 2012. Reported data is from the Surveillance, Epidemiology, and End Results (SEER) Program, SEER*Stat Database: Incidence, 2006-2010, available from the Connecticut Tumor Registry at the Connecticut Department of Public Health.

[347] Salama M, Winkler K, Murach K, Seeber B, Ziehr S, Wildt L. Female fertility loss and preservation: threats and opportunities. A*nnals of Oncology.* 2013; 24; 598-608.

The California Health Benefit Review Program estimated that in a one-year period, 24.4 percent of males and 2.1 percent of females of reproductive age (<45) who are diagnosed with cancer use cryopreservation.[348] Other estimates for fertility preservation range from 1.3 to 8 percent among females[349, 350, 351] and 8 to 27.9 percent among males.[352, 353] Across this range, definitions of reproductive age and relevant newly diagnosed cancer cases vary. Using these rates from the literature and Connecticut cancer incidence data from 2006-2010, annual average utilization of fertility preservation would be 7 to 42 females and 27 to 81 males. However, this may not be an accurate reflection of actual utilization.

CPHHP inquired with fourteen infertility clinics in Connecticut, of which eight reported offering sperm, embryo, and/or oocyte cryopreservation. Only the Center for Advanced Reproductive Services (CARS) provided information on use of fertility preservation counseling and treatment. These results may or may not be generalizable to other clinics in Connecticut. In the period from 2009-2012, only seventy-four calls were made to the CARS oncofertility hotline. Of those who called, 52.7 percent were seen for consultation. Of this group, 41 percent opted for fertility preservation. Only 21.6 percent (16 women) of those who initially called the hotline pursued treatment.[354] Using a crude estimate, this one clinic provided fertility preservation to roughly 0.7 percent of new cancer cases among reproductive age females.

2. The extent to which fertility preservation is currently available to the population, including, but not limited to coverage under Medicare, or through public programs administered by charities, public schools, the Department of Public Health, municipal health departments or health districts or the Department of Social Services.

Medicare: Medicare does not provide coverage for fertility preservation.[355, 356]

Public Programs Administered by Charities: Several national organizations offer resources and support to those seeking fertility preservation treatments as a result of fertility damaging cancer treatments. For example, Fertile Hope offers resources and support to those whose medical treatments put them at risk of infertility. Fertile Hope, through its Sharing Hope Program, arranges discounted prices for fertility preservation treatments with certain companies and clinics and also distributes donated medications to

[348] California Health Benefits Review Program. Analysis of Assembly Bill 428: Fertility Preservation. Accessed September 5, 2013 from: http://chbrp.ucop.edu/index.php?action=read&bill_id=124&doc_type=3.

[349] Goodman L, Balthazar U, Kim J, Mersereau J. Trends in socioeconomic disparities in referral patterns for fertility preservation consultation. *Human Reproduction.* 2012; 37(7): 2076-2081.

[350] Letourneau J, Ebbel E, Katz P, Katz A, et al. Pre-treatment fertility counseling and fertility preservation improve quality of life in reproductive age women with cancer. *Cancer.* 2012; 118(6): 1710-1717.

[351] Estimate based on personal communication with J Letourneau. 12/19/2013. Fertility preservation estimate of 8 percent is based on raw data for 2005-2007 study by Letourneau et al, 2012. 19 out of 235 with a non-gynecologic cancer with a treatment that could have affected their fertility received fertility preservation.

[352] Shnorhavorian M, Kroon L, Jeffries H, Johnson R. Creating a standardized process to offer the standard of care: continuous process improvement methodology is associated with increased rates of sperm cryopreservation among adolescent and young adult males with cancer. *Journal of Pediatric Hematology/Oncology.* 2012; 34(8): e315-e319.

[353] Sheth K, Sharma V, Helfand B, et al. Improved fertility preservation care for male patients with cancer after establishment of formalized oncofertility program. *The Journal of Urology.* 2012; 187: 979-986.

[354] Pepin L, Kaye L, Nulsen J, et al. Potential reasons for patients not pursuing fertility preservation after referral for consultation and counseling. The Center for Advanced Reproductive Services. PowerPoint presentation.

[355] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, What Medicare Covers, Preventative and Screening Services. Accessed October 15, 2013 from: http://medicare.gov/coverage/preventive-and-screening-services.html.

[356] Personal Communication. Gwen Jenkins, Customer Service for Medicare. Centers for Medicare and Medicaid Services. September 26, 2013.

eligible cancer patients. Eligibility is based on the applicant's income, cancer diagnosis, and not yet having started fertility damaging cancer treatments. Although Fertile Hope manages the program, it does not offer direct financial assistance to patients; it only arranges services and client referrals.[357] The Alliance for Fertility Preservation also provides fertility preservation resources and support to patients at risk and already diagnosed with infertility, but it does not offer financial assistance of any kind to patients.

Public Programs Administered by Public Schools: An investigation of the Connecticut Department of Education, municipal and regional boards of education, and other web-based inquiries found no information indicating public schools provide funding for or directly provide fertility preservation related care.

The Department of Public Health (DPH): CPHHP researchers found no information that indicates that the DPH provides funding for, or the provision of, fertility preservation treatments.

Municipal Health Departments or Health Districts: None of the seven municipal health departments and sixteen local health districts responding to a phone and web-based inquiry reported providing funding and/or directly providing fertility preservation treatments.

The Department of Social Services (DSS): An investigation of Connecticut Medical Assistance Programs and Connecticut Medicaid did not identify any evidence that Medicaid covers fertility preservation treatments. In correspondence, a DSS representative confirmed that Connecticut Medicaid does not provide coverage for fertility preservation treatment.[358]

3. The extent to which insurance coverage is already available for fertility preservation.

Generally, fully insured plans do not cover fertility preservation. Connecticut-domiciled carriers responding to the CPHHP survey suggest variation as to whether fertility preservation is a covered or excluded benefit. According to one carrier, "cryopreservation of oocytes or embryos is considered medically necessary in women facing infertility due to chemotherapy, pelvic radiotherapy, or other gonadotoxic therapies." Another carrier indicated "*sperm and embryo cryopreservation is covered when meeting medical necessity criteria*" but did not define the threshold for medical necessity. Conversely, three other carriers reported cryopreservation as excluded from coverage. Reviews conducted in California (8 percent) and Hawaii both indicated that insurance coverage for fertility preservation is generally unavailable.

4. If the coverage is not generally available, the extent to which such lack of coverage results in persons being unable to obtain necessary health care treatment.

Like infertility treatment, fertility preservation methods are high cost when paid out-of-pocket. Reported prices from a handful of Connecticut clinics reached as high as $1,250 for sperm cryopreservation, $10,000-17,000 for oocyte cryopreservation, and $20,000-22,000 for embryo cryopreservation.[359] At face value, this amount, especially paired with the future cost of the cancer treatment itself, could deter individuals from financing fertility preservation procedures. However, there is not definitive evidence to establish the extent to which lack of coverage directly translates into persons not receiving fertility preservation treatment. The discussion below highlights anecdotes from public hearing testimony and a Connecticut-based survey. It also raises questions about the ability to obtain care based on findings from several peer-reviewed studies.

At the public hearing for H.B. 5644 the Connecticut State Medical Society, the Center for Advanced

[357] Livestrong, Fertile Hope, Sharing Hope Program. Accessed September 18, 2013 from: http://www.fertilehope.org/financial-assistance/index.cfm.

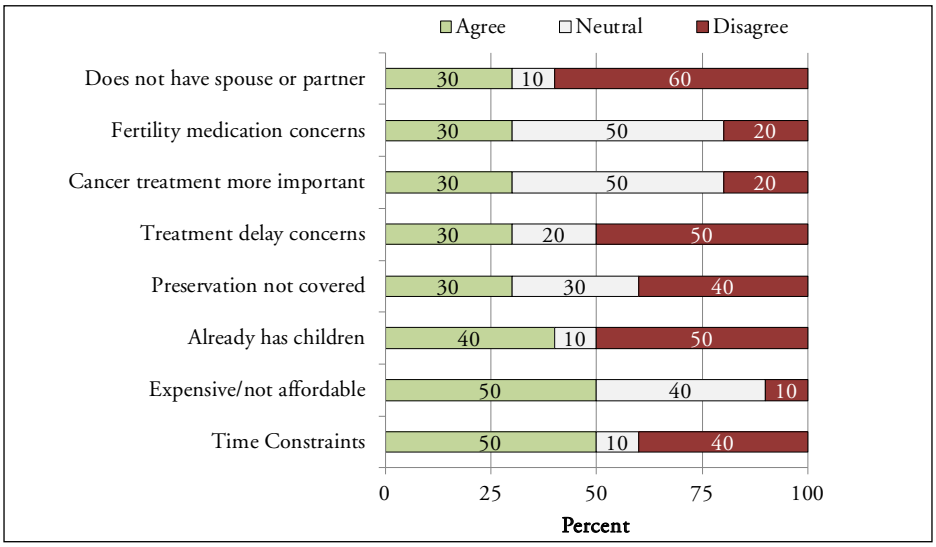
[358] Personal Communication. Barbara Fletcher, DSS Medical Policy & Regulations Unit. September 27, 2013.

[359] Center for Public Health and Health Policy. Infertility Clinic Survey. Conducted November, 2013.

Reproductive Services, the American Cancer Society, and the Permanent Commission on the Status of Women all indicated that lack of coverage causes patients to delay or be unable to obtain the necessary fertility preservation treatment.[360, 361, 362, 363]

Patient-related issues. A recent survey of women who received fertility preservation counseling through the Center for Advanced Reproductive Services in Connecticut during 2009-2012 identified time constraints and the cost of treatment as the most common reasons for decisions not to pursue treatment.[364] Of women who did not pursue treatment, fifty percent agreed that time constraints and cost were underlying reasons. (Shown in Figure 3.1, below). In addition, lack of insurance coverage for preservation, treatment delay concerns, prioritizing cancer treatment over preservation, concerns about fertility medication safety, and not having a spouse or partner were noted by thirty percent of women declining treatment as reasons for not pursuing preservation. A smaller portion of women reported not pursuing treatment due to low success rates not warranting delay of cancer treatment, not wanting additional medical treatment, ethical/religious reasons about embryo freezing, oncologist recommending against fertility preservation, cancer treatment not affecting fertility, or spousal concerns.

Figure 3.1: Reasons for Not Pursuing Fertility Preservation



Patient-physician communication issues. Beyond insurance coverage, there is the question of whether

[360] Public Hearing on H.B. 5644. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by Arthur Tarantino, MD., The Connecticut State Medical Society and the Connecticut Urology Society. February 19, 2013. Accessed from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013HB-05644-R000219-Arthur%20Tarantino,%20CT%20State%20Medical%20Society-TMY.PDF.

[361] Public Hearing on H.B. 5644. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by Lawrence Engmann, MD., The Center for Advanced Reproductive Services. February 19, 2013. Accessed from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013HB-05644-R000219-Lawrence%20Engmann,%20Center%20for%20Advanced%20Reproductive%20Services-TMY.PDF.

[362] Public Hearing on H.B. 5644. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by Michelle Wolf, the American Cancer Society. February 19, 2013. Accessed from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013HB-05644-R000219-Michelle%20Wolf,%20American%20Cancer%20Society-TMY.PDF.

[363] Public Hearing on H.B. 5644. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by the Permanent Commission on the Status of Women. February 19, 2013. Accessed from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013HB-05644-R000219-The%20Permanent%20Commission%20on%20the%20Status%20of%20Women-TMY.PDF.

[364] Pepin L, Kaye L, Nulsen J, et al. Potential reasons for patients not pursuing fertility preservation after referral for consultation and counseling. The Center for Advanced Reproductive Services. PowerPoint presentation.

patients scheduled for chemotherapy or radiation therapy receive counseling about their likelihood of infertility or referral for fertility preservation consultations. A 2009 review of twenty four studies found 34 to 72 percent of patients recalled counseling about the impact of cancer on fertility.[365] Findings from a national survey suggest only 47 percent of oncologists routinely refer cancer patients of childbearing age to a reproductive endocrinologist.

Higher odds of referral were found for female physicians, those with favorable attitudes about preservation, and those whose patients routinely ask about fertility preservation.[366] Discrepancies in referral rates also exist based on patient characteristics such as ethnicity, age, parity and cancer type.[367, 368] Other factors include the physician's knowledge about fertility preservation options and efficacy, knowledge of referral sources, personal comfort, patient prognosis, belief that addressing survivorship issues such as fertility detracts from the primary objective to treat malignancy, and concerns about delay in treatment.[369, 370]

There is conflicting evidence on whether a physician's perception of a patient's ability to pay for the treatment affects the decision to discuss fertility preservation option with the patient. However, to the extent that costs are the main barrier keeping oncologists from counseling on infertility risks and providing referrals for preservation, inclusion of fertility preservation as a covered benefit may lead to more counseling and referrals. Improved referrals would in turn increase the likelihood of patients obtaining fertility preservation treatment.[371, 372]

5. If the coverage is not generally available, the extent to which such a lack of coverage results in unreasonable financial hardships on those persons needing treatment.

Health care expenses can substantially affect other aspects of life. For example, an estimated half of all mortgage foreclosures are associated with unexpected health care expenses. Examining a sample of these foreclosures, researchers identified $2,000 in unreimbursed medical payments as a threshold for "significant medical distress."[373] It is clear that the cost burden for fertility preservation is substantially higher for females than males and reaches a threshold that would reasonably pose a substantial financial burden for females.

The average allowed cost calculated by Optum provides some insight into how the potential for financial hardship may occur for families paying for fertility preservation without insurance coverage. Optum reports an average allowed cost of $1,113 for sperm cryopreservation, $8,954 for oocyte cryopreservation,

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[365] Tschudin S, Bitzer J. Psychological aspects of fertility preservation in men and women affected by cancer and other life-threatening diseases. *Human Reproduction Update*. 2009; 15(5): 587-597.

[366] Quinn G, Vadaparampil S, Lee J-H. Jacobsen P, Bepler G, et al. Physician referral for fertility preservation in oncology patients: a national study of practice behaviors. *Journal of Clinical Oncology.* 2009; 27: 5952-5957.

[367] Goodman L, Balthazar U, Kim J. Mersereau J. Trends of socioeconomic disparities in referral patterns for fertility preservation consultation. *Human Reproduction*. 2012; 27(7): 2076-81.

[368] Letourneau J, Smith J, Ebbel E, Craig A, et al. Racial, socioeconomic, and demographic disparities in access to fertility preservation in young women diagnosed with cancer. *Cancer.* 2012; 118(18): 4579-4588.

[369] Quinn G, Vadaparampil S, Bell-Ellison B, Gwede C, Albrecht T. Patient-physician communication barriers regarding fertility preservation among newly diagnosed cancer patients. *Social Science & Medicine.* 2008; 66: 784-789.

[370] Schover L, Brey K, Lichtin A, Lipshultz L, Jeha S. Oncologists' attitudes and practices regarding banking sperm before cancer treatment. *Journal of Cl*inical Oncology 2002; 20(7): 1890-1897.

[371] Sheth K, Sharma V, Helfand B, et al. Improved fertility preservation care for male patients with cancer after establishment of formalized oncofertility program. *The Journal of Urology*. 2012; 187: 979-986.

[372] Shnorhavorian M, Kroon L, Jeffries H, Johnson R. Creating a standardized process to offer the standard of care: continuous process improvement methodology is associated with increased rates of sperm cryopreservation among adolescent and young adult males with cancer. *J Pediatr Hematol Oncol.* 2012; 34(8): e315-e319.

[373] Robertson C, Egelhof R, Hoke M. Get sick, get out: The medical causes of home mortgage foreclosures. *Health Matrix.* 2008; 18: 65-104.

and $16,240 for embryo cryopreservation (p.55). Since allowed costs are rates negotiated by carriers with providers, the fees for patients paying directly for services may be higher. Responses from a handful of Connecticut clinics, suggest higher prices. Reported prices reached as high as $1,250 for sperm cryopreservation, $10,000-17,000 for oocyte cryopreservation, and $20,000-22,000 for embryo cryopreservation.[374] Cash prices and other discounted rates may or may not be available.

The cost of fertility preservation for females is at least four to ten times the threshold for significant medical distress; for males the cost burden is 55 to 62 percent of the threshold for "significant medical distress." At the public hearing for H.B. 5644, no recipients provided testimony indicating unreasonable financial hardship in obtaining fertility preservation treatments. However, the testimony of one private organization and one elected official indicated that the cost gap between men and women is very large.[375]

6. The level of public demand and the level of demand from providers for fertility preservation.

Based on public hearing testimony for H.B. 5644 there is some evidence of demand for fertility preservation treatments as a result of necessary medical procedures. Providers articulated the dangers and side-effects of certain therapies for various medical conditions that may cause permanent damage to the reproductive system, and recommended the use of fertility preservation methods for future reproduction to counter this possibility. The University of Connecticut Health Center, Center for Advanced Reproductive Services testified, "Assisted reproductive technology provides real hope and treatment to people challenged by cancer during their reproductive years."[376] Two additional providers emphasized the need for fertility preservation treatment prior to any invasive treatment of a disease/disorder, in order to maintain the possibility of reproduction in the future.[377, 378] Although these testimonies suggest some demand, testimonies are not necessarily representative of whether or not the general public or broader health care community supports the use of fertility preservation treatments.

CPHHP's scan of Connecticut newspapers identified eighteen articles referencing fertility preservation. These publications reflect some demand for fertility preservation treatment, often referencing anecdotes and research studies.

The evidence for provider support for fertility preservation is mixed when guidelines are compared to practice. Major professional associations in the field of oncology, reproductive medicine, and pediatrics have all issued related guidelines. Existing guidelines and research are limited to patients undergoing chemotherapy or radiation therapy. Although guidelines have been established, a national survey found that only forty-seven percent of oncologists reported routinely referring cancer patients of childbearing age to a

[374] Center for Public Health and Health Policy. Infertility Clinic Survey. Conducted November, 2013.

[375] Public Hearing on H.B. 5644. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by the Permanent Commission on the Status of Women. February 19, 2013. Accessed from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013HB-05644-R000219-The%20Permanent%20Commission%20on%20the%20Status%20of%20Women-TMY.PDF.

[376] Public Hearing on H.B. 5644. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by Lawrence Engmann, MD., The Center for Advanced Reproductive Services. February 19, 2013. Accessed from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013HB-05644-R000219-Lawrence%20Engmann,%20Center%20for%20Advanced%20Reproductive%20Services-TMY.PDF.

[377] Public Hearing on H.B. 5644. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by Lawrence Engmann, MD., The Center for Advanced Reproductive Services. February 19, 2013. Accessed from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013HB-05644-R000219-Lawrence%20Engmann,%20Center%20for%20Advanced%20Reproductive%20Services-TMY.PDF.

[378] Public Hearing on H.B. 5644. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by Arthur Tarantino, MD., The Connecticut State Medical Society and the Connecticut Urology Society. February 19, 2013. Accessed from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013HB-05644-R000219-Arthur%20Tarantino,%20CT%20State%20Medical%20Society-TMY.PDF.

reproductive endocrinologist.[379]

7. The level of public demand and the level of demand from providers for insurance coverage [for fertility preservation}.

Public hearing testimony in favor of H.B. 5644 revealed there is some demand for insurance coverage for fertility preservation procedures when there is a likely risk of infertility as a result of a necessary medical procedure. Specifically, two providers and one legislator with personal experience of related coverage denial recommended that the insurance coverage for preservation methods be mandated as available prior to any disease/disorder treatments that may cause infertility, thus maximizing the possibility of reproduction.[380, 381, 382] Further, the Health Initiatives for the American Cancer Society, the Permanent Commission on the Status of Women, the Connecticut Urology Society, and the Connecticut State Medical Society all expressed their concern with the gender disparity between male and female fertility preservation treatments where women bear a greater cost for these treatments. The Connecticut Association of Health Plans, the Connecticut Business and Industry Association, and the Connecticut Conference of Municipalities all voiced their opposition to the proposal to mandate coverage for fertility preservation.[383, 384, 385] Although these testimonies suggest some demand for insurance coverage, testimonies are not necessarily representative of whether or not the general public or broader health care community supports insurance coverage for fertility preservation treatments.

Outside of public testimony, Anthem's decision to adopt coverage of oocyte and embryo cryopreservation "for women who would become infertile due to cytotoxic therapies such as, chemotherapy, radiation therapy or surgery" may be a reflection of public demand and provider association recommendations.[386] In addition, CPHHP's scan of Connecticut newspapers identified several articles detailing the high cost of fertility preservation. One article indicated that more than half of individuals in need of fertility preservation treatment lack sufficient insurance coverage to cover these costs. Thus, newspapers in Connecticut reflect a slight public and provider demand for insurance coverage for fertility preservation.
Conversely, in Hawaii, carriers reported few requests for coverage of fertility preservation. Three carriers

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[379] Quinn G, Vadaparampil S, Lee J-H. Jacobsen P, Bepler G, et al. Physician referral for fertility preservation in oncology patients: a national study of practice behaviors. *Journal of Clinical Oncology* 2009; 27: 5952-5957.

[380] Public Hearing on H.B. 5644. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by Lawrence Engmann, MD., The Center for Advanced Reproductive Services. February 19, 2013, Accessed from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013HB-05644-R000219-Lawrence%20Engmann,%20Center%20for%20Advanced%20Reproductive%20Services-TMY.PDF.

[381] Public Hearing on H.B. 5644. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by Arthur Tarantino, MD., The Connecticut State Medical Society and the Connecticut Urology Society . February 19, 2013, Accessed from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013HB-05644-R000219-Arthur%20Tarantino,%20CT%20State%20Medical%20Society-TMY.PDF.

[382] Public Hearing on H.B. 5644. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by State Representative Matthew Lesser, 100th District. December 3, 2013, Accessed from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013HB-05644-R000219-Matthew%20Lesser,%20100th%20District-TMY.PDF.

[383] Public Hearing on H.B. 5644. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by The Connecticut Association of Health Plans. February 19, 2013, Accessed from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013HB-05644-R000219-Connecticut%20Association%20of%20Health%20Plans-TMY.PDF.

[384] Public Hearing on H.B. 5644. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by the Connecticut Business and Industry Association. February 19, 2013, Accessed from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013HB-05644-R000219-Jennifer%20Herz,%20CBIA-TMY.PDF.

[385] Public Hearing on H.B. 5644. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by the Connecticut Conference of Municipalities. February 19, 2013, Accessed from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013HB-05644-R000219-The%20Connecticut%20Conference%20of%20Municipalities-TMY.PDF.

[386] Anthem. Medical Policy. MED.00080: Cryopreservation of oocytes or ovarian tissue. Effective date: 8/12/2013. Last review date: 8/8/2013. Accessed December 12, 2013 from: http://www.anthem.com/medicalpolicies/policies/mp_pw_a050519.htm.

reported that between one to ten requests for coverage occur per year; one carrier responded "fertility preservation is an issue that arises infrequently."[387]

8. The likelihood of achieving the objectives of meeting a consumer need as evidenced by the experience of other states.

The National Association of Insurance Commissioners (NAIC) maintains a database of health benefit mandates and the states in which they were enacted. As of September 5, 2013, the NAIC database showed no states require coverage of fertility preservation.[388] Therefore, the experience of other states does not provide any evidence on the likelihood of meeting a consumer need.

The database does show that twenty-four states have health benefit mandates for infertility-related services. Twenty states, including Connecticut, (Arkansas, California, Colorado, Florida, Georgia, Hawaii, Illinois, Maryland, Massachusetts, Montana, New Jersey, New Mexico, New York, North Dakota, Ohio, Rhode Island, Texas, Virginia, West Virginia) mandate at least some coverage for infertility treatment while two states (Minnesota, Utah) mandate that the diagnosis of infertility be covered. Arkansas, Colorado, Georgia, Hawaii, Massachusetts, Rhode Island and West Virginia have mandates similar to Connecticut.[389] Louisiana prohibits the exclusion of coverage of medical conditions on the basis of infertility.

9. The relevant findings of state agencies or other appropriate public organizations relating to the social impact of the mandated health benefit.

No states currently require coverage of fertility preservation. A search of the thirty states that require a fiscal note or an additional review process for any proposed health insurance benefit enactment[390] was conducted to identify the relevant findings of state agencies. California, Hawaii and New Jersey are the only states that had entertained a proposal to mandate coverage for fertility preservation. These states also require a fiscal note or additional review process. Both California and Hawaii published fertility preservation mandated benefit reviews. This section provides a brief summary of relevant findings from the reviews. However, these assessments reflect projected impacts not actual social impacts following implementation of a related mandate.

California. Evaluations were conducted by the California Health Benefit Review Program (CHBRP) for Assembly Bill 428 (2011)[391] and Assembly Bill 912 (2013).[392] Both bills proposed requiring managed health care and insurance carriers to offer coverage for fertility preservation services for patients whose medical treatment may result in infertility. Projections are provided for standard cryopreservation methods for those at risk of infertility resulting from cytotoxic treatments. The CHBRP made several conclusions regarding the social impact of the proposed legislation.

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[387] Office of the Auditor, State of Hawaii. Mandatory Health Insurance Coverage for Fertility Preservation Procedures for People of Reproductive Age Diagnosed with Cancer. Accessed September 5, 2013 from: http://www.state.hi.us/auditor/Reports/2012/12-09.pdf.

[388] National Association of Insurance Commissioners. Mandated Benefits: Women's Health, Pregnancy, Fertility and Preventive Care. August, 2011.

[389] Wakai S, Benson B. Chapter Five: Infertility diagnosis and treatment. Connecticut Mandated Health Insurance Benefits Reviews, 2010. Center for Public Health and Health Policy. January 2011. Accessed December 1, 2013 from: http://www.ct.gov/cid/lib/cid/2010_Connecticut_Mandated_Health_Insurance_Benefits_Reviews_-_Volume_II.pdf.

[390] California Health Benefits Review Program. Other States' Health Benefit Review Programs, 2011. Accessed September 5, 2013 from: http://www.chbrp.org/other_publications/docs/other_states_health_benefits2011.pdf.

[391] California Health Benefits Review Program. Analysis of Assembly Bill 428: Fertility Preservation. Accessed September 5, 2013 from: http://chbrp.ucop.edu/index.php?action=read&bill_id=124&doc_type=3.

[392] California Health Benefits Review Program. Analysis of Assembly Bill 912: Health Care Coverage: Fertility Preservation. Accessed September 5, 2013 from: http://chbrp.ucop.edu/index.php?action=read&bill_id=147&doc_type=3.

- If enacted, the proportion of enrollees with fertility preservation coverage would increase from 8.3 percent to 100 percent, with an average increase in premium of $0.01 PMPM. A 29 percent increase in fertility preservation utilization by those at risk for infertility from cytotoxic treatments was anticipated. CHBRP attributed the anticipated increase in utilization to the reduction in out-of-pocket costs or financial burden associated for procedures that were previously not covered.
- Of total persons expected to undergo preservation, fewer than 14 percent would be female, compared to 6.4 percent pre-mandate. By gender, utilization post-mandate would increase by 19 percent among male enrollees and 175 percent among female enrollees.
- Insurance coverage would decrease the gender disparity in the financial burden of expenses related to fertility preservation, though females would still face greater out-of-pocket costs given the substantially higher cost for procedures used for females.
- CHBRP suggests quality of life may improve for some of the patients who would have coverage as a result of A.B. 912. Projected annual long-term benefits could include an estimated twenty additional cancer patients having a biological child as a result of A.B. 912. No reduction in premature death or associated economic loss was anticipated.

Hawaii.[393] The evaluation was conducted for H.B. 2105, a bill requiring providers to offer coverage for fertility preservation services for people of reproductive age diagnosed with cancer. Social and financial impacts are described as difficult to determine based on the lack of data. However, the State Auditor of Hawaii made some conclusions, many based on carrier or other stakeholder survey responses, regarding the social impact of the proposed legislation.

- The population of individuals of reproductive age diagnosed with cancer that may be affected by H.B. 2105 is relatively small, the level of public demand is low and insurance coverage is generally not available.
- The Hawaii Medical Assurance Association (HMAA) claimed that mandating coverage will prevent resources from being applied to other medical care that may impact a broader base of individuals.
- The impact of providing coverage on morbidity and mortality would be low according to the American Cancer Society, the HMAA and University Health Alliance.

10. The alternatives to meeting the identified need, including but not limited to, other treatments, methods or procedures.

For individuals at risk of infertility from a necessary medical procedure, there are few alternatives. As described in the background section, less invasive surgical procedures may, at time, be appropriate. However, this is only relevant to certain cases of cancers impacting the reproductive organs. (For additional detail, refer to Table 3.2). Even so, individuals undergoing less invasive procedures may still need to undergo cytotoxic treatments.[394]

For individuals receiving pelvic radiation therapy, pelvic shielding is sometimes used to shield the abdomen. With females, this may or may not be combined with a method called ovarian transposition. However, due to radiation scatter, the ovaries are not always protected by transposition and this method is not always

[393] Office of the Auditor, State of Hawaii. Mandatory Health Insurance Coverage for Fertility Preservation Procedures for People of Reproductive Age Diagnosed with Cancer. Accessed September 5, 2013 from: http://www.state.hi.us/auditor/Reports/2012/12-09.pdf.

[394] Rodriguez-Macias Wallberg K, Keros V, Hovatta O. Review Clinical Aspects of Fertility Preservation in Female Patients. *Pediatric Blood & Cancer.* 2009; 53: 254-260.

successful for preserving female fertility.[395] Cryopreservation of sperm, oocytes or embryos is the only other recommended medical procedure. Alternative medical procedures, such as the cryopreservation of reproductive tissues and reimplantation, are investigational or experimental. Hormone suppression therapy is also sometimes used but current evidence indicates a lack of effectiveness.[396]

Individuals may also elect not to undergo medical procedures to preserve fertility, beyond gonadal shielding and less-invasive surgical procedures, as applicable. Of those who do not undergo fertility preservation, some may achieve a successful pregnancy without intervention. If female and infertile, the patient or a surrogate may elect to undergo IVF using a donor oocyte fertilized by partner or donor sperm. If male and infertile, the patient's female partner or surrogate may use donor sperm artificial insemination or assisted reproductive technology. Attempts at pregnancy following fertility preservation or using these options, does not guarantee success. Individuals may also choose to adopt or to forgo having children, as an alternative to undergoing fertility preservations procedures.

11. Whether the benefit is a medical or broader social need and whether it is consistent with the role of health insurance and the concept of managed care.

Medical or social need. It is possible to conceptualize fertility preservation as proposed in H.B. 5644 as meeting a medical need or broader social need. Child bearing is largely considered a social need, yet infertility unquestionably involves medical issues. Treatment of infertility and fertility preservation both involve medical procedures to address a medical issue or potential medical issue. However, some may suggest having a biologic child is a social need and not a medical need; therefore, any medical treatments to have a biologic child or preserve fertility is not a medical need.

An alternate approach to considering medical need is to apply the definition of medical necessity to the use of fertility preservation. The American Medical Association defines medical necessity as: "Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider."[397]

The proposed mandate is partially consistent with criterion (a). There are generally accepted standards for fertility preservation using cryopreservation for sperm, oocyte or embryos for cancer patients; therefore, to this extent, the proposed mandate can be considered a medical need.

Role of Health Insurance. In the current system, health providers often prescribe medication and perform treatment to minimize the risk of future medical problems, such as mole removal to prevent skin cancer and blood pressure medicine to prevent a heart attack.[398] This is generally covered by health insurance. This a change from the traditional purpose of insurance policies as a means of financial security in times of economic uncertainty following unexpected events such as premature death, disease, accident or disability.

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[395] Loren AW et al. Fertility preservation for patients with cancer: American society of clinical oncology clinical practice guideline update. *Journal of Clinical Oncology*. 2013; 31(19):2500-10.

[396] Ibid.

[397] Statement of the American Medical Association to the Institute of Medicine's Committee on Determination of Essential Health Benefits. Accessed January 14, 2011 from: http://www.iom.edu/~/media/Files/Activity%20Files/HealthServices/EssentialHealthBenefits/2011-JAN-13%20and%2014/Gerald%20Harmon%20Statement.pdf.

[398] Basco D, Campo-Engelstein L, Rodriguez S. Insuring against infertility: expanding state infertility mandates to include fertility preservation technology for cancer patients. *The Journal of Law, Medicine & Ethics.* 2010; 38(4): 832-839.

However, over time insurance benefits have expanded beyond catastrophic events or indemnity policies. Preventive medicine and follow-up care such as breast reconstructive surgery after mastectomy are now coverage norms. Whether the proposed mandate is consistent with the concept of health insurance is defined largely by how a person conceptualizes the role of the health care system. Fertility preservation procedures and ongoing storage are expensive. The desire to preserve fertility following an unexpected need to undergo treatment(s) likely to cause infertility could add to economic uncertainty for those who preserve. Alternatively, fertility preservation could be considered by some a departure from primary health care services or beyond the scope of what should be covered.

Concept of Managed Care. Merriam-Webster defines managed care as "a system of health care (as by an HMO or PPO) that controls costs by placing limits on physicians' fees and by restricting the patient's choice of physicians." Managed care uses a combination of provider selection and organization of providers, methods and levels of payment for providers, and monitoring and management of service utilization. Examples of managed care tools include prospective pricing, "usual, customary, and reasonable pricing of services; peer review, mandatory use review, benefit redesign, capitation payments, channeling, quality criteria, and health promotion."[399] In addition there are financial care reimbursement policies such as negotiated fees and service bundling. The only anticipated conflict between the proposed mandate and managed care techniques is that utilization management procedures that would otherwise deem fertility preservation as uncovered could no longer be used.

12. The potential social implications of the coverage with respect to the direct or specific creation of a comparable mandated benefit for similar diseases, illnesses, or conditions.

This proposal to cover fertility preservation can be conceptualized as an expansion on the current infertility treatment mandate, which requires the coverage of medically necessary costs for diagnosing and treating infertility. Testimony from State Representative Matthew Lesser recommended "to amend Sec. 38a-509," the current infertility mandate to include "when an individual's physician has determined that permanent infertility is likely to result from necessary treatment from cancer or another disease."[400] If discussions open on how to define infertility, infertility mandate coverage may be redefined to include those at risk of infertility and others who would like to conceive using artificial insemination or ART.

Further implications exist if the proposed language is enacted as written.

- A broad interpretation of "as a result of a necessary medical procedure" could include pharmaceuticals, surgical procedures or other treatments. For example, pelvic surgery, including those for infertility procedures, can result in pelvic adhesions. Pelvic adhesions are bands of scar tissue that bind the organs and are a known cause of female infertility. Would pelvic surgery to treat a medical condition invoke coverage of fertility preservation?
- Infertility may be interpreted as a permanent or temporary condition. The medical procedure may be interpreted to include pharmaceutical treatments where the infertility symptoms subside if the medication is discontinued. Many of these pharmaceuticals, when taken during pregnancy, pose a risk to the fetus during pregnancy.
- At what threshold will a medical procedure be considered likely to cause infertility? In many cases, existing evidence may make such a distinction difficult.

Proposing coverage for fertility preservation is also in some ways similar to Connecticut's existing coverage

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[399] Curtiss FR. Managed health care. *American Journal of Hospital Pharmacy.* 1989; 46(4): 742-63.

[400] Public Hearing on H.B. 5644. Conn. Joint Standing Committee Hearings, Insurance and Real Estate, 2013 Sess., testimony submitted by State Representative Matthew Lesser, 100th District., December 3, 2013. Accessed from: http://www.cga.ct.gov/2013/INSdata/Tmy/2013HB-05644-R000219-Matthew%20Lesser,%20100th%20District-TMY.PDF.

mandates for wigs or breast reconstruction (§38a-504a-c and §38a-542a-c), where the physical loss occurs as a result of non-negligent medical treatment for a medical condition. The primary difference is that cryopreservation occurs before the procedure, fertility may not be lost, and cryopreservation does not guarantee the ability to conceive a child in the future.

13. The impact of the benefit on the availability of other benefits currently offered.

It does not seem likely that providing the benefits under H.B. 5644 would reduce the availability of other benefits.

14. The impact of the benefit as it relates to employers shifting to self-insured plans and the extent to which the benefit is currently being offered by employers with self-insured plans.

Carrier responses suggest that a large majority of self-funded groups do not cover fertility preservation in a manner consistent with the proposed mandate. It is unknown whether self-funded groups in Connecticut may add fertility preservation if that becomes a norm of coverage for employers with fully insured plans. For example, in Connecticut, 75 percent of members in self-funded groups reported coverage for infertility diagnosis and treatment, which is a mandate for fully insured groups.[401]

Employer decisions to switch to self-funded are complex economic decisions involving multiple factors. Mandated benefits, specifically H.B. 5644 are not expected to play a primary role in such decisions. As estimated by Optum, proposed coverage for fertility preservation will account for approximately 0.012 percent of the average group premiums in 2014. Employers absorb only some of this cost increase through the premium contributions they make. In 2012, private sector employers contributed on average 70 to 79 percent of the median premium, depending on whether the plan was employee only, employee-plus one, or a family plan.[402]

Decisions to switch to self-funded are more likely to be driven by the extent of annual premium increase, the extent of employer desire to have control over plan design, Affordable Care Act requirements, and whether these concerns would be adequately addressed through self-funded status. The potential benefit of switching to self-funded comes from the federally legislated Employee Retirement Income Security Act (ERISA). Becoming self-funded translates into such plans being ERISA-exempted from state insurance mandates, Connecticut's 1.75 percent premium tax, and insurer profit margins and risk charges.

15. The impact of making the benefit applicable to the state employee health insurance or health benefits plan.

The State of Connecticut employee health benefits plan transitioned from fully insured to self-funded as of July 1, 2010. As a self-funded group, the State of Connecticut is exempt from state health insurance mandates under the federal Employee Retirement Income Security Act (ERISA) law. If the State Comptroller's Office or the Connecticut General Assembly decided to extend the proposed coverage to the state employee health plan, the social impact of the benefit for the approximately 161,368 covered lives under age 65 in state employee and retiree plans, of whom 28,913 are state retirees under age 65,[403] is expected to be the same or similar to the social impact for persons covered in non-state employee health insurance plans as discussed throughout Section IV of this report. In terms of financial impact, the Optum

[401] Wakai S, Benson B. Chapter Five: Infertility diagnosis and treatment. Connecticut Mandated Health Insurance Benefits Reviews, 2010. Center for Public Health and Health Policy. January 2011. Accessed December 1, 2013 from: http://www.ct.gov/cid/lib/cid/2010_Connecticut_Mandated_Health_Insurance_Benefits_Reviews_-_Volume_II.pdf.

[402] Medical Expenditure Panel Survey. Private-Sector Data Premium, Contribution and Cost Distributions. 2012.

[403] Personal communication. Tracy Dunn. State of Connecticut Comptroller's Office. November 8, 2013.

analysis estimates the total paid medical cost to the state employee health plan would total $8,019 per month or $96,228 annually in 2014.

Caveat: It should be noted that the estimated cost to the State plan is calculated using the same weighted averages as was used for the other cost calculations. The actual cost of the mandates to the State plan may be higher or lower, based on the actual benefit design of the State plan and the demographics of the covered lives (e.g., level of cost-sharing, average age of members, etc.).

16. The extent to which credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community determines the treatment, service or equipment, supplies or drugs, as applicable, to be safe and effective.

Cryopreservation of sperm, oocytes and embryos are not considered experimental or investigational. The American Society of Reproductive Medicine (ASRM) defines a treatment as experimental or investigational "until the published medical evidence regarding their risks, benefits and overall safety and efficacy is sufficient to regard them as established medical practice."[404] ASCO, ASRM and SART include cryopreservation of sperm, oocytes and embryos as standard practices for fertility preservation. As such, these procedures are considered to be safe and effective. However, the evidence level for oocyte cryopreservation, according to ASCO Guidelines, is not considered as strong as embryo cryopreservation. Existing guidelines do not support routine substitution of oocyte cryopreservation for embryo cryopreservation.

Safety. Although considered safe, a low level of risk exists for ovarian stimulation, surgical retrieval of oocytes and related anesthesia.[405]

- At the time of this review, debate exists around the appropriateness and risks of using conventional ovarian stimulation for estrogen sensitive cancers, such as breast, endometrial or gynecological cancers.[406, 407] Animal studies show a potential for accelerated tumor growth when using conventional methods; however, it is questioned whether increased short-term stimulation truly increases risk for humans.
- Use of ovarian stimulation can cause ovarian hyperstimulation syndrome (OHSS), in an estimated 2.1-4.7 percent of patients.[408] OHSS symptoms may include lower abdominal pain, fluid buildup in the abdomen, shortness of breath, nausea, vomiting, enlarged ovaries, abnormal blood chemistry and in rare cases, complications such as blood clot or kidney failure.
- Surgical complications, most of which occur during fewer than 0.1 percent of procedures, include vaginal bleeding, intra-abdominal bleeding, intestinal injuries, inflammation of the lining of the abdominal cavity, and ovarian torsion.[409]

In addition, the future use of cryopreserved sperm, oocytes or embryos requires the use of artificial insemination or assisted reproductive technology (ART). Use of ART elevates the risk for multiple

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[404] American Society for Reproductive Medicine. Definition of experimental procedures: a committee opinion. 2013; 99(1): 1197-8.

[405] Institute of Medicine (IOM) and National Research Council (NRC). Assessing the medical risks of human oocyte donation for stem cell research: Workshop Report. 2007. Washington, DC: The National Academies Press.

[406] Kim S, Klemp J, Fabian C. Breast cancer and fertility preservation. *Fertility and Sterility*®. 2011; 95(5): 1535-43.

[407] Loren AW et al. Fertility preservation for patients with cancer: American society of clinical oncology clinical practice guideline update. *Journal of Clinical Oncology.* 2013; 31(19):2500-10.

[408] Institute of Medicine (IOM) and National Research Council (NRC). Assessing the medical risks of human oocyte donation for stem cell research: Workshop Report. 2007. Washington, DC: The National Academies Press.

[409] Ibid.

gestations, congenital anomalies, preterm delivery, low birth weight, and the complications associated with these outcomes.[410]

Effectiveness. The cryopreservation procedures are considered effective. However, it is important to delineate that a minority of cryopreserved specimens are not viable for future use. It is also important to clarify that future use of a cryopreserved specimen does not guarantee fertilization, implantation, or a live birth will occur. According to the CDC's 2011 Assisted Reproductive Technology Success Rates Report, national norms of live birth rates per transfer with frozen embryos from non-donor eggs were 39 percent for women younger than 35, 35.5 percent for women ages 35-37, and 29.7 for women 38-40.[411]

The SART/ASRM guidelines report, "[T]here is good evidence that fertilization and pregnancy rates are similar to IVF/ICSI with fresh oocytes when vitrified/warmed oocytes are used as part of IVF/ICSI in young patients."[412] Findings from Noyes, et al. also suggest that frozen thawed embryos and frozen-thawed oocytes have comparable live birth rates.[413] Oocyte thaw success rates vary by freezing technique, with better success among vitrified oocytes. Vitrified oocyte success rates in four large randomized controlled trials ranged from 90-97 percent for oocyte survival after vitrification, 71-79 percent for fertilization, 17-41 percent for implantation and 36-61 percent for clinical pregnancy per oocyte transfer or 4.5-12 percent per thawed oocyte.[414] Another study suggests that success rates for implantation vary according to the age when the oocyte vitrification occurred. In this study, eggs vitrified at age forty had a 4 percent lower implantation rate. Vitrified oocytes had a thaw survival rate of 85 percent, a fertilization rate of 79 percent and an implantation rate of 13 percent for women younger than thirty years old at preservation.[415]

V. Financial Impact

1. The extent to which the mandated health benefit may increase or decrease the cost of the treatment, service or equipment, supplies or drugs, as applicable, over the next five years.

The Optum report does not anticipate a change in the unit cost of fertility preservation procedures. Although use of fertility preservation is anticipated to increase, this new utilization "is not expected to greatly increase the demand relative to the supply" of medical providers. This same finding, no change to unit cost is also reported by the California Health Benefit Review Program's review of two similar mandate proposals, A.B. 428[416] and A.B. 912.[417]

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[410] Paulson R. Pregnancy outcome after assisted reproductive technology. *UpToDate.*® Eds. Lockwood C, Barbieri R, Barss V. Literature review current through Nov. 2013. Topic last updated Nov 15, 2013.

[411] Centers for Disease Control and Prevention. American Society for Reproductive Medicine, Society for Assisted Reproductive Technology. 2011 Assisted Reproductive Technology Success Rates: National Summary and Fertility Clinic Reports. Accessed December 9, 2013 from: http://nccd.cdc.gov/DRH_ART/Apps/NationalSummaryReport.aspx.

[412] The Practice Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. Mature oocyte cryopreservation: a guideline. *Fertility and Sterility*®. 2013; 99(1)37-43.

[413] Kim S, Klemp J, Fabian C. Breast cancer and fertility preservation. *Fertility and Sterility*®. 2011; 95(5):1535-43.

[414] The Practice Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. Mature oocyte cryopreservation: a guideline. *Fertility and Sterility*®. 2013; 99(1)37-43.

[415] Cil A, Bang H, Oktay K. Age-specific probability of live-birth with oocyte cryopreservation: an individual patient data meta-analysis. *Fertility and Sterility*®, in press, 2013.

[416] California Health Benefits Review Program. Analysis of Assembly Bill 912: Health Care Coverage: Fertility Preservation. Accessed September 5, 2013 from: http://chbrp.ucop.edu/index.php?action=read&bill_id=147&doc_type=3.

[417] Ibid.

2. The extent to which the mandated health benefit may increase the appropriate or inappropriate use of the treatment, service or equipment, supplies or drugs, as applicable, over the next five years.

Adequacy of available data limits the ability to provide a five year projection for changes in utilization of fertility preservation. Optum suggested two scenarios for changes in utilization. The first scenario assumes a 10 percent annual increase beyond the normal trend while the second assumes an additional 5 percent increase in utilization each year. Per these scenarios, over five years use of fertility preservation would increase from 29 to 46.7 or 58.3 percent of males and 4 to 6.4 or 8 percent for females (p.58). This is holding the mandate language and population constant. Optum's projected increase is larger than that suggested in the California report, which assumed utilization post-mandate would increase by 19 percent among male enrollees and 175 percent among female enrollees. Applying the California assumption to Connecticut, utilization would be a much lower 34.5 percent for males and 7 percent for females.[418]

3. The extent to which the mandated health benefit may serve as an alternative for more expensive or less expensive treatment, service or equipment, supplies or drugs, as applicable.

The proposed benefit, cryopreservation of sperm, oocytes, or embryos can best be considered an additional medical procedure. There are no established alternative medical procedures recommended by professional guidelines. The medical care alternative is not conducting the procedure(s) for fertility preservation. For individuals who hope to conceive children after treatment, cryopreservation and subsequent use of assisted reproductive technology may be an alternative to future non-medical alternative treatments to infertility, such as surrogacy, adoption, and child-free living.[419] Depending on the adoption route taken, adoption cost can vary, averaging over $30,000 for domestic adoptions through agencies but less than $5,000 for foster care adoptions.[420]

4. The methods that will be implemented to manage the utilization and costs of the mandated health benefit.

Benefit plan limitations, plan structure and review processes are common strategies used to control utilization and costs. The proposed mandate does not include language that expressly prohibits or allows utilization management or benefit plan structure, other than requiring coverage of fertility preservation. It is anticipated that carriers will therefore, manage utilization and costs using standard methods. Notably, carriers frequently establish medical or administrative policies related to certain health conditions or specific treatments. This method seems likely to be adopted for fertility preservation since it is already used by some carriers for infertility treatment. Pre-service review may also be used. This review process explores consistency with medical necessity and benefit plan language by requiring that a treatment or procedure be pre-approved before a member obtains the service.

5. The extent to which insurance coverage for the treatment, service or equipment, supplies or drugs, as applicable, may be reasonably expected to increase or decrease the insurance premiums and administrative expenses for policyholders.

Insurance premiums include medical cost and retention costs. Retention costs comprise administrative cost and profit (for for-profit insurers/MCOs) or contribution to surplus (for not-for-profit insurers/MCOs). Optum's projected premium for fertility preservation coverage in 2014 would be an estimated $0.059 per

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[418] Ibid.

[419] Macaluso M. A public health focus on infertility prevention, detection and management. *Fertility and Sterility*®. 2008; 93(1): 16e1-16e10.

[420] Adoptive Families. Cost of Adoption Update; 2010-2011. 2010-2011 Cost & Timing of Adoption Survey. Accessed December 23, 2013 from: http://www.adoptiAB vefamilies.com/articles.php?aid=2350.

member per month (PMPM) for fully insured group policyholders, which is 0.012 percent of the average total premium for group plans. Optum projected $0.062 PMPM for individual policies, which is 0.021 percent of the average total premium for individual policies. Medical costs account for an average $0.05 of the PMPM for group plans and $0.051 of the PMPM for individual policies.

Based on 2012 Connecticut data from the Medical Expenditure Panel Survey, private sector employers offering health plans contributed an average of 70-79 percent of the median premium, depending on whether the plan was employee only, employee-plus one, or a family plan.[421] Therefore, the average employer would pay less than $56 per 100 employees for 2014.[422] Available research is inadequate to justify any savings from potential medical costs avoided in the future or any potential increases in employee productivity.

CPHHP identified two states as having completed analyses concerning fertility preservation mandate legislation. Optum's estimated PMPM and percent of premium are somewhat higher than those estimated for two similar mandate proposals in California. According to the California Health Benefit Review Program (CHBRP), the premium impact of A.B. 428 included an average increase of 0.00 to 0.017 percent in PMPM premium, which translates as a $0.00-$0.037 PMPM premium increase.[423] Similarly, an average $0.01 PMPM premium increase was estimated for A.B. 912.[424]

Carrier estimates for the cost of the mandate are much higher than those suggested by Optum and CHBRP. Connecticut-domiciled carriers responding to the CPHHP survey estimated a paid cost of $0 to $1.63, with a mean paid cost of $0.84 for group plans and $0.81 for individual policies. The mean paid costs are similar to the $0.84 PMPM suggested by one carrier during the evaluation of Hawaii's H.B. 2105, a bill requiring providers to offer coverage for fertility preservation services for people of reproductive age diagnosed with cancer.[425]

6. The extent to which the treatment, service or equipment, supplies or drugs, as applicable, is more or less expensive than an existing treatment, service or equipment, supplies or drugs, as applicable, that is determined to be equally safe and effective by credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community.

The only established safe and effective alternatives to sperm, oocyte and embryo cryopreservation is to substitute less invasive surgical methods when the course of treatment is surgery. (Refer to Background, Table 3.1). However, less-invasive surgical methods are only relevant as treatments for certain cancers and apply only to cases where later treatment does not involve cytotoxic treatments deemed risky to fertility. Generally speaking, when a less invasive surgical treatment is available and appropriate, it is assumed that this treatment is adopted. In addition, sperm, oocyte or embryo cryopreservation may be considered and pursued as an additional measure to preserve fertility.

7. The impact of insurance coverage for fertility preservation on the total cost of health care,

[421] Medical Expenditure Panel Survey. Private-Sector Data Premium, Contribution and Cost Distributions. 2012.

[422] Calculation uses $0.0585 PMPM x 79% x 12 months x 100 employees.

[423] California Health Benefits Review Program. Analysis of Assembly Bill 428: Fertility Preservation. Accessed September 5, 2013 from: http://chbrp.ucop.edu/index.php?action=read&bill_id=124&doc_type=3.

[424] California Health Benefits Review Program. Analysis of Assembly Bill 912: Health Care Coverage: Fertility Preservation. Accessed September 5, 2013 from: http://chbrp.ucop.edu/index.php?action=read&bill_id=147&doc_type=3.

[425] Office of the Auditor, State of Hawaii. Mandatory Health Insurance Coverage for Fertility Preservation Procedures for People of Reproductive Age Diagnosed with Cancer. Accessed September 5, 2013 from: http://www.state.hi.us/auditor/Reports/2012/12-09.pdf.

including potential benefits or savings to insurers and employers resulting from prevention or early detection of disease or illness related to such coverage.

The total cost of health care is understood to be the total medical cost paid by the carriers plus the total cost-sharing paid by the insureds; combined, this is referred to as the allowed cost. Holding the mandate language and population constant, Optum projected the 2014 allowed cost of the proposed benefit as $71,932 per month or $863,184 annually, of which $56,997 (79 percent) per month is for medical claims covered by the carrier and $14,935 (21 percent) per month is paid by employees as cost-sharing. The estimated total cost of health care does not include any potential benefits or savings that may result from fertility preservation. Although some savings or additional costs may occur, the existing literature does not adequately justify parameters for such an estimate.

8. The impact of the mandated health care benefit on the cost of health care for small employers, as defined in section 38a-564 , and for employers other than small employers.

Optum estimates on average, the 2014 total premium paid for fertility preservation is 0.012 percent of the average $482 premium paid PMPM for group health insurance plans. Both small (<50 employees) and larger employers contribute roughly 78 percent of the premium for single plans and 74 to 76 percent of family plans, respectively.[426] Given that utilization of fertility preservation is anticipated to account for a small percentage of the total premium, it appears reasonable to expect that the impact of H.B. 5644 would be minimal for employers, regardless of size. Further, the average impact for covering all employees for a small employer would be less than $28.00 for the year.

9. The impact of the mandated health benefit on cost-shifting between private and public payers of health care coverage and on the overall cost of the health care delivery system in the state.

The overall cost of the health delivery system in the state is understood to include total insurance premiums (medical costs and retention) and cost-sharing. The 2014 projection for the overall cost to the health care delivery system for the coverage of fertility preservation as proposed for the population enrolled in fully insured group plans and individual policies is $81,990 per month or $983,880 annually. $56,997 per month is attributed to paid medical claims, $14,935 per month to cost-sharing, and $10,058 per month to retention. Of the overall spending, an estimated 18.2 percent is paid by the insured as cost-sharing.

A shift in cost from the public to private sector for health care coverage is not anticipated as result of mandating insurance coverage of fertility preservation. This is not a service that would otherwise be paid for through the public sector. However, under the Affordable Care Act, the state may be responsible for covering any added cost as a result of the proposed mandate for plans purchased through the state Health Insurance Exchange.

[426] Medical Expenditure Panel Survey. Private-Sector Data Premium, Contribution and Cost Distributions. 2012.

Appendix I

Committee Letter of 07/19/2013

State of Connecticut
GENERAL ASSEMBLY

Senator Joseph J. Crisco, Jr.
CO-CHAIRMAN

Senator Joan V. Hartley, *Vice Chair*
Senator Kevin C. Kelly, *Ranking Member*

Representative Robert W. Megna
CO-CHAIRMAN

Representative Christopher A. Wright, *Vice Chair*
Representative Robert C. Sampson, *Ranking Member*

INSURANCE AND REAL ESTATE COMMITTEE

INSURANCE DEPARTMENT
STATE OF CONNECTICUT
2013 JUL 22 AM 7 55

July 19, 2013

Thomas B. Leonardi, Commissioner
State of Connecticut Insurance Department
P O Box 816
Hartford, CT 06142-0816

REVISED LETTER

Dear Commissioner Leonardi,

Pursuant to Section 1(c) of Public Act 09-179, we respectfully request that the Insurance Department through its statutory designees, review several particular proposed health benefits.

Specifically, we request a cost-benefit analysis of the following:

- **PANDAS (SB956)** To require health insurance coverage for the diagnosis and pediatric autoimmune neuropsychiatric disorder associated with streptococcal infections to require the Dept of Public health to develop programs and promote research on pediatric autoimmune neuropsychiatric disorder associated with streptococcal infections.
- **Lung Cancer Screening (SB 862)** To require health insurance coverage for lung cancer screening tests, in accordance with the recommendations established by the American Lung association after consultation with the American Cancer Society.
- **Fertility Preservation (HB 5644)** To require health insurance coverage of fertility preservation for insureds facing likely infertility as a result of a necessary medical procedure for insured with cancer and other medical conditions.

REVISED:

- **Mental Disorder and Drug Addiction(SB 1091)** To establish a task force to study health insurance coverage of and program enrollment options for treatment that is ordered by a court for mental disorders.

Thank you for your attention to our request. We look forward to hearing from you and /or your designees.

Best regards,

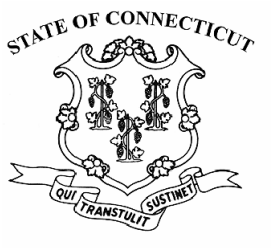
Senator Joseph Crisco, Jr.
Co-Chair Insurance & Real Estate Committee

Representative Robert W. Megna
Co-Chair, Insurance & Real Estate Committee

Room 2800 L.O.B., 300 Capitol Avenue, Hartford, CT 06106-1591 ❖ Phone: (860) 240-0510 ❖ FAX: (860) 240-0027

Appendix II

Public Act 09-179



House Bill No. 5018

Public Act No. 09-179

AN ACT CONCERNING REVIEWS OF HEALTH INSURANCE BENEFITS MANDATED IN THIS STATE.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective July 1, 2009*) (a) As used in this section:

(1) "Commissioner" means the Insurance Commissioner.

(2) "Mandated health benefit" means an existing statutory obligation of, or proposed legislation that would require, an insurer, health care center, hospital service corporation, medical service corporation, fraternal benefit society or other entity that offers individual or group health insurance or medical or health care benefits plan in this state to: (A) Permit an insured or enrollee to obtain health care treatment or services from a particular type of health care provider; (B) offer or provide coverage for the screening, diagnosis or treatment of a particular disease or condition; or (C) offer or provide coverage for a particular type of health care treatment or service, or for medical equipment, medical supplies or drugs used in connection with a health care treatment or service. "Mandated health benefit" includes any proposed legislation to expand or repeal an existing statutory obligation relating to health insurance coverage or medical benefits.

(b) (1) There is established within the Insurance Department a

health benefit review program for the review and evaluation of any mandated health benefit that is requested by the joint standing committee of the General Assembly having cognizance of matters relating to insurance. Such program shall be funded by the Insurance Fund established under section 38a-52a of the general statutes. The commissioner shall be authorized to make assessments in a manner consistent with the provisions of chapter 698 of the general statutes for the costs of carrying out the requirements of this section. Such assessments shall be in addition to any other taxes, fees and moneys otherwise payable to the state. The commissioner shall deposit all payments made under this section with the State Treasurer. The moneys deposited shall be credited to the Insurance Fund and shall be accounted for as expenses recovered from insurance companies. Such moneys shall be expended by the commissioner to carry out the provisions of this section and section 2 of this act.

(2) The commissioner shall contract with The University of Connecticut Center for Public Health and Health Policy to conduct any mandated health benefit review requested pursuant to subsection (c) of this section. The director of said center may engage the services of an actuary, quality improvement clearinghouse, health policy research organization or any other independent expert, and may engage or consult with any dean, faculty or other personnel said director deems appropriate within The University of Connecticut schools and colleges, including, but not limited to, The University of Connecticut (A) School of Business, (B) School of Dental Medicine, (C) School of Law, (D) School of Medicine, and (E) School of Pharmacy.

(c) Not later than August first of each year, the joint standing committee of the General Assembly having cognizance of matters relating to insurance shall submit to the commissioner a list of any mandated health benefits for which said committee is requesting a review. Not later than January first of the succeeding year, the

commissioner shall submit a report, in accordance with section 11-4a of the general statutes, of the findings of such review and the information set forth in subsection (d) of this section.

(d) The review report shall include at least the following, to the extent information is available:

(1) The social impact of mandating the benefit, including:

(A) The extent to which the treatment, service or equipment, supplies or drugs, as applicable, is utilized by a significant portion of the population;

(B) The extent to which the treatment, service or equipment, supplies or drugs, as applicable, is currently available to the population, including, but not limited to, coverage under Medicare, or through public programs administered by charities, public schools, the Department of Public Health, municipal health departments or health districts or the Department of Social Services;

(C) The extent to which insurance coverage is already available for the treatment, service or equipment, supplies or drugs, as applicable;

(D) If the coverage is not generally available, the extent to which such lack of coverage results in persons being unable to obtain necessary health care treatment;

(E) If the coverage is not generally available, the extent to which such lack of coverage results in unreasonable financial hardships on those persons needing treatment;

(F) The level of public demand and the level of demand from providers for the treatment, service or equipment, supplies or drugs, as applicable;

(G) The level of public demand and the level of demand from

providers for insurance coverage for the treatment, service or equipment, supplies or drugs, as applicable;

(H) The likelihood of achieving the objectives of meeting a consumer need as evidenced by the experience of other states;

(I) The relevant findings of state agencies or other appropriate public organizations relating to the social impact of the mandated health benefit;

(J) The alternatives to meeting the identified need, including, but not limited to, other treatments, methods or procedures;

(K) Whether the benefit is a medical or a broader social need and whether it is consistent with the role of health insurance and the concept of managed care;

(L) The potential social implications of the coverage with respect to the direct or specific creation of a comparable mandated benefit for similar diseases, illnesses or conditions;

(M) The impact of the benefit on the availability of other benefits currently offered;

(N) The impact of the benefit as it relates to employers shifting to self-insured plans and the extent to which the benefit is currently being offered by employers with self-insured plans;

(O) The impact of making the benefit applicable to the state employee health insurance or health benefits plan; and

(P) The extent to which credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community determines the treatment, service or equipment, supplies or drugs, as applicable, to be safe and effective; and

(2) The financial impact of mandating the benefit, including:

(A) The extent to which the mandated health benefit may increase or decrease the cost of the treatment, service or equipment, supplies or drugs, as applicable, over the next five years;

(B) The extent to which the mandated health benefit may increase the appropriate or inappropriate use of the treatment, service or equipment, supplies or drugs, as applicable, over the next five years;

(C) The extent to which the mandated health benefit may serve as an alternative for more expensive or less expensive treatment, service or equipment, supplies or drugs, as applicable;

(D) The methods that will be implemented to manage the utilization and costs of the mandated health benefit;

(E) The extent to which insurance coverage for the treatment, service or equipment, supplies or drugs, as applicable, may be reasonably expected to increase or decrease the insurance premiums and administrative expenses for policyholders;

(F) The extent to which the treatment, service or equipment, supplies or drugs, as applicable, is more or less expensive than an existing treatment, service or equipment, supplies or drugs, as applicable, that is determined to be equally safe and effective by credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community;

(G) The impact of insurance coverage for the treatment, service or equipment, supplies or drugs, as applicable, on the total cost of health care, including potential benefits or savings to insurers and employers resulting from prevention or early detection of disease or illness related to such coverage;

(H) The impact of the mandated health care benefit on the cost of health care for small employers, as defined in section 38a-564 of the general statutes, and for employers other than small employers; and

(I) The impact of the mandated health benefit on cost-shifting between private and public payors of health care coverage and on the overall cost of the health care delivery system in the state.

Sec. 2. (*Effective July 1, 2009*) The commissioner shall carry out a review as set forth in section 1 of this act of statutorily mandated health benefits existing on or effective on July 1, 2009. The commissioner shall submit, in accordance with section 11-4a of the general statutes, the findings to the joint standing committee of the General Assembly having cognizance of matters relating to insurance not later than January 1, 2010.

Approved June 30, 2009

Appendix III

Connecticut General Assembly Public Acts and Bills Evaluated in this Report

- Senate Bill 956
- Senate Bill 862
- House Bill 5644

Senate

General Assembly

File No. 72

January Session, 2013

Senate Bill No. 956

Senate, March 20, 2013

The Committee on Insurance and Real Estate reported through SEN. CRISCO of the 17th Dist., Chairperson of the Committee on the part of the Senate, that the bill ought to pass.

AN ACT CONCERNING PEDIATRIC AUTOIMMUNE NEUROPSYCHIATRIC DISORDER ASSOCIATED WITH STREPTOCOCCAL INFECTIONS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective January 1, 2014*) Each individual health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes delivered, issued for delivery, renewed, amended or continued in this state shall provide coverage for the diagnosis and treatment of pediatric autoimmune neuropsychiatric disorder associated with streptococcal infections.

Sec. 2. (NEW) (*Effective January 1, 2014*) Each group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes delivered, issued for delivery, renewed, amended or continued in this state shall provide coverage for the diagnosis and treatment of pediatric autoimmune neuropsychiatric disorder associated with streptococcal

infections.

Sec. 3. (NEW) (*Effective October 1, 2013*) The Department of Public Health shall develop programs to educate the relevant medical community and the general public and promote research on pediatric autoimmune neuropsychiatric disorder associated with streptococcal infections. Such programs shall include, but not be limited to: (1) Clinical awareness programs for physicians and informational outreach programs for teachers and the general public; (2) epidemiological studies of pediatric neuropsychiatric disorder associated with streptococcal infections within this state; (3) the establishment of a panel consisting of experts in the clinical and research communities in the diagnosis, care and treatment of pediatric neuropsychiatric disorder associated with streptococcal infections to assist with the development of practice guidelines for such diagnosis, care and treatment in this state; and (4) the establishment of a state liaison to develop science-based guidelines for the diagnosis, care and treatment of pediatric neuropsychiatric disorder associated with streptococcal infections with the National Institute of Mental Health and the Centers for Disease Control and Prevention.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*January 1, 2014*	New section
Sec. 2	*January 1, 2014*	New section
Sec. 3	*October 1, 2013*	New section

INS *Joint Favorable*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 14 $	FY 15 $
State Comptroller- Fringe Benefits (State Employee and Retiree Health Plan)	GF, TF - Cost	Indeterminate	Indeterminate
Public Health, Dept.	GF - Cost	541,706	452,859
State Comptroller - Fringe Benefits[1]	GF - Cost	51,614	68,818
The State	Indeterminate	Indeterminate	Indeterminate

Municipal Impact:

Municipalities	Effect	FY 14 $	FY 15 $
Various Municipalities	STATE MANDATE - Cost	Indeterminate	Indeterminate

Explanation

Sections 1 and 2 of the bill will result in a potential cost to the state employee and retiree health plan[2], municipalities, and the state, for providing coverage for the diagnosis and treatment of pediatric autoimmune neuropsychiatric disorder associated with streptococcal infections (PANDAS).

PANDAS does not currently have an established diagnostic criteria

[1]The fringe benefit costs for most state employees are budgeted centrally in accounts administered by the Comptroller. The estimated active employee fringe benefit cost associated with most personnel changes is 34.54% of payroll in FY 14 and FY 15.

[2] The state employee and retiree health plan is currently self-insured. Pursuant to federal law, self-insured health plans are exempt from state health mandates. However, the state has traditionally adopted all state health mandates.

or treatment regimen.[3] The cost to the state employee and retiree health plan will depend on the number of members diagnosed with PANDAS, the diagnostic tools, and treatment mechanisms employed. It is important to note, the state employee and retiree health plan does not currently provide coverage for experimental or investigational treatments, except under specific circumstances for individuals with cancer.[4]

PANDAS has a diverse symptomatology, including but not limited to obsessive compulsive disorder (OCD), separation anxiety, personality changes, major depression and other psychiatric symptoms. In the event an individual has symptoms/conditions whose diagnosis and treatment is already covered, there is no additional cost to the state employee or retiree health plan.[5]

Municipal Impact

The bill may increase costs to certain fully insured, municipal plans that do not currently provide coverage for PANDAS. The coverage requirements may result in increased premium costs when municipalities enter into new health insurance contracts after January 1, 2014. In addition, many municipal health plans are recognized as "grandfathered" health plans under the Patient Protection and Affordable Care Act (PPACA)[6]. It is unclear what effect the adoption of certain health mandates will have on the grandfathered status of certain municipal plans under PPACA[7]. Pursuant to federal law, self-

[3] Leisman, G. et al., *A Comprehensive Analysis of Research on the Diagnoses and Treatment Pediatric Autoimmune Neuropsychiatric Disorder (PANDAS/PANS*). February 1, 2013.

[4] Source: *State of Connecticut Health Benefit Plan, Plan Document*

[5] For example, outpatient mental health treatment for various psychiatric conditions or anxiolytics for the treatment of anxiety.

[6] Grandfathered plans include most group insurance plans and some individual health plans created or purchased on or before March 23, 2010.

[7] According to the PPACA, compared to the plans' policies as of March 23, 2010, grandfathered plans who make any of the following changes within a certain margin may lose their grandfathered status: 1) Significantly cut or reduce benefits, 2) Raise co-insurance charges, 3) Significantly raise co-payment charges, 4) Significantly raise deductibles, 5) Significantly lower employer contributions, and 5) Add or tighten annual limits on what insurer pays. (www.healthcare.gov)

insured health plans are exempt from state health mandates.

The State and PPACA

Lastly, PPACA requires that, effective January 1, 2014; all states must establish a health benefit exchange, which will offer qualified health plans that must include a federally defined essential health benefits package (EHB). The federal government is allowing states to choose a benchmark plan to serve as the EHB until 2016 when the federal government is anticipated to revisit the EHB.

While states are allowed to mandate benefits in excess of the EHB, the federal law requires the state to defray the cost of any such additional mandated benefits for all plans sold in the exchange. The extent of these costs will ultimately depend on the mandates included in the federal essential benefit package, which have not yet been determined. State mandated benefits enacted after December 31, 2011 cannot be considered part of the EHB for 2014-2015 unless they are already part of the benchmark plan[8]. However, neither the agency nor the mechanism for the state to pay these costs has been established.

Section 3 of the bill results in a cost to the Department of Public Health (DPH) of $541,706 in FY 14 and $452,459 in FY 15 as well as a costs to the State Comptroller – Fringe Benefits of $51,614 in FY 14 and $68,818 in FY 15, for a total state cost of $593,320 in FY 14 and $521,677 in FY 15. Costs to DPH reflect salary expenses for: three staff positions and costs associated with (1) a pediatric neuropsychiatric disorder associated with streptococcal infections (PANDAS) clinical awareness and informational outreach campaign, (2) PANDAS epidemiological studies and (3) the establishment of PANDAS expert panel. Costs to the State Comptroller – Fringe Benefits are associated with fringe benefit expenses for the three DPH staff positions. A breakout of these state costs is presented in the table below. Following this table, further detail on these items is provided.

[8] *Source*: Dept. of Health and Human Services. *Frequently Asked Questions on Essential Health Benefits Bulletin* (February 21, 2012).

State Cost for DPH Programs Required Under SB 956

Item	9 months	full year
Department of Public Health (DPH) positions	**FY 14 $**	**FY 15 $**
Epidemiologist 3	59,400	79,200
Epidemiologist 2	47,119	62,825
Health Program Assistant	42,913	57,217
DPH positions subtotal	**149,432**	**199,243**
DPH Other Expenses (OE)		
Awareness & outreach campaign[1]	300,000	200,000
Database modification	50,000	-
Physician consultant	24,860	33,147
Visiting experts	9,718	13,908
Software licenses	2,500	2,500
Office supplies	1,500	2,000
In-state travel	1,356	2,712
Survey Monkey	300	300
DPH OE subtotal	**390,234**	**254,567**
Equipment (staff computers)	2,040	-
DPH TOTAL	**541,706**	**453,810**
State Comptroller - Fringe Benefits	51,614	68,818
STATE TOTAL	**593,320**	**522,628**

[1]One-time message, materials/media and marketing plan development costs of $100,000 are reflected in FY 14.

Staff positions are provided to oversee and implement a PANDAS clinical awareness and informational outreach campaign, conduct epidemiological studies of PANDAS within the state, organize meetings of a panel of PANDAS experts, and act as a state liaison to develop guidelines for the diagnosis, care and treatment of PANDAS with the National Institute of Mental Health and the Centers for Disease Control and Prevention. Staff will be supported in these tasks by a physician consultant to act as the chair of the expert panel aid and aid the state liaison in the development of science-based PANDAS guidelines. Consultant costs are estimated at $71.53 per hour for 7

hours of work per week for 30 weeks in FY 14 of $24,860. Full year consultant costs are annualized at $33,147.

Awareness & outreach campaign costs include message, materials/media and marketing plan development costs in the first fiscal year and on-going costs for educational brochures, postage, and television and radio announcements. The one-time database modification cost of $50,000 is associated with modifying the Connecticut Electronic Diseases Surveillance System to include PANDAS and is based on costs to develop a foodborne diseases surveillance module in the past. Costs reflected for visiting experts include airfare, accommodation and stipend expenses for six experts to attend two seven-hour-long meetings at two separate times of the fiscal year in FY 14. This is increased to three seven-hour-long meetings at three separate times of the fiscal year in FY 15. Software licenses are for Statistical Analysis System and Geographic Information System (for the geographic display and analysis of infectious disease epidemiological data). Survey Monkey costs reflect the "Gold Plan" which allows for integration with analytical software. Surveys will be utilized to monitor the level of PANDAS recognition in the medical community. In-state travel expenses are provided for DPH staff to retrieve medical charts not available electronically for the review of medical information.

The Out Years

The annualized costs for the on-going expenses identified above would continue in the future. In addition, normal annual pension costs (currently estimated at 7.5% of payroll) attributable to the identified personnel changes will be recognized in the state's annual required pension contribution in future actuarial valuations.

OLR Bill Analysis

SB 956

AN ACT CONCERNING PEDIATRIC AUTOIMMUNE NEUROPSYCHIATRIC DISORDER ASSOCIATED WITH STREPTOCOCCAL INFECTIONS.

SUMMARY:

This bill requires the Department of Public Health (DPH) to develop programs to educate the medical community and general public and promote research on pediatric autoimmune neuropsychiatric disorder associated with streptococcal infections (PANDAS).

The bill also requires certain health insurance policies to cover the diagnosis and treatment of PANDAS. It applies to individual and group policies delivered, issued, renewed, amended, or continued in Connecticut that cover (1) basic hospital expenses; (2) basic medical-surgical expenses; (3) major medical expenses; or (4) hospital or medical services, including coverage under an HMO plan. Due to the federal Employee Retirement Income Security Act (ERISA), state insurance benefit mandates do not apply to self-insured benefit plans.

EFFECTIVE DATE: October 1, 2013 for the DPH requirement and January 1, 2014 for the insurance coverage requirement

DPH PROGRAMS

The bill requires DPH's PANDAS programs to include:

1. clinical awareness programs for physicians;
2. informational outreach programs for teachers and the general public;
3. epidemiological studies of PANDAS within Connecticut;

4. the establishment of a panel of PANDAS experts in the clinical and research communities to help develop practice guidelines for the diagnosis, care, and treatment of PANDAS in the state; and

5. the establishment of a state liaison to develop science-based guidelines for the diagnosis, care, and treatment of PANDAS with the National Institute of Mental Health and the Centers for Disease Control and Prevention.

BACKGROUND

Related Federal Law

The Patient Protection and Affordable Care Act (P.L. 111-148) allows a state to require health plans sold through the state's health insurance exchange to offer benefits beyond those included in the required "essential health benefits," provided the state defrays the cost of those additional benefits. The requirement applies to benefit mandates enacted after December 31, 2011. Thus, the state is required to pay the insurance carrier or enrollee to defray the cost of any new benefits mandated after that date.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable
Yea 13 Nay 4 (03/07/2013)

Senate

General Assembly **File No. 31**

January Session, 2013 Senate Bill No. 862

Senate, March 11, 2013

The Committee on Insurance and Real Estate reported through SEN. CRISCO of the 17th Dist., Chairperson of the Committee on the part of the Senate, that the bill ought to pass.

AN ACT REQUIRING HEALTH INSURANCE COVERAGE FOR LUNG CANCER SCREENING.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective January 1, 2014*) (a) Each individual health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes delivered, issued for delivery, renewed, amended or continued in this state, shall provide coverage for lung cancer screening tests, in accordance with the recommendations established by the American Lung Association, after consultation with the American Cancer Society, based on age, family history and frequency provided by such recommendations.

(b) Benefits under this section shall be subject to any policy provisions that apply to other services covered by such policy.

Sec. 2. (NEW) (*Effective January 1, 2014*) (a) Each group health insurance policy providing coverage of the type specified in

subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes delivered, issued for delivery, renewed, amended or continued in this state, shall provide coverage for lung cancer screening tests, in accordance with the recommendations established by the American Lung Association, after consultation with the American Cancer Society, based on age, family history and frequency provided by such recommendations.

(b) Benefits under this section shall be subject to any policy provisions that apply to other services covered by such policy.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*January 1, 2014*	New section
Sec. 2	*January 1, 2014*	New section

INS *Joint Favorable*

OFA Fiscal Note

State Impact: See Below

Municipal Impact:

Municipalities	Effect	FY 14 $	FY 15 $
Various Municipalities	STATE MANDATE - Cost	Potential	Potential

Explanation

The bill results in no fiscal impact to the state employees and retirees health plan. The state employees and retirees health plan currently provides coverage for lung cancer screening based on medical necessity and prior authorization.

The bill may increase costs to certain fully insured, municipal plans that do not currently provide coverage for lung cancer screenings. The coverage requirements may result in increased premium costs when municipalities enter into new health insurance contracts after January 1, 2014. Many municipal health plans are recognized as "grandfathered" health plans under the Patient Protection and Affordable Care Act (PPACA)[1]. It is unclear what effect the adoption of certain health mandates will have on the grandfathered status of

[1] Grandfathered plans include most group insurance plans and some individual health plans created or purchased on or before March 23, 2010. Pursuant to the PPACA, all health plans, including those with grandfathered status are required to provide the following as of September 23, 2010: 1) No lifetime limits on coverage, 2) No rescissions of coverage when individual gets sick or has previously made an unintentional error on an application, and 3) Extension of parents' coverage to young adults until age 26. (www.healthcare.gov)

certain municipal plans under PPACA[2]. Pursuant to federal law, self-insured health plans are exempt from state health mandates.

In addition, the federal health care reform act requires that, effective January 1, 2014, all states must establish a health benefit exchange, which will offer qualified health plans that must include a federally defined essential health benefits package (EHB)[3]. The federal government is allowing states to choose a benchmark plan to serve as the EHB until 2016 when the federal government is anticipated to revisit the EHB.

While states are allowed to mandate benefits in excess of the EHB, the federal law requires the state to pay the cost of any such additional mandated benefits for all plans sold in the exchange[4]. The extent of these costs will ultimately depend on the mandates included in the federal essential benefit package, which have not yet been determined. If the benchmark plan does not include certain state mandated health benefits, the state would be responsible for the cost of those additional mandated benefits. Lastly, state mandated benefits enacted after December 31, 2011 cannot be considered part of the EHB for 2014-2015 unless they are already part of the benchmark plan[5].

The Out Years

[2] According to the PPACA, compared to the plans' policies as of March 23, 2010, grandfathered plans who make any of the following changes within a certain margin may lose their grandfathered status: 1) Significantly cut or reduce benefits, 2) Raise co-insurance charges, 3) Significantly raise co-payment charges, 4) Significantly raise deductibles, 5) Significantly lower employer contributions, and 5) Add or tighten annual limits on what insurer pays. (www.healthcare.gov)

[3] EHB requires coverage in 10 categories. In addition, Section 2711 of the Public Service Act prohibits annual dollar limits or lifetime maximums on EHBs.

[4] As of December 2011, Connecticut had 32 mandated health benefits in law. Maryland has the most, with 35 and Indiana has the least with 6. (*Source:* The Blue Cross/Blue Shield Association. *State Legislative Healthcare and Insurance Issues 2011*. Prepared by: Susan S. Laudicina, Joan M. Gardner, Kim Holland. As reported by NCSL, http://www.ncsl.org/issues-research/health/state-ins-mandates-and-aca-essential-benefits.aspx. Accessed 3/2/12.)

[5] *Source*: Dept. of Health and Human Services. *Frequently Asked Questions on Essential Health Benefits Bulletin* (February 21, 2012).

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation.

Sources: Office of the State Comptroller

OLR Bill Analysis

SB 862

AN ACT REQUIRING HEALTH INSURANCE COVERAGE FOR LUNG CANCER SCREENING.

SUMMARY:

This bill requires certain health insurance policies to cover lung cancer screening tests, in accordance with recommendations established by the American Lung Association after consultation with the American Cancer Society, based on age, family history, and frequency, as provided in such recommendations. The coverage is subject to any policy provisions that apply to other covered services.

The bill applies to individual and group health insurance policies delivered, issued, renewed, amended, or continued in Connecticut that cover (1) basic hospital expenses; (2) basic medical-surgical expenses; (3) major medical expenses; or (4) hospital or medical services, including coverage under an HMO plan.

Due to the federal Employee Retirement Income Security Act (ERISA), state insurance benefit mandates do not apply to self-insured benefit plans.

EFFECTIVE DATE: January 1, 2014

BACKGROUND

Lung Cancer Screening Recommendation

The American Lung Association currently recommends low-dose computed tomography (CT) chest scans for certain individuals at highest risk for lung cancer. To be considered high risk, a patient must be 55 to 74 years old, be a current or former smoker, and have a 30 pack-year smoking history (e.g., one pack a day for 30 years, 2 packs a day for 15 years, etc.).

Related Federal Law

The Patient Protection and Affordable Care Act (P.L. 111-148) allows a state to require health plans sold through the exchange to offer benefits beyond those included in the required "essential health benefits" provided the state defrays the cost of those additional benefits. The requirement applies to benefit mandates enacted after December 31, 2011. Thus, the state is required to pay the insurance carrier or enrollee to defray the cost of any new benefits mandated after that date.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable
Yea 15 Nay 4 (02/26/2013)

General Assembly

Proposed Bill No. 5644

January Session, 2013

LCO No. **2375**

Referred to Committee on INSURANCE AND REAL ESTATE

Introduced by:
REP. LESSER, 100th Dist.
SEN. BARTOLOMEO, 13th Dist.

AN ACT REQUIRING HEALTH INSURANCE COVERAGE OF FERTILITY PRESERVATION.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

That the general statutes be amended to require health insurance coverage of fertility preservation for insureds facing likely infertility as a result of a necessary medical procedure for insured with cancer and other medical conditions.

Statement of Purpose:
To require health insurance coverage of fertility preservation for insureds facing likely infertility as a result of a necessary medical procedure for insured with cancer and other medical conditions.

Appendix IV

Actuarial Report

ACTUARIAL REPORT FOR THE STATE OF CT

ON 2014 HEALTH INSURANCE MANDATES

By

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I. Executive Summary

This report serves to record the findings of Optum pursuant to our engagement to provide actuarial services to the State of CT in conjunction with Public Act 09-179. It is intended to communicate the results of our work.

Based on Optum's study of the proposed mandates, the coverage requirements will increase costs to certain fully insured plans that do not currently provide coverage for PANDAS, lung cancer screening, and fertility preservation. The numbering of the mandates below does not reflect their relative importance.

A. Mandate one involves the coverage for the diagnosis and treatment of pediatric autoimmune neuropsychiatric disorder associated with streptococcal infection. It is expected to add the premium of $0.012 PMPM (0.003%) in 2014. The five year projection for the cost of the mandate through additional premium is estimated at $323 thousand dollars.

B. Mandate two involves coverage for lung cancer screening tests, in accordance with the recommendations established by the American Lung Association, after consultation with the American Cancer Society, based on age, family history and frequency provided by such recommendations. It is expected to add the premium of $0.266 PMPM (0.055%) in 2014. The five year projection for the cost of the mandate through additional premium is estimated at $18.8 million dollars.

C. Mandate three involves the coverage of fertility preservation for insureds facing likely infertility as a result of a necessary medical procedure for insured with cancer and other medical conditions." It is expected to add the premium of $0.058 PMPM (0.012%) in 2014. The five year projection for the cost of the mandate through additional premium is estimated at $4.5 million dollars.

D. Mandate four involves the coverage for treatment that is ordered by the court for mental disorders. Review of this mandate will be covered in the later report.

Note: In the estimates above, a range of projected cost estimates has been used as well as a point estimate in some cases. The point estimate is not intended to imply a false sense of precision. Some aspects of the calculations may involve actuarial judgment. The actual 2014 cost could be greater or less than the expected values that have been projected.

The term de minimis is used to describe the projected incremental cost of any mandate that we expect to be less than $0.05 per member per month (PMPM) when the cost is spread to all the insured people covered by the plan. We also use the terms per person per month and per insured person per month to mean the same thing as PMPM. When considering the term PMPM, bear in mind that the average "person" is a blend of all ages and genders.

II. Introduction

A. Context of this report

This report serves to record the findings of Optum pursuant to our engagement to provide actuarial services to the State of CT in conjunction with Public Act 09-179. It is intended to communicate the results of our work.

Optum is pleased to have been chosen to serve the State of CT in this valuable project. A team approach has been employed, both internally at Optum and with the workgroup that includes the CT Insurance Department and the CT Center for Public Health and Health Policy. Consulting health actuaries, Steven Stender, FSA, MAAA and Julia Xiao, CERA, ASA, MAAA of Optum in New York, NY managed the actuarial work for this project. Dr. Thomas Knabel, MD was responsible for clinical guidance and support.

Optum was retained by the state to assess several health insurance mandates for 2014. In this document, our findings and conclusions related to the actuarial evaluation are presented for each of the mandates. Each one has been reviewed with respect to cost and utilization, with additional commentary on their socio-economic impact and effect on the finance and delivery system. This is referred to as the Phase Five Actuarial Report.

The results are presented in several steps: First, in summary form, and subsequently, the additional data and calculations that support the findings are layered into the report.

B. Proposed mandates under review

A) SB 956: Diagnosis and Treatment of Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection (PANDAS). The proposed language would require health insurance "coverage for the diagnosis and treatment of pediatric autoimmune neuropsychiatric disorder associated with streptococcal infections."

Since PANDAS does not currently have an established diagnostic criteria, children are considered as having PANDAS if they are ages 3 to 12 and tested positive for strep A within 6 months of receiving an OCD or tic disorder diagnosis. There is no treatment regimen established either. The types of diagnosis and treatment under review include the following: strep tests; immune-based treatments such as intravenous immunoglobulin (IVIG), therapeutic plasma exchange or plasmapheresis; antibiotics, including routine and preventive use; cognitive behavior therapy for OCD or tic-like disorders; SSRIs, and other standard treatments for OCD and tic-like disorders.

Even though SSRIs, and other standard treatments for OCD and tic-like disorders are possible treatments for PANDAS, they were excluded from the cost impact of the mandate because they are the standard treatment for OCD or tics and thus they are already covered under existing typical health plans.

Intravenous immunoglobulin (IVIG) and therapeutic plasma exchange or plasmapheresis are experimental treatments. Coverage of these treatments is anticipated to be required under the mandate even if the treatment is considered experimental and investigational and/or not medically necessary under carrier policy.

The types of prophylactic antibiotics recommended by NIMH and relevant literature were extracted and analyzed to obtain the prescription drug cost estimates for PANDAS. Preventive use of antibiotics refers to the extended use of antibiotics beyond the routine 7 to 10 days (minimum 300 days per year), with the purpose of preventing future infections. NIMH states that "it may be helpful to use antibiotics as prophylaxis (prevention) against strep infections." It directs clinicians to follow the American Heart Association's guidelines for prophylactic use of antibiotics to prevent rheumatic fever.[1][1] The AHA (2009) recommends that an intramuscular injection of Benzathine Penicillin G be administered once every four weeks for 5 years or until the patient reaches age 21, whichever period is longer. Alternatively, the AHA recommends orally administered treatments of 250 mg Penicillin V to be taken every day; or 1.0 g Sulfadiazine every day. Macrolide or azalide is available for patients who are allergic to penicillin and sulfadiazine, though the AHA provides no specific dose recommendation.[2][2] NIMH cites Snider, et al. (2005), who reported on a study that administered Penicillin V-K 250 mg two times a day every day to one group and azithromycin 250 mg two times a day for one day per week to a second group. The study lasted 12 months.[3][3] An earlier study, by Garvey et al. (1999) administered penicillin V 250 mg twice a day for 4 months, but found no evidence that this significantly prevented PANDAS associated symptoms.[4][4] A trial currently being conducted by the University of South Florida and the Massachusetts General Hospital will administer azithromycin once a day, every day, for eight weeks. The strength of each dose is not stated on the public description.[5][5] For the purpose of this study, we assumed the protocol of prophylactic use of antibiotics until age 21.

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[1][1] NIMH Pediatrics and Developmental Neuroscience Branch, Intramural Research Program, General Information: PANDAS, updated March 12, 2012. http://intramural.nimh.nih.gov/pdn/web.htm

[2][2] American Heart Association (2009). Prevention of Rheumatic Fever and Diagnosis and Treatment of Acute Streptococcal Pharyngitis: A Scientific Statement from the American Heart Association Rheumatic Fever, Endocarditis, and Kawasaki Disease Committee of the Council on Cardiovascular Disease in the Young, the Interdisciplinary Council on Functional Genomics and Translational Biology, and the Interdisciplinary Council on Quality of Care and Outcomes Research. Circulation, the Journal of the American Heart Association.

[3][3] Snider, L, Lougee, L., Slattery, M., Grant, P., Swedo, S. (2005). Antibiotic prophylaxis with azithromycin or penicillin for childhood-onset neuropsychiatric disorders. Biological Psychiatry vol. 57, p. 788-792.

[4][4] Garvey, M., Perlmutter, S., Allen, A., Hamburger, S., Lougee, L., Leonard, H., Witowski, E., Dubbert, B., and Swedo, S. (1999). A pilot study of penicillin prophylaxis for neuropsychiatric exacerbations triggered by streptococcal infections. Biological Psychiatry, vol. 45, p. 1564-1571.

[5][5] Antibiotic Treatment Trial for the PANDAS /PANS phenotype, clinical trials, National Institutes of Health. http://clinicaltrials.gov/show/NCT01617083

B) SB 862: Lung Cancer Screening. The proposed language would require health insurance "coverage for lung cancer screening tests, in accordance with the recommendations established by the American Lung Association, after consultation with the American Cancer Society, based on age, family history and frequency provided by such recommendations....Benefits under this section shall be subject to any policy provisions that apply to other services covered by such policy." The bill applies to individual and group health insurance policies delivered, issued, renewed, amended, or continued in Connecticut that cover (1) basic hospital expenses; (2) basic medical-surgical expenses; (3) major medical expenses; or (4) hospital or medical services, including coverage under an HMO plan.

This mandate requires coverage for screening based on the recommendations of the American Lung Association (ALA) after consultation with the American Cancer Society (ACS) based on age, family history and frequency. The common risk factors between the ACS, ALA and the US Preventive Services Task Force entities include: 1) Current or former smokers aged 55 to 74 years; 2) A smoking history of at least 30 pack-years; 3) No history of lung cancer/In fairly good health. The common test recommended for screening by each source is the low-dose computed tomography (LDCT). There appears to be no consensus on any other screening method. The ACS recommends annual screening until age 74. For the purpose of this study, we use the common risk factors, the annual screening recommendation, and payment for LDCT as the screening method. We limit the population to ages between 55 and 64.

As reported in the landmark National Lung Cancer Screening Trials study (NLST) published in the New England Journal of Medicine in July 2011, early detection enabled by low -dose CT scans resulted in a 20% reduction in lung cancer mortality. However, there are issues with utilizing CT scans. These include:

- High false-positive rate
- Out-of-pocket cost for patients for subsequent unnecessary testing
- Radiation exposure
- Cost effectiveness in the context of competing interventions such as smoking cessation

Those false positives create untold patient anxiety and, in nearly all cases, inconvenience, cost, and physical risk associated with follow-up testing. Many patients undergo lung biopsies and/or surgery for lung nodules that prove to be nonmalignant. Costs associated with follow-up testing were estimated using the study from the US Preventive Services Task Force.

C) HB 5644: Fertility Preservation. The proposed language would require health insurance "coverage of fertility preservation for insureds facing likely infertility as a result of a necessary medical procedure for insured with cancer and other medical conditions."

Fertility preservation services provide patients at risk of iatrogenic (medically-induced) infertility with the potential ability to conceive children following treatments that may damage reproductive tissue (e.g., surgery, radiation, chemotherapy, prescription drugs, etc.). In order to preserve reproductive capabilities, fertility preservation services would be decided upon prior to disease treatment.

Iatrogenic infertility is medically induced infertility caused by a medical intervention used to treat a primary disease or condition. The medical intervention resulting in iatrogenic infertility is often gonadotoxic or surgical treatment. Gonadotoxic treatment includes radiation, chemotherapy, and prescription drugs. Iatrogenic infertility is typically caused by cancer treatments, such as radiation and chemotherapy or surgical removal of reproductive organs. Less frequently, fertility is compromised by treatments for autoimmune disorders such as systemic lupus erythematosus, rheumatoid arthritis, or Crohn's disease.

This study focuses on fertility preservation among cancer patients because it is estimated that approximately 90% of iatrogenic infertility is caused by cancer treatment[1]. In addition, there are no recommendations for fertility preservation for patients outside of cancer patients, and thus the research on fertility preservation has focused almost exclusively on this group.

This mandate is limited to benefits to cover the cost of preservation. This proposal does not address the infertility treatment, which is provided pursuant to the infertility mandates. In cases where the generally accepted treatment of a condition has a likely risk of infertility, the patient will be eligible for fertility preservation benefits following certification of determination by a physician. A minimum eligibility age of 10 years old will be used for this survey since accepted fertility preservation methods typically require the individual to be post-pubertal. A maximum eligibility age of 38 years old will be used. The medically necessary fertility preservation services to be covered will be those that are determined to be generally accepted as standard and effective based on clear and convincing medical/scientific evidence. Fertility preservation services, for the purposes of this study include: sperm cryopreservation, embryo cryopreservation, oocyte cryopreservation, and trachelectomy plus the associated medically necessary expenses (e.g., labs, facility charges, etc.). Sperm cryopreservation is standard fertility preservation treatment for males. Embryo cryopreservation, oocyte cryopreservation, and trachelectomy are standard fertility preservation treatment for females.

- Sperm cryopreservation (the collection and freezing of sperm) is an effective method of fertility preservation. This is the standard fertility preservation service offered to males at risk for iatrogenic infertility.

- Embryo cryopreservation (the harvesting of eggs followed by in vitro fertilization and freezing of resulting embryos for later implantation) is an effective method of fertility preservation. Embryo cryopreservation is the standard fertility preservation service available for females at risk for iatrogenic infertility who have a male partner or who want to use donor sperm.

- Oocyte (egg) cryopreservation (the collection and freezing of eggs) is an effective method of fertility preservation. This is the standard fertility preservation service offered to females at risk for iatrogenic infertility who do not have a male partner or who do not want to use donor sperm.

1 Lawrenz B, Jauckus J, Kupka MS, Strowitzki T, von Wolff M. Fertility preservation in >1,000 patients: patient's characteristics, spectrum, efficacy and risks of applied preservation techniques. *Archives of Gynecology and Obstetrics.* 2011;283:651-656

- Trachelectomy (treatment for cervical cancer where the cervix is surgically removed while the uterus is preserved) and ovarian cancer surgery (where the uterus with one ovary can be preserved) are effective methods of conservative gynecologic surgeries (minimal removal of diseased organs to preserve fertility) for fertility preservation. The available evidence indicates that for specific patient populations, these surgeries do not lead to an increase in cancer recurrence or mortality. Note that since trachelectomy is usually covered by insurance, it was excluded from the analysis of the impact of this mandate.

D) SB 1091: Court-Ordered Treatment for Mental Disorders. Health insurance coverage for treatment that is ordered by the court for mental disorders.

Review of this mandate will be covered in a later report.

C. Objective

The objective of the report is to communicate our findings related to the actuarial evaluation of each of the proposed mandates with respect to cost and utilization along with comments on their economic impact.

D. Components of health insurance premium

With respect to the cost of health insurance mandates and their effect on commercial health insurance premiums, two separate pieces were examined—these are the two components of health insurance premiums:

1. Medical costs, also called benefit expense, and
2. Non-medical cost, also called non-benefit expense.

More emphasis has been devoted to the former since it represents the far greater portion of overall premium cost. This is described in more detail later in this report. The term “retention” is also used for non-medical expense; it comprises both administrative cost and a profit/risk charge. Medical cost is also referred to as Paid cost; it is the liability of the health insurer that is responsible for payment. Paid cost is to be distinguished from “Allowed” cost. In addition to Paid cost, Allowed cost includes member cost-sharing, which is not part of health insurance premiums. Allowed cost is examined at greater length later in this report.

Elsewhere in this report, the terms “benefit expense” and “non-benefit expense” are also used in reference to these two mutually exclusive components of health insurance premium.

For commercial group health insurance plans, non-medical (non-benefit) cost has been about 17% of premium, which is 21% to 22% of medical cost. Thus, for

every dollar of health care cost paid by the insurer in group coverage, there was approximately twenty-one cents of associated cost that also went into health insurance premiums—this non-medical expense covered the operational costs associated with payment of claims, collection of premium, medical management, profit, and more. For individual coverage, non-benefit expense is and has been a larger portion of health care cost—it was approximately 23% of premium. This leads to roughly thirty cents of associated cost for every dollar of medical cost paid by insurers providing individual coverage. The Affordable Care Act requires insurers to comply with a minimum loss ratio of 85% on large group and 80% for small group and individual. This will tend to compress retention. That is, non-benefit expense will be limited as a percentage of health insurance premium for commercial insurance coverage.

In this report, it was assumed that 2014 medical costs on average will be 85% of health insurance premiums for all group plans combined. Historically, on average, this medical cost ratio has been higher for large groups than for small groups.

These two components, medical cost and non-medical expense, are the two basic building blocks of health insurance premiums. There is yet another separate category of health care cost that is not part of health insurance premiums—this is the cost-sharing paid by the member at the time of service or later. It is mentioned only briefly here, but covered in more detail elsewhere in this report. Cost-sharing (or "member cost-sharing") generally takes the form of deductibles, copays, and coinsurance. It may also include balance billing, out of network costs, and the cost of non-covered services. For covered services, the sum of cost-sharing and paid cost is referred to as Allowed Cost. Most of the focus in this report is on paid cost, since it is ultimately the primary underlying driver of health insurance premiums.

Any change in health benefits resulting from the mandates will need to be considered and addressed by health insurers. The mandates will necessitate changes in various operational and technological processes, such as premium billing and claims payments systems. Health insurers will need to configure benefit systems to handle the required benefit changes. They may also need to notify members or policy-holders of the changes and perhaps revise marketing and sales material. Even for a mandate whose medical cost is *de minimis*, there may still be an associated one-time administrative cost involved in implementation. This one-time administrative cost is separate from the ongoing cost that occurs in subsequent years. Most health insurance companies, HMOs, and third party administrators have become more adept with the operational aspects of benefit changes, although some systems and companies may accommodate change more easily. Some mandates may involve more first-time implementation expense than others.

The year one 2014 non-medical expense for these mandates is expected to be about $0.05 PMPM in addition to the $0.29 of paid medical cost for group plans. This is the total non-benefit expense and reflects more than operational costs only. As a range, this total non-medical cost is expected to be about $0.01 to $0.09 PMPM, depending on the level of medical cost and the operational changes that insurers and HMOs will need to make in order to comply with the mandates. These changes may include revisions to online and printed marketing materials, changes in the coding of claim payment systems in order to adjudicate claims in compliance with the mandates, staff training, etc.

It is possible that the mandates may reduce some minor existing administrative cost that insurers now bear as a result of claim denials and appeals in conjunction with denied services pertaining to the four mandates. If such cost exists, it would be *de minimis* and minor in relation to other operational expenses, and no such reductions to non-benefit expense are included in this report.

In addition to administrative cost, insurers build a profit charge into their premiums in order to cover their cost of capital. Unlike non-insurance businesses, insurers build a risk charge into their profit margin so that they have sufficient surplus capital on hand to pay more claims than usually expected, and thereby assure their financial security. This enables health insurers and HMOs to avoid insolvency due to a confluence of catastrophically large claims in a short period of time. In the case of for-profit insurers, their profits also benefit their shareholders, and the taxes they pay inure to the common good. The term "retention" is used in this report to describe administrative cost plus profit, which is all non-medical cost.

In the prior mandate reports, the portion of health insurance premium that was assumed to apply to administrative cost, excluding profit, on average, was approximately:

Non Benefit Expense as Percentage of Total Premium:	
Individual	**17% to 24%**
Small Group	**13% to 18%**
Large Group	**10% to 15%**

This was reasonably consistent with the retention percentages provided by the CT Insurance Department based on 2013 CT HMO filings. For 2014, we assumed the average medical cost ratio for group would be 85%. As previously, this will generally vary by plus or minus a few percent depending on the insurer. As medical costs increases, particularly as more services are rendered and claims are paid, administrative cost also tends to increase. Over time, however, as medical claim cost increases at a faster rate than administrative cost, administrative cost as a percentage of the premium dollar should decrease. The

effect of this differential increase is mitigated somewhat by the effect of benefit "buy-downs" whereby more of the allowed cost is shifted to the member in the form of higher copays and deductibles. Although buy-downs mitigate the differential increase, they do not entirely eliminate it, so eventually administrative cost should represent a smaller and smaller percentage of overall premium. In general, at time of renewal, employers have been shifting some of the cost of the annual premium increase to the employees and dependents in two ways. First, employees may be asked to share a greater percentage of the premium. Second, all members may be asked to pay more in the form of cost-sharing, such as higher copays for services.

III. Health Insurance Context

A. Group vs. Individual Coverage

The term "commercial" insurance is used to distinguish it from public programs, such as Medicaid, Medicare, or HUSKY. Commercial coverage is generally for people less than 65 years of age who do not have public coverage. The term commercial coverage can be used to describe two forms of health coverage—fully insured and self-funded. Self-funded coverage is not technically a form of health insurance. State health insurance mandates apply only to fully insured coverage.

Commercial health insurance can be broken into two types of policies:

- Group coverage—a policy typically sponsored by an employer who is the policy holder. Employees who elect to participate are certificate holders, and they generally pay a portion of the premium, usually less than half,
- Individual coverage—a policy sold to an individual to cover that person and possibly some or all that person's dependents.

At present in CT, individual policies are purchased by individuals and paid for by them in their entirety. In the CT insurance market of December, 2012, there are no government subsidized individual policies as there are in MA under Commonwealth Care. Beginning in 2014, under the Affordable Care Act, the federal government will subsidize individual policies sold in other states through exchanges that meet federal qualifications.

The individual market is characterized by a larger percentage of leaner benefit plans that involve greater member cost-sharing, often in the form of a high deductible or higher copays. All else equal, higher cost-sharing is associated with lower overall utilization. This may translate into lower utilization and cost for some of the mandates. The leaner benefit plans in the individual market are used to help control cost since the populations enrolled in individual plans often have more medical conditions, on average, than those in group plans, especially large

group plans in which everyone is covered. The individual insurance market is known for a higher rate of adverse selection since those who need health insurance and do not have it, must generally buy an individual plan.

Individual insurance is not inexpensive, however, and the policy-holder must bear the entire premium cost alone. This also helps explain why individual policies are subject to more adverse selection than group policies. As long as applicants can pass initial underwriting for coverage, individuals can purchase individual health insurance for themselves and their family when they think they will need it. More importantly, people may drop coverage when the economic value diminishes; and they may renew coverage when their health deteriorates and they know they need to retain it. As "individual insurance is believed to be much more costly (per dollar of expected benefits) than group insurance" [2], people tend to purchase less benefit, and therefore the average cost of an individual health policy is less than the average per-employee cost of a group policy. For example, the cost-sharing on an individual plan may be higher—this means higher deductibles, copays, and more coinsurance. This is an important consideration when assessing the financial burden for those covered by individual plans, especially less healthy people. People with individual coverage pay for their entire premium, as well as all the cost-sharing associated with their plan. Those with plans that have an out of pocket maximum have some assurance that their personal financial burden will not exceed that maximum and lead to personal bankruptcy.

One last point to note regarding individual coverage is that conversion policies fall into this category. These policies help provide access to insurance for those who lose group coverage. (This includes those whose COBRA coverage has run out.) Conversion policies tend to be purchased by those that need continued coverage, and they can experience significant adverse selection as the small pool acquires an increasing percentage of higher risk individuals with known health conditions. Conversion policies are sold to those singles, couples, and families who wish to maintain individual coverage after they lose group status. Unlike the vast majority of group policy holders, conversion policy holders pay the full cost of their coverage. If someone expects to have large medical costs, they are more likely to purchase conversion coverage than someone who is healthy and expects no upcoming medical expenses other than routine care.

2 Cost and Performance: A Comparison of the Individual and Group Health Insurance Markets, Mark V. Pauly, Allison M. Percy, *Journal of Health Politics, Policy and Law* 25.1 (2000) 9-26

B. Types of group coverage—fully funded vs. self-funded

Fully-insured coverage does not include self-funded group coverage. According to the Oliver Wyman study[3], the number of people covered by self-funded coverage in CT was 1.5 times as large as the number covered by fully insured group coverage. Through 2013, there are expected to be even more people in CT with health coverage through a self-funded employer plan than from fully insured group and individual coverage combined. It is also a consequence of the continued migration of fully-insured groups into self-funded coverage due to the impact of the Affordable Care Act. Finally, it reflects the increase in the number of uninsured people resulting from a larger decrease in fully-insured than self-funded.

The rising popularity of self-funding stems from different trends. Rising health care costs have lead many firms to attempt to manage health care more directly and reduce overhead related to health insurance administration. Innovation in insurance products, such as consumer-driven health plans, allows more flexibility in moving to partially self-funded programs. An employer can purchase high deductible insurance to cover major health events and costs, and insure up to the amount of the deductible directly or through medical savings accounts. Firms choose self-funding to avoid the additional cost of state health insurance mandates and the restrictions the ACA imposed. Separately, state health mandates may have minimal costs but many low-cost mandates can increase the cost of health insurance substantially. Firms that are self-funded are exempt from implementing these coverage mandates. It may be the cases that, as additional mandates cause premiums to rise, more employers will choose self-funding to avoid premium increases.

It is important to note that self-funded groups are not subject to state mandates; however, they are subject to certain federal mandates, of which there are far fewer than those required by the state of CT. As the fully insured population shrinks relative to the self-funded, state health insurance mandates have jurisdiction over a decreasing percentage of the state's residents.

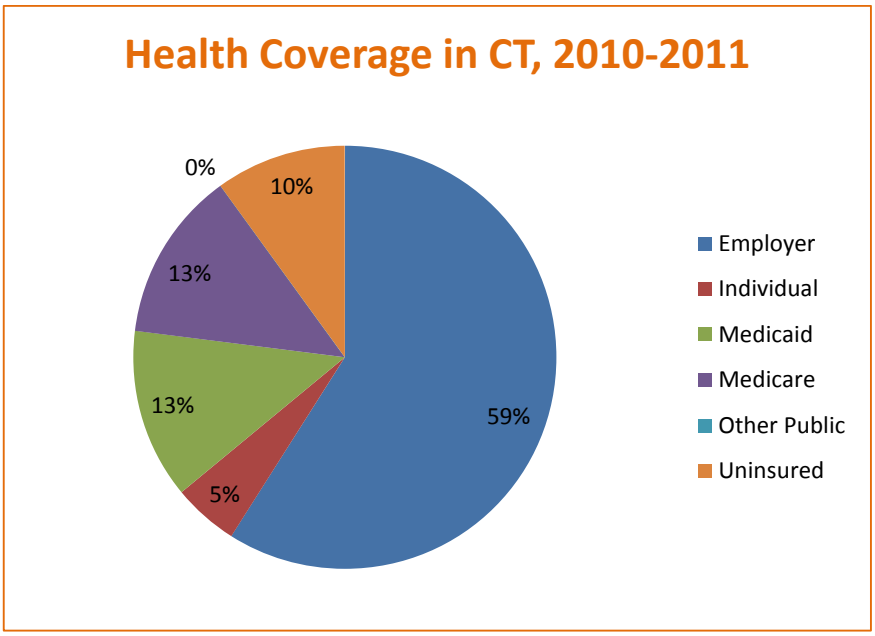
C. <65 CT Population--Proportion of CT population by insurance coverage type

First, health coverage for all people of all ages is considered—this includes everyone residing in CT. According to the 2012 projected census, that is approximately 3.6 million people. This includes people of all ages. It includes people who have any type of health coverage whether fully insured or not, whether private or public. It also includes people who have no health coverage—

3 Oliver Wyman report " Annual Tax on Insurers Allocated by State" November 2012 based on data from Health Leaders- InterStudy Managed Market Surveyor, July 2011

the uninsured. This is shown below in the table of percentages by coverage type and Table 1(a).

Table 1(a)



The pie chart in Table 1(a) depicts the statistics above for all people in CT. The data comes from the Kaiser Family Foundation(KFF) and represents 2010 to 2011.

A second group includes only those with "commercial health coverage." This view excludes those 65 years of age or older. It also excludes anyone with any type of public coverage through any government program, such as Medicare, Medicaid, Husky (the State Children's Health Insurance Program), the Department of Defense TriCare, or the Veterans Health Administration. According to the 2012 projected census, that is approximately 3.1 million people less than 65 years old.

The third group is a yet smaller subset and includes only those with fully insured commercial coverage—both group and individual policies. In addition to all excluded in the second group, this third group also excludes everyone with self-funded employer coverage. It is the only population legally subject to CT's health insurance mandates.

L CT RESIDENTS, 2012, <65 years

TYPE OF HEALTH COVERAGE*	
Group, Fully Insured	27.3%**
Individual, Fully Insured	7.5%
Self-Funded Group	41.8%**
Medicaid (including Duals)	12.9%
Medicare	0.8%
Uninsured	9.2%
Military	1.2%
Other Public	0%

*rounding exceeds 100%

**Split between Group Fully Insured and Self-Funded based on Oliver Wyman 2012 study for 2011 enrolled

The term "employer based coverage" consists of two non-overlapping subsets:

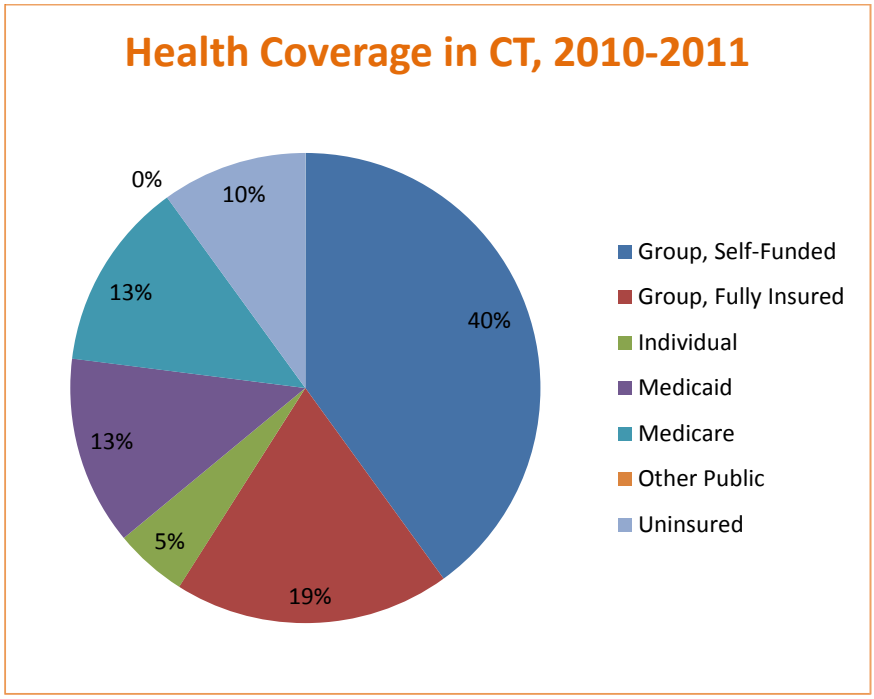
1. Fully insured groups, and
2. Self-funded groups

Although about 70% of CT residents have private, employer-based group coverage, most is self-funded (not fully insured) and is thus not subject to the state health insurance mandates. Many authors on the subject of health care use the terms coverage and insurance as if they mean the same thing. Technically, self-funded health coverage is not health insurance; that distinction is maintained here because state health mandates do not apply to self-funded coverage. The 69% with employer coverage is 60.5% self-funded and 39.5% fully insured[4] resulting in 42% self-funded group and 27% fully insured group. The state employees and their dependents are approximately 5% of the CT population and are the largest commercial self-funded group in the state.

The next chart, table 1(a2) takes the KFF chart above and splits the employer-based coverage into fully insured vs. self-funded based on 2011 membership data submitted by CT carriers and reconciled to the KFF data. Note: this includes population 65 years of age and older

4 Oliver Wyman report " Annual Tax on Insurers Allocated by State" November 2012 based on data from Health Leaders- InterStudy Managed Market Surveyor, July 2011

Table 1(a2) All Ages



Data source: Kaiser Family Foundation(KFF) data and carrier survey

The two charts that follow next provide the demographics of the uninsured in CT. They are based on Kaiser Family Foundation 2011 data, and they view only the "non-elderly population," that is, people less than 65 years of age. Since the vast majority of elderly citizens are covered by Medicare, most studies of the uninsured analyze the uninsured as a subset of the non-elderly population rather than the entire population as shown in Table 1(a). If we exclude the elderly, the uninsured non-elderly in CT are 13% of the non-elderly population. Although males are 48.3% of the total population in CT, there are almost 18% more uninsured adult non-elderly males than females.

FIGURE 1(b)—By Age and Gender

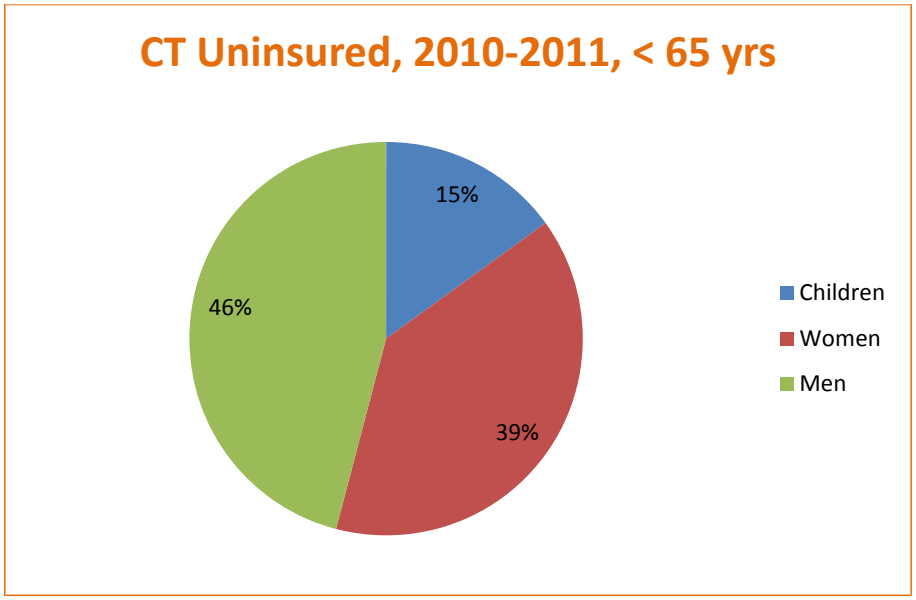
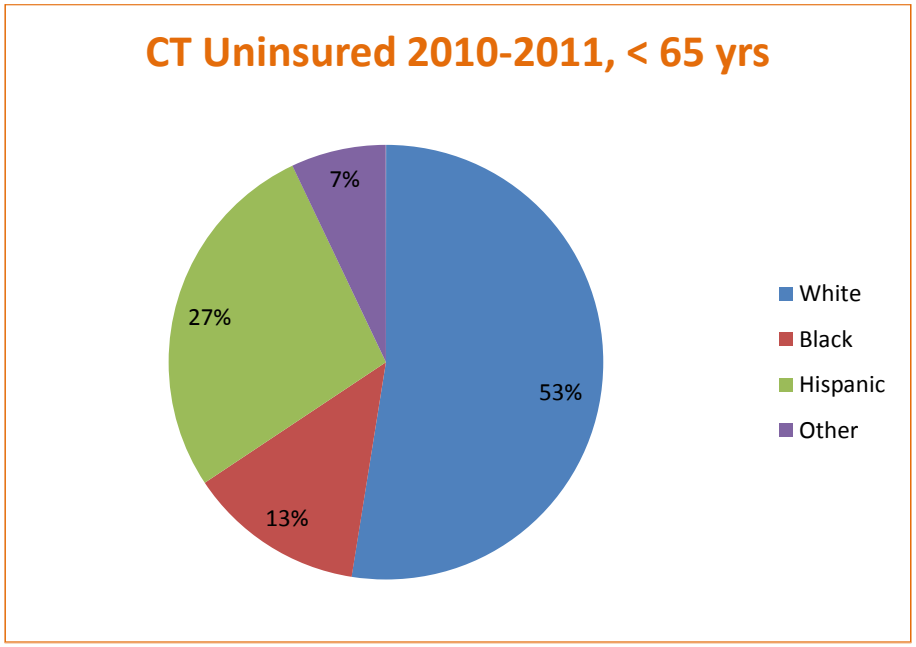


FIGURE 1(c)—By Ethnicity



Impact of the Affordable Care Act

The healthcare landscape has changed significantly over the last several years. High deductible health plans are increasingly common, especially in the individual and small group markets. America's Health Insurance Plans (AHIP)

estimates that nationally over 15.5 million lives were covered in 2013 under Health Savings Account/High-Deductible Health Plans (HSA/HDHP)[5].

In Connecticut, almost 10% of the lives covered by commercial health insurance have an HSA/HDHP plan[5]. Per IRS rules, these plans have an inflation indexed minimum deducible for individual and family coverage. Without some modification of benefit design, the high deductible in such plans can be a deterrent to services that are of high value and much needed. For example, if one had to wait until a deductible is satisfied in order to get a medically necessary service, the tendency might be to wait rather than pay. As a result of the Affordable Care Act (ACA), however, crucial preventive services are now provided by health insurance plans with no member cost-sharing. For higher value services that do involve member cost-sharing, the tendency to wait is greater for people at a lower income level.

Even prior to the passage of the ACA, insurers recognized this member propensity to delay care and countered with new and improved plan designs designed to encourage access to benefits that bring higher value for cost. Preventive benefits are often covered without satisfying the deductible or even requiring any cost-sharing at all. Certain high value services may be made available in high deductible plans, with or without copay, prior to satisfying the deductible. The idea is that the benefit design should help the member obtain high-value needed services with minimal economic barriers to access. Health insurers may refer to these as wellness or preventive benefits. The mandate for Lung Cancer screening is not categorized as a preventive benefit under the federal Affordable Care Act (ACA) at this time, but could be in the future if the US Preventive Services Task Force approved the recommendation. Under the ACA, preventive services must be covered with zero cost-sharing for the patient.

D. Average premium by policy type

Average baseline health insurance costs varied by policy type in 2012. With some exceptions, premiums paid by small group employers appear to be higher on average than those paid by large group employers. For large firms, the size of their employee-base allows them to spread health risks and costs over a large population. In this way, the cost of catastrophic health events only marginally impacts costs per individual. In principle, costly health events for one member of a small insurance pool can substantially affect per person expenses. Note that small group employers are defined as firms with less than 50 employees while large group employers are defined as firms with 50 employees or more.

When health insurance is priced, it is broken into cost categories depending on the "tier" that is purchased. A single employee will purchase a single policy. An

5 AHIP report, "January 2013 Census Shows 15.5 Million People Covered by Health Savings Account/High-Deductible Health Plans (HSA/HDHPs)," June 2013 (enrollment includes individual and group coverage).

employee with one dependent will purchase the employee plus one policy. And a couple with children will purchase a family policy.

PREMIUM BY FIRM SIZE

Plan Type	Single		Single +1		Family	
	Small Group	Large Group	Small Group	Large Group	Small Group	Large Group
Average Total Premium	$6,348	$5,830	$12,508	$11,811	$16,444	$16,968
HMO	$5,610	$6,223	N/A	N/A	$17,319	$16,302
PPO/POS	$6,709	$5,769	N/A	N/A	$16,063	$17,179
Any Provider Plans	$6,368	$5,106	N/A	N/A	$16,869	$15,484

Data source: AHRQ (2012) Medical Expenditure Panel Survey (MEPS) – insurance component

As individual health insurance component is not available in MEPS, we supplemented the average premium analysis using the plan enrollment and premium data in the carrier survey for CT as shown in the table below.

Large Group		Small Group		Individual	
Covered Lives	**Avg. Premium**	**Covered Lives**	**Avg. Premium**	**Covered Lives**	**Avg. Premium**
332,159	$4,545	304,258	$5,970	110,355	$3,302

Data source: CPHHP 2013 CT Carrier survey 2012 data average costs per member

E. Average cost sharing by policy type

Average cost sharing varied by policy type in 2012. As the table below shows, small group plans have more member cost-sharing than large group plans; this is similar to the way that individual policies have more cost-sharing than group. Note that small group employers are defined as firms with less than 50 employees while large group employers are defined as firms with 50 employees or more.

COST SHARING BY FIRM SIZE			
	Overall	**Small Group**	**Large Group**
Average individual deductible	$1,368	$2,189	$1,176
Average family deductible	$2,782	$5,024	$2,411
Average coinsurance	18%	20%	18%
Average copay	25	27	25

Data source: AHRQ (2012) Medical Expenditure Panel Survey (MEPS) – insurance component

As individual health insurance component is not available in MEPS, we supplemented the average cost sharing analysis using the plan enrollment and cost sharing data in the carrier survey for CT as shown in the table below.

Large Group		Small Group		Individual	
Covered Lives	**Avg. Cost Share**	**Covered Lives**	**Avg. Cost Share**	**Covered Lives**	**Avg. Cost Share**
403,434	$1,474.27	228,047	$2,981.01	90,314	$2,690.45

Data source: CPHHP 2013 CT Carrier survey 2012 data per member

With the introduction of the Affordable Care Act, individual and small group plans must at minimum cover 60% on average of the health care benefit. When going through the Access Health CT marketplace or other exchanges within Connecticut, a member or group must choose between different metallic levels representing different levels of cost sharing. Specifically, members can choose between bronze (40% member cost sharing), silver (30%), gold (20%) and platinum (10%). It is expected the vast majority of individuals choosing coverage in Connecticut will select silver with 30% cost sharing.

Since the health insurance reforms in the early 1990's, a small group has been defined in CT as an employer with 50 employees or less. With the Affordable Care Act (ACA), the definition will be expanded so that a small group employer can have 100 employees or less. Small groups tend to purchase lower cost, leaner plans than large groups. "Lean" plans shift more cost to the insured in the form of higher copays, deductibles, and coinsurance. Employees of small business also tend to pay a larger share of the premium. In this respect, the cost burden of the mandates will be somewhat greater for those whose insurance is provided through a small group employer for two reasons:

- Insured employees in small groups pay a larger percentage of the overall premium, on average, and
- Insured employees in small groups and their dependents pay more in cost-sharing than those in large groups.

The small group market is more sensitive to the cost of health insurance. A significant increase in premium cost, all else equal, is expected to cause more small groups than large ones to drop health insurance coverage. In general, mandates push up the cost of health insurance for small and large groups alike, but a somewhat higher percentage of small groups may drop coverage as a result. This is driven in part by the fact that there is generally more variation in the annual premium increases of small groups relative to large. The small groups with the largest increases tend to lapse coverage first.

For the smallest employer groups, the owner who purchases group health insurance on behalf of the group may know more about the health conditions of the employees and their dependents. This may cause the employer to purchase a richer plan or to renew coverage when they might have otherwise terminated it.

One consequence of additional mandates is that some groups may switch to a self-funded approach, which enables them to avoid complying with the mandates if they wish. Most of the larger employers in the US have already switched to a self-funded approach, and thus state mandates do not apply to them. There are other reasons for them to switch beyond the minor freedom of not having to comply with state mandates. There is emerging evidence that more mid-size groups are switching to self-funding as a result of the ACA.

An objection to mandates that is raised by some organizations is that the cost of mandated services, when added to the overall cost of care, adds a substantial increment to the cost of health insurance. This argument is often raised more forcefully when mandates are for services that are perceived to be non-essential or of lesser value. It may also be raised against benefits that are vital but only for a small minority of insured people, such as those affected by rare “orphan” diseases. There is no easy answer to the question of which services to include in the essential benefits package of a health plan.

Excluding some benefits from the package of essential benefits covered by the health plan is a complex problem. Furthermore, if insured people are allowed wide-ranging choice to pick and choose the benefits they wish to include in their coverage, they will tend to select those they expect to best meet their medical needs. Too much self-selection of benefits can defeat the underlying insurance principle of pooling. At the other extreme, an insurance plan that covers all possible services for all insured members could become prohibitively expensive. Such a “rich” plan would need to impose substantial member cost-sharing in order to make it a reasonably priced insurance product. This describes the two-edged problem of covered benefits vs. member cost-sharing. As health technology evolves and increasingly expensive services are added to health insurance plans, there needs to be a trade-off established between covered benefits and cost-sharing, otherwise plans become prohibitively expensive. This is a bigger issue for individual plans in a world in which some members can add or drop coverage as their medical condition and personal finances change over

time. It is less an issue for group plans because employers substantially subsidize the premium cost of these plans on behalf of their employees, and the employer receives a tax benefit for doing so. Whereas the cost burden for individual plans includes 100% of the premium cost, for group plans, employees may pay roughly anywhere from 5% to 50% of the premium cost of the group coverage—the average is approximately 25%. For both group and individual coverage, the cost-sharing is also a significant part of the cost-burden.

IV. Methods

A. Data/Survey

i. Optum Large Group Commercial database

Optum data was extracted for the purposes of this study. Optum's internal commercial health claims data for 2010 – 2011 was examined. The database captured approximately 135,000 covered lives less than 65 years of old for CT. Various outside data sources were also reviewed in order to establish incidence and prevalence rates, utilization levels, unit cost of services, and overall spending on types of service. Optum used national and CT-specific health claims data.

ii. Carrier claims data

A survey was developed by the workgroup consisting of the CT Center for Public Health and Health Policy and Optum. This survey was sent to each of the six health insurance carriers domiciled in CT. They were asked to provide responses reflective of the group health plans, individual policies, and Administrative Service Only (ASO) contracts. They were also asked to provide internal documents describing their medical management policies pertaining to the four mandates.

At the time this actuarial report was completed, all the carriers had returned their survey responses. However, the quality and usefulness of the responses varied. Some were not entirely complete, and in some cases, data pertaining to frequency of utilization raised questions.

iii. External data sources

Average premium and cost sharing by policy type is based on AHRQ (2012) Medical Expenditure Panel Survey (MEPS) – insurance component. MEPS is a nationally representative survey of medical insurance, expenditure, utilization, and health status.

State-specific demographic information and income estimates come from the Census (2012) Current Population Survey.

Average premium by plan type for CT is based on 2012 CT Insurance Department filings.

B. Estimation/Projections

Optum's internal commercial health claims data for 2010-2011 was examined. Other data sources were also reviewed to establish the incidence and prevalence rates. The cost estimates were done on both a national level and a state level, with emphasis on the CT data. Where CT data was unavailable, national data was substituted with an area adjustment to reflect CT cost levels. The methodology Optum for each mandate is outlined below.

PANDAS

- Obtain plan enrollment and characteristics including number of children between ages 3-12 and total member months
- Obtain plan enrollment information with prescription drug coverage
- Compile medical and prescription drug claims with PANDAS-related diagnosis codes and procedural codes for children between ages 3-12
- Identify the treatment patterns for children between ages 3-12 who had OCD or tic disorder
- The treatments studied include standard treatments for OCD and tics (cognitive behavior therapy and SSRI) and experimental treatments for PANDAS such as immune-based treatments IVIG, therapeutic plasma exchange or plasmapheresis, and extended use of antibiotics.
    - For plasmapheresis, a treatment protocol consisted of five treatment
    - For IVIG, a treatment protocol consisted of 12 treatments
    - For antibiotics, average annual costs were calculated for members with >300 days supply
- Determine the cost of diagnosis and treatment for 2010 and 2011
    - Calculate total allowed cost, total paid cost, total cost share, and average cost of procedure for each treatment
    - Calculate allowed cost, paid cost, cost share for the diagnosis and each treatment
    - Calculate distribution of allowed cost, paid cost, and cost share
- Determine the utilization rate of treatment for 2010 and 2011
- Model the incremental cost of the proposed mandate
    - Extract the dataset for children between ages 3-12 who had OCD or tic disorder
    - Remove those who had strep tests for the incremental costs of the additional strep tests
    - Calculate the incremental cost of diagnosis
    - Assume the percentage of children having PANDAS for those with OCD or tics

- Determine the overall incremental cost for the first year of treatments
- Forecast the cost of antibiotic use for the earlier of until age 21 or five years. Since this study stops at age 12, five years was used.

Lung Cancer Screening

- Obtain plan enrollment and characteristics including number of covered lives between ages 55-64 and total member months
  - The minimum age was determined according to recommendations established by the American Lung Association, the American Cancer Society, and the US preventive Services Task Force. The maximum age was below age 65 to eliminate the impact of Medicare.
- Identify number of members between ages 55-64 in study
- Determine percentage of population who are smokers from CDC studies (use 45-64 age grouping)
- Estimate take up rate for lung cancer screening – if possible, identify similar screening to base estimate
- Estimate both positive and false positive screening results from preventive task force study
- Obtain costs for screening (all smokers) and additional tests (for those with false positive results) to incorporate in studies. Obtain estimates on utilization based on Preventive task force study
- Determine the cost of lung cancer screening for 2010 and 2011
  - Calculate total allowed cost, total paid cost, total cost share, and average cost of procedure
  - Calculate allowed cost, paid cost, cost share for the screening and additional tests due to positive results of the screening (for those who really do not have cancer)
  - Calculate distribution of allowed cost, paid cost, and cost share
- Determine the utilization rate of lung cancer screening for 2010 and 2011
- Model the incremental cost of the proposed mandate
  - Calculate the number of covered lives between ages 55-64
  - Multiply by the prevalence rate of smokers aged 55-64
  - Calculate the number of the smokers aged 55-64
  - Estimate the take-up rate of lung cancer screening for smokers
  - Estimate the cost of additional testing due to false positives
  - Determine the overall incremental cost

Fertility Preservation

- Obtain plan enrollment and characteristics including number of covered lives between ages 10-38 and total member months

    - The age limit was determined due to the requirements of accepted fertility preservation methods and the mandate.
- Compile medically induced infertility diagnosis codes and fertility preservation procedural codes for covered lives between ages 10-38
- Determine the cost of fertility preservation by treatment and gender for 2010 and 2011
    - Calculate total allowed cost, total paid cost, total cost share, and average cost of procedure
        - For oocyte cryopreservation, since data was limited, we used embryonic fertility approach until the retrieval of the oocyte and added the cost of the cryopreservation assuming a typical network discount for the services provided. The cost of the cryopreservation was based on a sampling of providers typical fees.
    - Calculate allowed cost, paid cost, cost share
    - Calculate distribution of allowed cost, paid cost, and cost share
- Determine the utilization rate of fertility preservation for 2010 and 2011
- Model the incremental cost of the proposed mandate
    - Calculate the number of covered males/females between ages 10-38 who had medically induced infertility
    - Calculate the portion where the medically induced fertility was within its first year
    - Obtain the prevalence rate of males/females between ages 10-38 with medically induced infertility choosing fertility preservation
    - Calculate the number of covered males/females between ages 10-38 choosing fertility preservation
    - Determine the overall incremental cost
    - Increase the overall results to reflect non-cancer related medically induced infertility

C. Limitations

In estimating the 2014 medical cost of the mandates reviewed in this report, it was assumed that the mandates would become effective on January 1, 2014 and remain in effect throughout the entire calendar year. In the five year projection, future cost increases are explained. This is a complicating factor especially in the case of PANDAS and fertility preservation mandate because it is expected that the frequency of those services will increase in time as medical practice patterns change and public awareness increases.

When mandates are introduced, there may be a growth period during which utilization is increasing but the overall level is less than the ultimate level it will reach after this initial growth period is over and utilization reaches a mature level. During this period, utilization may increase at a rate far greater than medical cost trend. It may take months or years to reach this ultimate level, depending on the mandate and other factors. The medical system is a highly complex system in

which many different forces play a role, and these will affect how quickly the costs of these proposed mandates escalate over the next several years.

Due to the experimental nature of the PANDAs treatments, it is unknown if these treatments will be approved and if the medical professional community will adopt these treatment protocols. The results of this report will be largely impacted by the results of the treatment study.

The US Preventive Services Task Force currently has a recommendation for lung cancer screenings for smokers and former smokers with thirty pack years. Actual utilization of services may be impacted if the recommendation is approved and screenings are included as a preventive service with no cost sharing.

Utilization of the fertility preservations services is dependent in large part on the willingness of a patient's oncologist to recommend the procedures to the patient. The medical professionals who perform these services do not have direct access to the patients themselves.

Throughout the calculations, due to limited available data, various assumptions were made. Where possible, points of reference for similar methodologies were considered in developing these assumptions. Actual experience may differ from these assumptions impacting the results of the study.

V. Actuarial Report

A. 2014 Projections

We have used the term PMPM (per member per month) and per insured person per month to mean the same thing in the following projections. The latter term is meant to convey that the cost of the mandated benefit has been spread to the entire insured population.

In examining the cost of the mandates, we looked at the frequency (or utilization) of the mandated services separate from the unit cost per service. The PMPM cost is the product of the monthly frequency per member times the unit cost. Utilization may be expressed as per person or per thousand people basis. Utilization is usually expressed on an annual basis but may also be on a per month basis. Appropriate conversion was used to obtain a PMPM cost.

1. Mandates 1: PANDAS

The mandate covers both diagnosis and treatment of PANDAS. Since PANDAS does not currently have an established diagnostic criteria, children are considered as having PANDAS if they are ages 3 to 12 and tested positive for strep A within 6 months of receiving an OCD or tic disorder diagnosis. There is no treatment regimen established either. In order to model the incremental cost of the proposed PANDAS mandate, a model was developed using the Optum Large Group Commercial

Database, to estimate the cost differential resulting from the implementation of the mandate. The cost of the proposed mandate will depend on the number of members diagnosed with PANDAS, the diagnostic tools, and the treatment mechanisms employed.

The statute requires the PANDAS to be associated with strep. For the diagnosis element of the statute, that will require initially either a throat culture that yields a Group A beta-hemolytic streptococcal bacteria or an anti-streptococcal titer. The titer can also be used to diagnose a strep throat, but requires that two separate blood tests are done several weeks apart and timed just right to show a "rising titer." If a positive step test is presented, then medically necessary diagnostic services and treatment can be performed.

Since the mandate covers both diagnosis and treatment of PANDAS, the cost estimation consisted of two parts: the incremental cost of diagnosis and the incremental cost of treatment. To determine the cost of diagnosis, we first calculated the utilization rate of strep tests for children between ages 3-12 who had OCD or tic disorder.

Strep tests for children with OCD/Tics	CT		Nation	
	2010	2011	2010	2011
Unique claimants with any strep test*	1	4	195	191
Children 3-12 with OCD or Tics*	114	88	3,402	3,133
Utilization % of strep tests	0.88%	4.55%	5.73%	6.10%

*Covered lives within Optum Large Group Database

Using the dataset for children between ages 3-12 who had OCD or tic disorder, the number of additional strep tests and cost of additional strep tests were estimated as shown in the following table. The diagnosis of PANDAS will add at most $0.0010 to the monthly per member cost of medical care when spread to all members.

Cost of Diagnosis	CT		Nation	
	2010	2011	2010	2011
Children 3-12 with OCD or Tics*	114	88	3,402	3,133
% of children 3-12 with OCD or Tics	0.63%	0.51%	0.39%	0.38%
Children w/ OCD or Tics and no recent strep test*	113	84	3207	2942
Average cost of strep test	9	9	9	10
Cost of additional Strep Tests	$1,248	$749	$40,349	$40,626
Total Member months*	1,264,061	1,095,346	68,140,080	58,393,256
PMPM costs of diagnosis (trended)	0.0010	0.0008	0.0007	0.0008

*Covered lives within Optum Large Group Database

PANDAS has a diverse symptomatology, including but not limited to obsessive compulsive disorder (OCD), separation anxiety, personality changes, major depression and other psychiatric symptoms. The types of treatment in this study include strep tests; immune-based treatments such as intravenous immunoglobulin (IVIG), therapeutic plasma exchange and preventive use of antibiotics.

In the event an individual has symptoms/conditions whose diagnosis and treatment is already covered, there is no additional cost. Even though SSRIs, and cognitive behavior therapy for OCD and tic-like disorders are possible treatments for PANDAS, they were excluded from the cost impact of the mandate because they are the standard treatment for OCD or tics and thus they are already required to be covered under existing mandates. Since there were no claimants found in CT having Plasmapheresis or IVIG, the treatment cost analysis was based on national data only and adjusted to reflect Connecticut level costs.

The PANDAS mandate in SB956 is expected to add about $0.01PMPM to the paid cost of group coverage in 2014. This calculation is based on several simplifying assumptions:

- 7.5 percent of children with OCD or tic disorder between ages 3-12 will have PANDAS. The assumption was determined by the following factors:
  - Public awareness of PANDAS with the implementation of the mandate

- Medical providers advocacy – only a small portion of the medical community are advocates for these treatments
- Percent of PANDAS diagnosis using strep tests
- Percent of children with PANDAS who would follow through the treatments

- The lower and higher take up PANDAS rates are 2.5 percent and 12.5 percent, respectively.

To the extent that the actual experience differs from any of the assumptions shown above, the actual average annual treatment cost will differ from the projected PMPM cost.

	Connecticut 2010	Connecticut 2011
Assumed children w/ OCD or Tics who have PANDAS	7.5%	7.5%
Cost of additional annual treatments	$8,958	$10,305
PMPM Cost of additional annual treatments (trended)	$0.009	$0.011
Total costs(including diagnosis costs)	$10,206	$11,054
Total member months	1,264,061	1,095,346
Costs PMPM(trended)	0.010	0.012
Costs at 25th percentile	0.004	0.005
Costs at 75th percentile	0.018	0.018
Assumed lower rate of Pandas	2.5%	2.5%
Assumed higher rate of PANDAS	12.5%	12.5%
PMPM based on lower PANDAS	$0.004	$0.004
PMPM based on higher PANDAS	$0.015	$0.019

Assuming the average medical cost ratio for group would be 85%, estimated premium for this mandate is shown below including low, middle, high end PMPM based on the paid medical cost distribution.

Estimated premium PMPM

Low (25th percentile)	$0.005
Middle (mean)	$0.012
High (75th percentile)	$0.02

Carrier data:

Of six carriers requested in the survey, five carriers responded to questions regarding their existing benefit coverage as compared to the proposed mandate. Two carriers cover diagnosis and treatment of PANDAS if medically necessary and not experimental. For the two carriers providing the coverage, opinions vary as to whether a particular treatment is experimental or not. One carrier cover plasmapheresis but IVIG is treated as part of a clinical trial and reviewed on a case-by-case basis to determine whether or not it is experimental. The other carrier stated clearly that IVIG and plasmapheresis are not covered. The carrier that does not provide any coverage for diagnosis and treatment of PANDAS expressed the following concern regarding the mandate:

"We are concerned that coverage of these treatments is anticipated to be required under the mandate even if the treatment is considered Experimental & Investigational and/or not medically necessary under carrier policy. This language seems to specifically target the use of expensive treatments such as IVIG and plasmapheresis which have limited evidence of efficacy and may be harmful for some."

In the carrier data, only one of the carriers had IVIG claims and for this carrier, only one claimant used IVIG.

Mandate 2: Lung Cancer Screening

This mandate requires coverage for screening based on the recommendations of the American Lung Association (ALA) after consultation with the American Cancer Society (ACS) based on age, family history and frequency.

For lung cancer screening, the distribution of total allowed cost, paid cost, and cost share for all smokers is summarized by year and area, including minimum, 25th percentile, mean, median, mode, 75th percentile, and maximum.

Total allowed cost

[total $ Allowed per unique claimant, where >$0]	Screening			
	CT(N=14,7)		Nation (N=539,468)	
	2010	2011	2010	2011
Min	$81	$107	$12	$22
25th percentile	$99	$118	$85	$77
Mean	$205	$255	$229	$218
Median	$149	$278	$111	$112
Mode	$102	$321	$67	$67
75th percentile	$321	$321	$294	$271
Max	$501	$486	$1400	$2518

Total paid cost

[total $ paid per unique claimant, where > $0]	Screening			
	CT(N=14,7)		Nation (N=539,468)	
	2010	2011	2010	2011
Min	$72	$94	$0	$0
25th percentile	$92	$96	$71	$67
Mean	$196	$238	$199	$176
Median	$149	$222	$106	$100
Mode	$102	$321	$0	$0
75th percentile	$321	$321	$258	$222
Max	$456	$487	$1400	$2095

Total cost share

[total $ Cost Share per unique claimant, where > $0]	Screening			
	CT(N=13,6)		Nation (N=531,463)	
	2010	2011	2010	2011
Min	$0	$0	$0	$0
25th percentile	$0	$0	$0	$0
Mean	$10	$20	$31	$43
Median	$0	$18	$0	$0
Mode	$0	$0	$0	$0
75th percentile	$0	$31	$25	$46
Max	$100	$56	$844	$2430

Note: that the total cost share table was developed by first calculating cost share to be equal to allowed cost less paid cost and then obtaining statistics from the distribution of cost share. Therefore, the values in the total cost share table are not equal to the difference between the total allowed cost table and paid cost table.

For those screening with positive results, additional tests are needed (with estimated percentages):

100%-Office visit-CPT 99214
90%-Chest CT-CPT 71250-71270
25%-Chest PET scan-CPT 78814
10%-Bronchoscopy with lung biopsy-CPT 31625-31633
2%-Open lung biopsy-CPT 32096-32098
1%- Percutaneous lung biopsy-CPT 32405

While the mandate only covers the screenings, the resulting tests from a false-positive are directly correlated and therefore are included in the cost projection. The distribution of total allowed cost, paid cost, and cost share for follow- up tests is summarized by year and area, including minimum, 25th percentile, mean, median, mode, 75th percentile, and maximum.

[total $ paid per unique claimant, where >$0]	Office Visit			
	CT		Nation	
	2010	2011	2010	2011
Min	$0	$0	$0	$0
25th percentile	$81	$84	$53	$50
Mean	$93	$102	$73	$77
Median	$99	$104	$72	$75
Mode	$106	$116	$0	$0
75th percentile	$112	$128	$94	$98
Max	$240	$286	$360	$479

[total $ paid per unique claimant, where >$0]	Chest CT			
	CT		Nation	
	2010	2011	2010	2011
Min	$0	$0	$0	$0
25th percentile	$75	$72	$67	$67
Mean	$168	$179	$180	$186
Median	$99	$104	$98	$99
Mode	$0	$0	$0	$0
75th percentile	$166	$203	$221	$224
Max	$1518	$1451	$3614	$2901

[total $ paid per unique claimant, where >$0]	Chest PET			
	CT		Nation	
	2010	2011	2010	2011
Min	$0	$0	$0	$0
25th percentile	$139	$136	$115	$113
Mean	$1036	$1078	$859	$894
Median	$191	$231	$1580	$192
Mode	$139	$136	$115	$113
75th percentile	$1142	$1961	$947	$1627
Max	$5334	$5041	$4425	$4182

[total $ paid per unique claimant, where >$0]	Bronchoscopy			
	CT		Nation	
	2010	2011	2010	2011
Min	$0	$0	$0	$0
25th percentile	$239	$271	$157	$160
Mean	$246	$736	$343	$358
Median	$270	$339	$243	$256
Mode	$326	N/A	$0	$0
75th percentile	$326	$552	$389	$411
Max	$357	$3645	$3595	$4625

[total $ paid per unique claimant, where >$0]	Open Lung Biopsy			
	CT		Nation	
	2010	2011	2010	2011
Min	106	$110	$125	$130
25th percentile	494	$563	$581	$663
Mean	405	$483	$477	$569
Median	631	$632	$743	$744
Mode	N/A	N/A	N/A	N/A
75th percentile	4879	$2644	$5745	$3114
Max	106	$110	$125	$130

[total $ paid per unique claimant, where >$0]	Percutaneous lung biopsy			
	CT		Nation	
	2010	2011	2010	2011
Min	$143	128	$0	$0
25th percentile	$143	$147	$100	$103
Mean	$161	$257	$175	$197
Median	$169	$198	$140	$148
Mode	N/A	N/A	$0	$0
75th percentile	$170	$382	$186	$193
Max	$170	$487	$1,475	$1,772

The lung cancer screening mandate is expected to add about $0.23 PMPM to the paid medical cost of group coverage in 2014. Since lung cancer screening is not currently recommended practice for current or former smokers, very low utilization of lung cancer screening was found in our internal data as expected. This calculation is based on several simplifying assumptions:

- According to the CDC studies, the percentage of population between ages 45-64 who are smokers is approximately 15.83 percent in Connecticut and 21.10 percent nationally.
- According to our internal clinical guidance, the take up rate for lung cancer screening is 22 percent after the passage of the mandated benefit. The lower and higher take up rates are 10 percent and 40 percent, respectively.
- Based on the US preventive task force study, 25 percent of smokers will get positive screening results from which 95 percent will get false positive results

To the extent that the actual experience differs from any of the assumptions shown above, the actual average annual treatment cost will differ from the projected PMPM cost.

Lung Cancer Screening				
	CT		Nation	
	2010	2011	2010	2011
Average procedure cost	205	255	229	218
Covered lives 55-64 years	17,594	17,580	1,185,648	1,201,935
Assumed percentage of smokers	15.83%	15.83%	21.10%	21.10%
Assumed (former) smokers	2,784	2,782	250,172	253,608
Assumed take up rate for screening	22%	22%	22%	22%
Assumed (former) smokers obtaining screening	613	612	55,038	55,794
Net cost of screening	$125,809	$155,986	$12,603,652	$12,151,337
Positive test rate	25%	25%	25%	25%
False Positives	95%	95%	95%	95%
Cost of additional testing	$548	$587	$506	$528
Net cost of additional testing	$79,743	$85,274	$6,614,618	$6,995,102
Cost of mandate	$205,552	$241,261	$19,218,269	$19,146,439
Member months	1,264,061	1,095,346	68,140,080	58,393,256
PMPM costs (trended)	$0.20	$0.25	$0.34	$0.38
Low take-up rate	10%	10%	10%	10%
High take-up rate	40%	40%	40%	40%
Low take-up rate PMPM (trended)	$0.09	$0.12	$0.16	$0.17
High take-up rate PMPM (trended)	$0.36	$0.46	$0.62	$0.69
Lower positive rate for repeats	10%	10%	10%	10%
Lower false positive rate	75%	75%	75%	75%
Percentage of repeats	33%	33%	33%	33%
PMPM due to repeats (trended)	$0.18	$0.25	$0.32	$0.37
PMPM costs using 25th percentile (trended)	$0.13	$0.16	$0.20	$0.24
PMPM costs using 75th percentile (trended)	$0.27	$0.33	$0.41	$0.46

Assuming the average medical cost ratio for group would be 85%, estimated premium for this mandate is shown below including low, middle, high end PMPM based on the paid medical cost distribution.

Estimated premium PMPM

Low (25th percentile)	$0.18
Middle (mean)	$0.27
High (75th percentile)	$0.35

Carrier data:

Of six carriers requested in the survey, five carriers responded to questions regarding their existing benefit coverage as compared to the proposed mandate. All of the three carriers provide some coverage for lung cancer screening though on a different basis. One carrier covers lung cancer screening up to the limits of the preventive general benefit for adult preventive care for plans offered in Connecticut prior to March 12, 2009. The other carrier offers the benefit as of September 2013 due to PPACA. Another carrier offer the coverage based on medical necessity and expressed the concern that people without symptomology might be requesting tests, and " Increase in the number of tests requested that may not be medically necessary. In addition, CT scans do have some radiation risk and the benefits of the test should be weighed against the radiation risk especially for people who have had many X-rays or CT scans".

The projected PMPM cost varied by carrier. Excluding those carriers that did not submit sufficiently reliable data, the average paid PMPM cost for lung cancer screening was $0.18, which is consistent with estimates using our internal data.

Mandate 3: Fertility Preservation

HB5644 requires group and individual plans and policies to provide "coverage of fertility preservation for insureds facing likely infertility as a result of a necessary medical procedure for insured with cancer and other medical conditions." The bill does not specify the necessary medical procedures that might cause infertility. Enrollees diagnosed with one of the top 10 cancers associated with treatments that could cause iatrogenic infertility were considered potential users of fertility preservation services.

Fertility preservation services include three medical procedures that are standard practice to protect against iatrogenic infertility: (1) sperm cryopreservation (freezing) for men; (2) embryo cryopreservation for women; and (3) oocyte (egg) cryopreservation for women.

Currently, the per-unit costs vary depending on whether the extraction and storage services are for men or for women. Both face initial charges for the extraction procedure, along with annual fees for storage. The annual in-network

storage costs were estimated to be sperm ($192.50), embryos ($275), and oocytes ($275).

Sperm cryopreservation paid costs are an average of $826 (including the first-year storage cost). Both embryo and oocyte procurement are surgical procedures and require several weeks of prescription drug treatment prior to the actual surgical procedure itself. The cost of embryo cryopreservation is $14,177, which includes oocyte retrieval, in vitro fertilization (IVF), the cost of the first-year storage, and the prescription drug treatment.

As oocyte cryopreservation usage was not found in our internal database (note that only one member was identified with undergoing oocyte cryopreservation in the carrier data), alternative methodology was employed to develop the cost - all fertility related medical and Rx costs for oocyte retrieval beginning two months prior to the procedure date identified by the two CPT codes 58970 (Follicle puncture of oocyte retrieval, any method) and 89254 (Oocyte identification from follicular fluid) plus the actual cost of cryopreservation. The cost of oocyte cryopreservation is approximately $7,204, which includes surgical procedure, the first-year storage, and the prescription drug treatment. Oocyte cryopreservation costs are a little less than embryo cryopreservation because the former does not require an oocyte fertilization procedure (IVF) or embryo culture in the laboratory for 3–5 days prior to freezing.

For sperm cryopreservation, the distribution of total allowed cost, paid cost, and cost share is summarized by year and area, including minimum, 25th percentile, mean, median, mode, 75th percentile, and maximum.

[total $ Allowed per unique claimant, where >$0]	Sperm Cryopreservation			
	CT (assumed 15% higher than nation)		Nation	
	2010	2011	2010	2011
Min	$3	$37	$3	$32
25th percentile	$183	$178	$159	$155
Mean	$781	$1,083	$679	$941
Median	$468	$441	$407	$384
Mode	$109	$305	$95	$265
75th percentile	$968	$1,357	$842	$1,180
Max	$7,182	$6,906	$6,245	$6,005

[total $ Paid per unique claimant]	Sperm Cryopreservation			
where >=$0]	CT (assumed 15% higher than nation)		Nation	
	2010	2011	2010	2011
Min	-	-	-	-
25th percentile	$113	$97	$98	$84
Mean	$571	$828	$496	$720
Median	$232	$260	$202	$226
Mode	-	-	-	-
75th percentile	$752	$1,093	$654	$950
Max	$6,967	$6,132	$6,058	$5,332

[total $ Cost Share per unique]	Sperm Cryopreservation			
claimant, where >=$0]	CT (assumed 15% higher than nation)		Nation	
	2010	2011	2010	2011
Min	-	-	-	-
25th percentile	$18	$35	$16	$30
Mean	$224	$261	$195	$227
Median	$123	$125	$107	$109
Mode	-	-	-	-
75th percentile	$358	$327	$312	$284
Max	$2,336	$1,244	$2,031	$1,082

For embryo cryopreservation, the distribution of total allowed cost, paid cost, and cost share is summarized by year and area, including minimum, 25th percentile, mean, median, mode, 75th percentile, and maximum.

[total $ Allowed per unique claimant, where >$0]	embryo cryopreservation			
	CT (N=9,10)		Nation	
	2010	2011	2010	2011
Min	$10,024	$952	$44	$86
25th percentile	$12,163	$10,984	$7,275	$7,909
Mean	$13,262	$14,133	$11,413	$12,323
Median	$12,934	$14,074	$10,420	$10,946
Mode	N/A	N/A	$4,395	$7,909
75th percentile	$14,107	$15,243	$14,692	$14,920
Max	$17,500	$29,983	$49,310	$58,793
[total $ Paid per unique claimant, where > $0]	**embryo cryopreservation**			
	CT (N=9,10)		Nation	
	2010	2011	2010	2011
Min	$9,142	$750	-	-
25th percentile	$10,728	$10,931	$5,641	$5,929
Mean	$11,099	$12,839	$10,058	$10,826
Median	$10,946	$12,203	$8,719	$9,259
Mode	N/A	N/A	N/A	N/A
75th percentile	$11,421	$14,609	$13,417	$13,229
Max	$13,616	$29,760	$48,962	$56,787
[total $ Cost Share per unique claimant, where > $0]	**embryo cryopreservation**			
	CT (N=9,10)		Nation	
	2010	2011	2010	2011
Min	-	-	-	-
25th percentile	$1,344	$202	$385	$317
Mean	$2,163	$1,293	$1,369	$1,530
Median	$1,565	$1,760	$920	$949
Mode	N/A	N/A	$250	$250
75th percentile	$2,364	$1,938	$1,770	$2,231
Max	$7,096	$3,078	$10,451	$11,554

For oocyte cryopreservation, the distribution of total allowed cost, paid cost, and cost share is summarized by year and area, including minimum, 25th percentile, mean, median, mode, 75th percentile, and maximum.

[total $ Allowed per unique claimant, where >$0]	oocyte cryopreservation			
	CT (N=35,25)		Nation	
	2010	2011	2010	2011
Min	$2,225	42,723	$198	$12
25th percentile	$5,500	$4,921	$4,162	$3,786
Mean	$7,564	$7,474	$6,658	$6,395
Median	$6,847	$6,836	$5,818	$5,266
Mode	$7,072	N/A	$3,453	$1,432
75th percentile	$8,345	$8,961	$7,995	$7,644
Max	$25,729	$18,138	$55,132	$35,999

[total $ Paid per unique claimant, where > $0]	oocyte cryopreservation			
	CT (N=35,25)		Nation	
	2010	2011	2010	2011
Min	$1,375	$2,725	-	$12
25th percentile	$3,731	$4,032	$3,215	$2,894
Mean	$5,970	$6,176	$5,469	$5,320
Median	$5,396	$5,918	$4,687	$4,328
Mode	#N/A	#N/A	$2,167	$1,477
75th percentile	$6,995	$7,184	$6,820	$6,483
Max	$23,844	$16,575	$24,304	$35,499

[total $ Cost Share per unique claimant, where > $0]	oocyte cryopreservation			
	CT (N=35,25)		Nation	
	2010	2011	2010	2011
Min	-	$128	-	-
25th percentile	$400	$533	$330	$310
Mean	$1,593	$1,352	$1,202	$1,088
Median	$730	$1,018	$692	$710
Mode	$N/A	N/A	N/A	N/A
75th percentile	$2,085	$1,543	$1,484	$1,406
Max	$7,865	$4,481	$39,323	$10,709

The model shows an incremental paid cost of approximately 0.05 PMPM. This calculation is based on several simplifying assumptions:

- Base assumption of 29% of males and 4% of females would undergo fertility preservation if made aware[6].
- Incremental 10 and 5 percent of males and females respectively with cancer between ages 10-38 will undergo fertility preservation treatment in addition to the current utilization of the services under the mandate due to the following factors:
    - Public awareness with the passage of the mandate
    - Oncologist engagement in recommending fertility preservation procedures to their patients
    - Higher expected utilization increase for males due to the fertility preservation being less invasive and contains a shorter time period to perform.

To the extent that the actual experience differs from any of the assumptions shown above, the actual average annual treatment cost will differ from the projected PMPM cost.

The types of cancers considered in this study include the following:

- Colon and rectum—in situ and malignancy
- Breast—in situ and malignancy
- Cervix—malignancy only
- Ovarian
- Hodgkin lymphoma
- Non-Hodgkin lymphoma
- Leukemia
- Uterine
- Brain/CNS

6 Schover LR, Brey K, Lichtin A, Lipshultz L, Jeha SI. Oncologists' attitudes and practices regarding banking sperm before cancer treatment. *Journal of Clinical Oncology*. 2002;20:1890-1897.

	Fertility Preservation			
	Male		Female	
	2010	2011	2010	2011
Covered lives with cancer – Ages 10-38	64	48	92	60
Covered lives with first-year cancer – Ages 10-38	33	24	47	31
Percentage of cancer patients going through a fertility treatment according to study	29.0%	29.0%	4.0%	4.0%
Estimated take-up rate with mandate	39%	39%	9%	9%
Projected costs	7,264.48	7,907.28	44,461.35	33,320.75
Costs of Mandate	7,264.48	7,907.28	44,461.35	33,320.75
Total Member months	1,264,061	1,095,346	1,264,061	1,095,346
Costs PMPM (trended and adjusted for non-cancer)	0.008	0.009	0.048	0.039
Using lower (baseline) take up rate	29%	29%	4%	4%
Using higher take up rate	49%	49%	14%	14%
Projected costs using lower take up rate	0.006	0.006	0.017	0.015
Projected costs using higher take up rate	0.010	0.010	0.061	0.053
Projected costs using 25th percentile	0.002	0.001	0.037	0.0284
Projected costs using 75th percentile	0.01	0.012	0.049	0.045

Assuming cancer represents 90% of iatrogenic infertility and the average medical cost ratio for group would be 85%, estimated premium for this mandate is shown below including low, middle, high end PMPM based on the paid medical cost distribution.

Estimated premium PMPM

Low (25th percentile) $0.04

Middle (mean) $0.06

High (75th percentile) $0.07

Carrier data:

Of six carriers requested in the survey, five carriers responded to questions regarding their existing benefit coverage as compared to the proposed mandate. One carrier considers cryopreservation of oocytes or embryos or sperm as medically necessary and therefore has provided the coverage since December 2012. However, information about the pending chemotherapy or radiotherapy would need to be submitted with prior authorization. The insurer would need to know that the member is going to be treated with chemotherapy in the future to know to pay the claims for the fertility preservation services. One carrier offers only trachelectomy and another carrier does not provide any coverage related to fertility preservation services.

For the language of the mandate legislation, one carrier made the following suggestion:

“The legislation needs to specify whether the male, female, or both need to be 38 years of age or younger to qualify for coverage of the harvesting and storage of the sperm or egg. The legislation would also need to specify whether the thawing and egg or sperm transfer would be covered for persons who are over age 38.”

Financial and Economic Analysis of Phase Five 2014 Mandates

INTRODUCTION:

In prior phases reviewing the State of Connecticut's mandated benefits, this section containing the financial and economic analysis began with a summary of the state of health coverage in the state of CT. Most of that same summary is incorporated here with minor revisions and some updating consistent with the 2013 mandates. The original write-up was completed in early 2011 by Tanvir Khan and Krista King with assistance from Dr. Tom Knabel and Dan Bailey:

The availability of healthcare coverage and its impact on families by income are discussed in this report. Additionally, the expected financial burden and socioeconomic aspects of the 2013 mandates are analyzed in this report. Cost-burden to the individual and family is discussed, both in the presence and absence of the 2013 mandates. A broader interpretation of financial burden was considered; it includes socioeconomic factors, in addition to other cost burden considerations. Lost productivity was not reviewed since they are expected to be very limited for the 2013 mandates. (The PANDAS mandate impacts children. The lung cancer screening and fertility preservation are not diseases causing significant lost productivity)

Economic status of CT population

A. Demographics -- Income

To understand health coverage in CT, first the entire CT population is examined; then, two smaller subsets:

Prior to any mandate, the entire burden of the disease is borne by the member (lacking any external form of financial assistance). Therefore, to understand the impact of the illness on the population, it is important to demonstrate the current financial landscape of Connecticut residents.

According to the US Census bureau, the mean income of CT households is $95,032 with a median income of $67,544. The 25th Percentile is approximately $34,000 and the 75th percentile is $120,000.

B. Demographics – Population

As mentioned earlier, for those with health coverage, all people of all ages are considered—this includes everyone residing in CT. According to the census annual estimate for 2012, that is 3,590,347 people of which 3,058,976 are under 65 years of age. It includes people who have any type of health coverage whether fully insured or not, whether private or public. It also includes people who have no health coverage—the uninsured. This is shown below in the table of percentages by coverage type

ALL CT RESIDENTS, 2012, <65 years

TYPE OF HEALTH COVERAGE	
Group, Fully Insured	**27.3%**
Individual, Fully Insured	**7.5%**
Self-Funded Group	**41.8%**
Medicaid	**12.9%**
Medicare	**0.8%**
Military	**9.2%**
Uninsured	**1.2%**
Other Public	**0%**

A second group includes only those with "commercial health coverage." This view excludes those 65 years of age or older. It also excludes anyone with any type of public coverage through any government program, such as Medicare, Medicaid, Husky (the State Children's Health Insurance Program), the Department of Defense TriCare, or the Veterans Health Administration.

The third group is a yet smaller subset and includes only those with fully insured commercial coverage—both group and individual policies. In addition to all excluded in the second group, this third group also excludes everyone with self-funded employer coverage. It is the only population legally subject to CT's health insurance mandates.

The term "employer based coverage" consists of two non-overlapping subsets:

1. Fully insured groups, and
2. Self-funded groups

Although about 60% of CT residents have private, employer-based group coverage, most is self-funded (not fully insured) and is thus not subject to the state health insurance mandates. Many authors on the subject of health care use the terms coverage and insurance as if they mean the same thing. Technically, self-funded health coverage is not health insurance; that distinction is maintained here because state health mandates do not apply to self-funded coverage. The 69% with employer coverage is 60.5% self-funded and 39.5% fully insured. That is, the 69% employer-based coverage breaks down further into 42% self-funded group and 27% fully insured group. Although the State plans currently have chosen to comply with all insurance benefit mandates, they are not required to do so and therefore they are included in the self-funded 65%. The state EEs and their dependents are approximately 5% of the CT population and are the largest commercial group in the state.

According to the Connecticut Insurance Department, it is expected due to ACA, there will approximately 200,000 additional individuals obtaining insurance either through the individual coverage or through employer-based coverage. Of those, we expect 90% to be fully insured and potentially impacted by these mandates. Additionally, from the employer-covered population we expect there to be an additional shift of employers moving towards self-funding up to 65% of the employer sponsored coverage population and removing the covered individuals from these mandates. The resulting assumption is approximately 1.1 million individuals to be covered by insurance plans impacted by these mandates. The state of CT has historically included the mandates in the coverage of their employees. If this continues, there would be just over 1.3 million individuals covered by these mandates. The chart below shows the expected distribution in 2014:

ALL CT RESIDENTS, Projected 2014,<65 years

TYPE OF HEALTH COVERAGE	
Group, Fully Insured	**24.2%**
Individual, Fully Insured	**7.5%**
Self-Funded Group	**44.9%**
Medicaid	**12.9%**
Medicare	**0.8%**
Military	**9.2%**
Uninsured	**1.2%**
Other Public	**0%**

C. Cost of Health Care Medical Insurance

As mentioned earlier in section III (D), the cost of insurance is very different between with employer coverage and those purchasing directly for individual coverage. The total premiums and insured's portion of the average premium are reflected in the chart below:

Large Group		Small Group		Individual	
Covered Lives	**Avg. Premium**	**Covered Lives**	**Avg. Premium**	**Covered Lives**	**Avg. Premium**
332,159	$5,011.11	304,258	$6,582.26	110,355	$3,640.61

Data source: CPHHP 2013 CT Carrier survey 2012 data average costs per member projected to 2014

Even with these typical policies and average premium mentioned above, the healthcare landscape has changed significantly reflecting two very different types

of coverage with very different costs. High deductible health plans are increasingly common, especially in the individual and small group markets. America's Health Insurance Plans (AHIP) estimates that nationally over ten million lives were covered in 2010 under Health Savings Account/High-Deductible Health Plans (HSA/HDHP).

In Connecticut, almost 10% of the lives covered by commercial health insurance have an HSA/HDHP plan. Per IRS rules, these plans have an inflation indexed minimum deductible for individual and family coverage (for 2013, the minimum family deductible is $2,500). Without some modification of benefit design, the high deductible in such plans can be a deterrent to services that are of high value and much needed. For example, if one had to wait until a $2,500 deductible is satisfied in order to get a medically necessary service, the tendency might be to wait rather than pay. As a result of the Affordable Care Act (ACA), however, crucial preventive services are now provided by health insurance plans with no member cost-sharing.

Financial Burden

Upon reviewing each mandate, there is a potential burden impacting a member

1. Without health care coverage
2. With health care coverage that is not subject to the mandate
3. With fully-insured health care coverage that is subject to the mandate

When the member has no insurance coverage, he or she will be responsible for the submitted charge or some discount thereof. This may be higher than the allowed costs used by insurers in calculating their initial liability. Hence, the full burden of the costs falls upon the patient.

When the member has insurance coverage and without the mandate existence, the member would still need to bear the burden of the costs where the procedures are not typically covered through the insurance. However, depending on the contract with the provider, the member may receive a discount for the services covered. This would be typically represented by the allowed costs

When the mandate applies and the member has insurance coverage, the member would be responsible for any cost sharing. The actual cost sharing is determined based on the type of plan covering the member, its benefit richness, and the services being provided.

Even prior to the passage of the ACA, insurers recognized this member propensity to delay care and countered with new and improved plan designs designed to encourage access to benefits that bring higher value for cost. Preventive benefits are often covered without satisfying the deductible or even requiring any cost-sharing at all. Certain high value services may be made

available in high deductible plans, with or without co-pay, prior to satisfying the deductible. The idea is that the benefit design should help the member obtain high-value needed services with minimal economic barriers to access. Health insurers may refer to these as wellness or preventive benefits. The mandate for Lung Cancer screening may be categorized as a preventive benefit under the federal Affordable Care Act (ACA). Under the ACA, preventive services must be covered with zero cost-sharing for the patient.

Under the Affordable Care act, there is a limit on out of pocket expenses which can be borne by the member. Where a member is already bearing significant out of pocket costs because of the existence of a disease, the member may more easily reach their out of pocket limits and therefore the procedures covered under the mandate may result in little or no additional cost sharing responsibilities for the member. Two of the mandates (PANDAS and Fertility Preservation) may fall under this category if covered.

When there is cost sharing to be borne by the member, a member may defer or delay treatment due to its financial impact. This can be stretched further depending on why the service is being provided. For the three mandates under review, we can categorize them in three very different categories.

1. Treatment for an existing and prevalent condition – PANDAS
2. Screening for potential existence of a condition – Lung cancer screening
3. Procedures not related to an existing disease or its cure. However, the procedure treats a side-effect of the treatments currently being undertaken by the member – Fertility preservation

Each of these categories of conditions and the related services would impact the member decision process for bearing the financial burden for the treatments. This is relevant whether the entire cost is borne by the patient or there is only cost sharing borne by the member.

In the reports for earlier phases, individual/family cost burden was modeled along two axes:
Family Income Level vs. Member Cost-Sharing paid by the individual or family. The portion of cost paid by the individual or family reflects the adequacy of the benefit. This is also called “actuarial value.” If there is no cost-sharing, the paid cost equals the allowed cost; such a plan would have an actuarial value of 100%. If the mandated service, or some aspect of it, is not a covered service, however, then the individual or family must bear 100% of the non-covered cost. Essentially, the families with the lowest income and highest cost-sharing have the greatest cost-burden. Thus, the poorest uninsured people have the greatest cost-burden. Additionally, the poorest uninsured people do not have access to the substantial discounts on provider reimbursement that payers have, thus increasing their cost-burden. In general, there is little transparency in hospital charges in the US, and so this fact is often overlooked.

LEVEL OF COST-BURDEN				
Relationship between Income and Level of Member Cost-Sharing				
Cost-Burden decreases as Income increases and cost-sharing decreases				
	INCOME LEVEL	**< $50k**	**$50k - $80k**	**> $80k**
Benefit "Richness"				
Uninsured		**Most**	More →	
HDHP		More	↘	
20% Cost Sharing		↓		Less
10% Cost Sharing			Less	**Least**

Not everyone is uninsured, however, and not all the uninsured are poor. Those who have health insurance or self-funded health coverage may have varying levels of member cost-sharing. In general, some people are covered by "rich" health plans that cover health services with very little cost-sharing. Others may have "lean" plans with high deductibles, and or significant coinsurance and co-pays. Along this continuum, the model evaluates cost-burden for those with varying levels of member cost-sharing. On the extreme are those individuals not impacted by the mandate who must bear the full burden of these medical costs. This report also considers the impact of those individuals.

Along the continuum of family income, the model examines cost burden with respect to the family's means to pay. Obviously, someone as wealthy as Bill Gates can afford to pay for any health insurance he wants; he could also afford to go without insurance and pay for care entirely out of pocket. Moreover, even if a very wealthy person has health coverage, a $20 co-pay for a physician office visit does not serve as a deterrent to marginally necessary care, as it would for an individual at the other end of the income continuum. For this reason, the model looks at combinations of income and health benefit plan richness to assess cost burden. Due to their nature, the examination of cost-burden is less relevant to these 2013mandates than it was to the mandates reviewed in earlier phases of this CT mandate project.

Many of the mandates covered by fully insured plans are also covered by self-funded plans in CT. Historically, self-funded plans have covered larger groups, which tend to offer "richer" health benefit coverage than smaller groups. CT residents covered by self-funded plans enjoy coverage of many of the mandated services, and they often have lower cost-sharing than individual plans and small group plans that are fully insured.

As more smaller-size employer groups also migrate into self-funded coverage, the average benefit level of their self-funded plans will be less than that of the larger groups with richer benefits that moved to self-funded arrangements much earlier. Like fully insured group employers, many self-funded employers require their employees to share an increasing portion of overall annual cost. They

require employees to contribute an increasing amount annually to pay for the coverage itself. Fully insured plans refer to this cost as the health insurance premium, and the average fully insured employee also pays an increasing portion of it annually. Self-funded plans do not have premiums per se, but they have costs that are essentially equivalent to premiums. Self-funded plans refer to this cost as "contributions", and they split it into the employer contribution and employee contribution. The average employee contribution has been rising annually for employees in self-funded groups at a rate faster than the employer contribution. Due to the annual increase in medical costs at a rate greater than general CPI, some employers are moving toward a "defined contribution" approach to health coverage. The employer sets a maximum annual dollar amount it will pay toward their employees' health coverage, and the employee pays the remainder. The employer can increase this amount annually at a rate that does not keep pace with medical trend. This forces an increasing percentage of total health coverage cost onto the employee.

The portion of insurance premium that must be paid by the employee in a group plan is not incorporated into the cost-burden chart above. This is a price that must be paid before any services are incurred. The more the employee must pay for this, however, the less will remain for member cost-sharing. This is especially true for those individuals and families at lower income levels.

Financial Burden Review of Individual Mandates

Cost Burden of PANDAS Diagnosis and Treatment

For the PANDAS mandate, we are referring to a potential treatment for an existing condition. It is important to note the treatments proposed under this mandate are considered experimental and are currently under review for effectiveness. In this situation, the member is considering whether the treatment will be successful and whether they have the financial means for covering the treatment. Therefore, there should be an expected tendency to wait, especially at a lower income level. First the member will need to take an ASO titer strep test. The cost is relatively low and the ranges hover at approximately $10 per test. In the scope of costs for members with the underlying OCD or tic disorder, this is expected to have relatively minimal impact on utilization. If the insured is considered positive for having PANDAS and the member chooses to undergo the treatments covered by the mandate, there are different treatments and resulting financial paths the insured would consider. One protocol is cheaper in the short term although potentially expensive for the longer term through a treatment protocol of prophlylactic antibiotic use. Other approaches include an IVIG treatment pattern and/or plasmapheresis. Some treatment protocols include a combination of the treatment methodologies. It is possible that due to the increasing deductibles in particular, some of the mentioned treatment protocols may not be used. On the other hand, since these conditions typically cause

additional claims, they may reach their out of pocket maximum and have no additional out of pocket.

Based on the review of Connecticut data, only 0.1% of children or 1,143 members are expected to be eligible for the diagnosis. With the assumption of 7.5% of children with OCD or Tics being diagnosed and some treated for PANDAS, we expect 77 children within Connecticut to be treated and potentially covered under the mandate

For members with OCD and Tics, the following is the expected cost share distribution amongst members

Cost Share Distributions for Members Aged 3-12 with OCD or Tics Disorder -- 2010 (trended) and 2011

Cost Share amount	National Member Distribution (n=6521)	Connecticut Member Distribution (n=185)
$0	6.7%	6.5%
$0 to $200	70.4%	68.1%
$200 to $400	10.3%	13.0%
$400 to $600	4.4%	2.7%
$600 to $800	2.5%	2.7%
$800 to $1000	1.4%	3.2%
$1000 to $2000	3.2%	3.8%
$2000 to $3000	0.5%	0.0%
More than $3000	0.6%	0.0%

The cost for the diagnosis and treatments are as follows

	Allowed	Paid	Average cost sharing		Individual Silver	High Deductible
	(Uninsured)		10% Cost Share	20% Cost Share	30% cost sharing	Assumed $2500/20%
Strep	$14	$10	$1	$3	$4	$14
IVIG	$4,357	$3,522	$436	$835	$1,307	$ 1,714
Plasmaphresis	$32,001	$27,528	$3,200	$4,473	$6,350	$6,350
Antibiotics	$1,205	$1,017	$120	$187	$361	$1,205
IVIG and Antibiotics	$5,561	$4,539	$556	$1,022	$1,668	$2,015
Plasmaphresis and antibiotics	$33,205	$28,545	$3,321	$4,660	$6,350	$6,350

Note: For high deductible plans, we assumed $2,500 deductible of which half would already be exhausted and an average cost sharing of 25% above the deductible. For all plans, cost sharing was capped at the ACA mandated $6,350 out of pocket limit.

For various income levels, the following is the expected financial burden as a percentage of income for the uninsured and for those with varying levels of coverage if the mandate is approved.

	Allowed	Paid	Average cost sharing		Individual Silver	Average cost sharing
	(Uninsured)		10% Cost Share	20% Cost Share	30% cost sharing	High Deductible
Income level	$35,000	$35,000	$ 35,000	$35,000	$ 35,000	$35,000
Medium cost treatment	5,561	4,539	556	1,022	1,668	2,015
% of income	15.9%	13.0%	1.6%	2.9%	4.8%	5.8%
Lower cost treatment	1,205	1,017	120	187	361	1,205
% of income	3.4%	2.9%	0.3%	0.5%	1.0%	3.4%
Higher Cost treatment	33,205	28,545	3,321	4,660	6,350	6,350
% of income	94.9%	81.6%	9.5%	13.3%	18.1%	18.1%
Income level	$65,000	$65,000	$65,000	$65,000	$65,000	$65,000
Medium cost treatment	5,561	4,539	556	1,022	1,668	2,015
% of income	8.6%	7.0%	0.9%	1.6%	2.6%	3.1%
Lower cost treatment	1,205	1,017	120	187	361	1,205
% of income	1.9%	1.6%	0.2%	0.3%	0.6%	1.9%
Higher Cost treatment	33,205	28,545	3,321	4,660	6,350	6,350
% of income	51.1%	43.9%	5.1%	7.2%	9.8%	9.8%
Income level	$95,000	$95,000	$95,000	$ 95,000	$ 95,000	$ 95,000
Medium cost treatment	5,561	4,539	556	1,022	1,668	2,015
% of income	5.9%	4.8%	0.6%	1.1%	1.8%	2.1%
Lower cost treatment	1,205	1,017	120	187	361	1,205
% of income	1.3%	1.1%	0.1%	0.2%	0.4%	1.3%
Higher Cost treatment	33,205	28,545	3,321	4,660	6,350	6,350
% of income	35.0%	30.0%	3.5%	4.9%	6.7%	6.7%
Income level	$120,000	$120,000	$120,000	$120,000	$120,000	$120,000
Medium cost treatment	5,561	4,539	556	1,022	1,668	2,015
% of income	4.6%	3.8%	0.5%	0.9%	1.4%	1.7%
Lower cost treatment	1,205	1,017	120	187	361	1,205
% of income	1.0%	0.8%	0.1%	0.2%	0.3%	1.0%
Higher Cost treatment	33,205	28,545	3,321	4,660	6,350	6,350
% of income	27.7%	23.8%	2.8%	3.9%	5.3%	5.3%

Cost Burden of Lung Cancer Screening

For the Lung Cancer Screening mandate, to qualify for the screening, a member must:

1. Be a current or former smokers aged 55 to 74 years;
2. Contain a smoking history of at least 30 pack-years;
3. Have no history of lung cancer/be in fairly good health.

This population due to their elongated smoking history and still overall favorable health is likely adverse to participation in healthcare initiatives.

For those who obtain a screening, the expected cost of the mandate includes additional testing resulting from false-positive reads on the screening, requiring more invasive testing. This is similar to a mammogram showing a lesion requiring a biopsy to determine if cancerous. The mammogram would be the preventive screening while the biopsy would be the additional costs due to the impact of obtaining the screening and showing a non-cancerous lesion.

Since there is currently a proposal from the US Preventive Task Force to include the screening as a required preventive service, and ACA's requirement for preventive cost sharing to be covered in full without member cost sharing, there is potential for no member cost sharing on the screening portion of the mandate. Regardless of this decision, the recommendation can also result in no cost for the screening portion of the mandate provided the mandate falls within the parameters of the USPTF recommendation and carriers' implementation.

As indicated in bullet 3 above, the lung cancer screening mandate only applies where there are no symptoms of the disease present. If there was a disease already knowingly manifesting in the body, the screening and/or subsequent testing would have already been covered under most plans' existing healthcare insurance coverage. Since there is no disease prevalent, we would expect those with lower income to delay any screenings. Even with the screening covered we expect there to be a relative low take-up rate due to the resistance to healthcare initiatives within this population as evident from their prolonged smoking.

The additional testing due to false positive results from the screening is not considered a preventive service. The costs are often higher and can result in cost sharing by the member. Since this screening contains a very high false positive rate, we expect a large portion of covered individuals to need these additional tests. This can impose a financial burden on those with lower income and potentially causing individuals to delay obtaining the further testing , essentially defeating the purpose of the mandate.

Based on the review of Connecticut data, only 15.83% of adult smokers (or former smokers) within the 55-64 age band or 23,547 members are expected to be eligible for the diagnosis. We estimate 5,179 smokers (or former smokers) to be screened and 1,288 smokers (or former smokers) to be tested due to a false-positive result from the screening as a result of this mandate

The cost for the screening and testing are as follows

Diagnosis: Average cost $275

Testing including some of the following: Office Visit, Chest CT, Chest PET, Bronchoscopy, Open Lung Biopsy, Percutaneous Lung Biopsy

Ranges from: $256-$877 with an average cost $672

For various income levels, the expected financial burden as a percentage of income for the uninsured and for those with varying levels of coverage if the mandate is approved is expected to range from 0.2%-0.5% for those undergoing the screening and 0.5%-3.0% for those undergoing the screening and additional testing

Cost Burden of Fertility Preservation

For the Fertility Preservation mandate, individuals undergoing a medical procedure potentially causing future infertility are covered by this mandate. The individuals covered under this mandate are likely undergoing or will soon be undergoing expensive elongated procedures and treatments due to their medical condition. Previously, due to lack of coverage, unawareness of the coverage, significant cost sharing expenses, as well as potential religious beliefs accompanying the availability of some procedures, there has been very little use of the fertility preservation procedures. With coverage of the mandate and newly defined ACA out of pocket limits being reached by many cancer patients, the cost burden impact are likely to be reduced and the potential use of fertility preservation may be increased.

To be covered under the mandate, the individual must be of age to produce viable eggs or sperm for later fertilization. For the purposes of this report, we assumed a minimum age of 10 and an upper limit of 38 to coincide with the infertility preservation previously reviewed under a different mandate. Based on the review of Connecticut data, only 0.1% of members within the 10-38 age band or 1119 members are estimated to be diagnosed with cancer. Of the 1119 members, we estimate 571 to be newly diagnosed and potentially eligible for fertility preservation. We estimate 170 new cancer patients to undergo fertility preservation treatments as a result of this mandate

Regarding the cost burden for the fertility preservation, there is a disparate cost burden between the male undergoing the retrieval and cryopreservation of the sperm versus the female undergoing the oocyte retrieval of the egg and either the cryopreservation of the oocyte or the retrieval of male sperm, fertilization of the egg and subsequent cryopreservation of the embryo.

For members with OCD and Tics, the following is the expected cost share distribution amongst members

Cost Share Distributions for Members Aged 10-38 with a cancer diagnosis -- 2010 (trended) and 2011

Annual Cost Share Amount		
	National N=10,564	CT n=220
$0	2.2%	2.3%
$0-50	11.3%	12.7%
$50-100	8.9%	5.5%
$100-200	13.3%	15.0%
$200-350	12.5%	8.2%
$350-600	12.1%	11.4%
$600-1000	12.5%	12.7%
$1000-2000	13.4%	16.4%
$2000-4000	9.2%	10.9%
$4000-10000	3.7%	4.1%
>$10000	0.8%	0.9%

The cost for the diagnosis and treatments are as follows

	Allowed	Paid	Average cost sharing (not high deductible) 10% cost share		Individual Silver	Average cost sharing
	(Uninsured)		10% Cost Share	20% Cost Share	30% cost sharing	High Deductible
Sperm	$1,113	$826	$111	$223	$334	$1,113
Oocyte	$8,954	$7,204	$895	$1,791	$2,686	$2,864
Embryonic	$16,240	$14,177	$1,624	$3,248	$4,872	$4,685

Note: For high deductible plans, we assumed $2,500 deductible of which half would already be exhausted and an average cost sharing of 25% above the deductible. For all plans, cost sharing was capped at the ACA mandated $6,350 out of pocket limit.

For various income levels, the following is the expected financial burden as a percentage of income for the uninsured and for those with varying levels of coverage if the mandate is approved.

	Allowed	Paid	Average cost sharing (not high deductible)		Individual Silver	Average cost sharing
	(Uninsured)		10% Cost Share	20% Cost Share	30% cost sharing	High Deductible
Income level	$ 35,000	$35,000	$35,000	$35,000	$35,000	$35,000
Sperm	1113	826	111	223	334	1113
% of income	3.2%	2.4%	0.3%	0.6%	1.0%	3.2%
Oocyte	8954	7204	895.4	1790.8	2686.2	2863.5
% of income	25.6%	20.6%	2.6%	5.1%	7.7%	8.2%
Embryonic	16240	14177	1624	3248	4872	4685
% of income	46.4%	40.5%	4.6%	9.3%	13.9%	13.4%
Income level	$65,000	$65,000	$65,000	$65,000	$65,000	$65,000
Sperm	1113	826	111	223	334	1113
% of income	1.7%	1.3%	0.2%	0.3%	0.5%	1.7%
Oocyte	8954	7204	895.4	1790.8	2686.2	2863.5
% of income	13.8%	11.1%	1.4%	2.8%	4.1%	4.4%
Embryonic	16240	14177	1624	3248	4872	4685
% of income	25.0%	21.8%	2.5%	5.0%	7.5%	7.2%
Income level	$95,000	$ 95,000	$ 95,000	$95,000	$95,000	$ 95,000
Sperm	1113	826	111	223	334	1113
% of income	1.2%	0.9%	0.1%	0.2%	0.4%	1.2%
Oocyte	8954	7204	895.4	1790.8	2686.2	2863.5
% of income	9.4%	7.6%	0.9%	1.9%	2.8%	3.0%
Embryonic	16240	14177	1624	3248	4872	4685
% of income	17.1%	14.9%	1.7%	3.4%	5.1%	4.9%
Income level	$120,000	$120,000	$120,000	$120,000	$120,000	$120,000
Sperm	1113	826	111	223	334	1113
% of income	0.9%	0.7%	0.1%	0.2%	0.3%	0.9%
Oocyte	8954	7204	895	1791	2686	2864
% of income	7.5%	6.0%	0.7%	1.5%	2.2%	2.4%
Embryonic	16240	14177	1624	3248	4872	4685
% of income	13.5%	11.8%	1.4%	2.7%	4.1%	3.9%

Five Year Projections

Five Year Projections for PANDAS Mandate

A. Change in Utilization

For 2014, we assumed 7.5% of children with OCD or Tics would obtain a PANDAS diagnosis and some related treatment. Currently, treatments of PANDAS are under NIMH study and clinical trial. Any expected change in utilization is dependent largely on the result of the study. Therefore no expected change in utilization is currently assumed acceptance and utilization by the medical professional community in Connecticut will still take a number of years. This is likely to put any significant change in utilization as a result of the mandate beyond the five year projection of this report.

B. Change in Unit Cost

The three treatment protocols being reviewed for treatment of PANDAS are all currently used for other diseases not related to PANDAS. The impact of the additional treatments due to PANDAS patients is not expected to raise the demand relative to the available supply.

C. PMPM Costs

In calculating the PMPM costs over five years, we assumed those undergoing prophylactic use of antibiotics to continue until age 21. Therefore, their costs would be in effect for five additional years. We made no assumption for continued use of IVIG or Plasmapheresis treatments protocols after the initial year of use.

Due to the relatively low number of individuals assumed to have OCD or Tics, we continued to assume a similar number of individuals would be diagnosed with PANDAS in additional years.

For PANDAS, the expected five year cost of the mandate is projected as a premium increase of $0.023 PMPM or $323,200 over five years

Five Year Projection for Lung Cancer Screening Mandate

A. Change in Utilization

The USPSTF is recommending smokers and former smokers obtain a screening each year. If this is approved, there will likely be a push by the health care professionals for these individuals for their patients to get screened. However, since this population is considered otherwise healthy and they have been resistant to healthcare initiatives, we do not expect significant use of this screening compared to other diagnostic preventive screenings such as mammograms. For the purpose of these projections, since the recommendation is currently in draft form, we assumed the USPSTF recommendation

would be implemented. We also considered a similar utilization of services for each year as well as an alternative scenario of a one-time flat 25% reduction in post-screening testing services in subsequent years due to monitoring previously-identified lesions from previous year tests.

If the screening services are not included as preventive care or ultimately not approved by the USPSTF, the likelihood of the services being used may be further reduced.

B. Change in Unit Cost

The screening covered under this mandate is provided to a limited group of insured for a single service per year. The expected increase in the screening and the subsequent testing protocols are not expected to significantly impact unit costs of the procedures enough to raise costs.

C. PMPM Costs

As mentioned above, for the purpose of calculating the PMPM costs over five years, we assumed two scenarios. The first scenario assumed a similar take up rate of 22% of the eligible population each year with a resulting projected premium increase for this mandate of approximately $0.294 PMPM for the entire insured population over five years. When multiplying by the number of insured for a five year period, the overall premium costs are estimated at $20,248,030. If there is a reduction in people getting tested in future years as mentioned in section A above, we estimate the five year premium increase of $0.273 PMPM or $18,795,394.

Five Year Projection for Fertility Preservation Mandate

A. Change in Utilization

As mentioned earlier, due to various cost and ethical hurdles, fertility preservation is often not obtained for someone undergoing a medical procedure with a potential of impacting their fertility. Due to the differences in costs and procedures between males and females, we assumed a baseline of 29% male utilization and 4% female utilization if made aware of availability of services without the mandate. With the potential passing of this mandate, there would still be an educational and informational challenge to disseminate to the potential population. Therefore, we assumed two versions in our projections. The first method assumed a flat 10% increase in utilization of services each year from those eligible. The second assumed and additional 5% each year as oncologists would more likely counsel their patients concerning the possibility of getting fertility preservation services prior to beginning cancer treatments.

B. Change in Unit cost

Compared to those using the same procedures undergoing infertility treatment, the incremental number of individuals expect to use the cryopreservation services is not expected to greatly increase the demand relative to the supply. Therefore, no change in unit costs are assumed in future years

C. PMPM costs

As mentioned above, for the purpose of calculating the PMPM costs over five years, we assumed two scenarios. The first scenario assumed a similar take up rate each year with a resulting projected premium increase for this mandate of approximately $0.065 PMPM for the entire insured population. When multiplying by the number of insured for a five year period, the overall five year premium costs are estimated at $4,498,637. If there is an increase in usage of services, we estimate the five year projected premium increase at $0.105 PMPM or $7,208,504 over five years.

[END OF FINANCIAL AND ECONOMIC SECTION]

LIMITATIONS IN USE:

This study was conducted by Optum exclusively for the State of CT and specifically and solely as it applies to the evaluation of the benefit mandates discussed in this report. This statement of opinion is not intended for any other application or purpose.

I, Steven J. Stender, am a consulting health actuary and Director with Optum. I am a fellow of the Society of Actuaries and a member of the American Academy of Actuaries, in good standing, and I meet the Qualification Standards of the American Academy of Actuaries to render the actuarial opinion contained herein. Please contact me if you have questions. My e-mail address is steven.stender@optum.com, and my office phone is 212-817-6018.

Steven J Stender, FSA, MAAA

APPENDICES

Utilization-related information

Utilization information	Nation		CT	
	2010	2011	2010	2011
Covered Population	8,736,775	8,577,607	152,382	148,843
Covered Population (age < 65)	7,553,238	7,410,375	137,475	133,788
OCD/Tic Diagnoses	3,402	3,133	114	88
Strep Tests	274	277	1	4
IVIG Tx (1 tx = 1 admit dt)	131	61	0	1
Plasmapheresis Tx (1 tx = 1 admit dt)	13	11	0	0
Plasmapheresis Proc's (assuming 5 procs/tx)	65	55	0	0
Lung Cancer Screening Claimants	539	468	14	7
Fertility-Pres-Related Cancer Diag's (10 < age < 38)	5,617	5,097	156	108
Sperm Cryopreservation Claimants	14	5	1	0
Embryo Cryopreservation Claimants	6	8	1	0
Oocyte cryopreservation Claimants	5	7	0	0

PMPM COST INDIVIDUAL COVERAGE PLANS PROJECTED 2014 COSTS (PMPM)	
Individual premium developed as weighted average from carrier surveys	
Average Individual Premium:	$303.38

NOTE: Individual data is less credible than group data due to small sample size

PROJECTED 2014 PMPM COST FOR INDIVIDUAL COVERAGE PLANS						
			=A - B		= C + D	
	A	**B**	**C**	**D**	**E**	**F**
Mandate	**Allowed Cost**	**Cost Share**	**Paid Cost**	**Retention**	**Paid Cost + Retention**	**% of Premium**
Lung Cancer Screening	0.2887	0.0866	0.2021	0.0444	0.2465	0.081%
PANDA D&T	0.0159	0.0048	0.0112	0.0025	0.0136	0.005%
Fertility Preservation	0.0729	0.0219	0.0511	0.0112	0.0623	0.021%

PMPM COST GROUP COVERAGE	
PROJECTED 2014 COSTS (PMPM)	
Group premium developed as weighted average from carrier surveys	
Average Group Premium	
Any Size	$482.42
<100 Employees	$548.52
100+ Employees	$417.59

PROJECTED 2014 PMPM COST FOR GROUP COVERAGE PLANS								
		=A - B			= C + D			
	A	**B**	**C**	**D**	**E**	**F**	**G**	**H**
							% of Premium	
Mandate	**Allowed Cost**	**Cost Share**	**Paid Cost**	**Retention**	**Paid Cost + Retention**	**% of Premium**	**Group Size < 100 Ees**	**Group Size 100+ Ees**
Lung Cancer Screening	0.2495	0.0232	0.2263	0.0399	0.2663	0.055%	0.049%	0.0638%
PANDA D&T	0.0127	0.0021	0.0106	0.0019	0.0125	0.003%	0.002%	0.0030%
Fertility Preservation	0.0588	0.0091	0.0497	0.0088	0.0585	0.012%	0.011%	0.0140%

TOTAL DOLLAR COST CALCULATION	
PROJECTED 2014 COSTS (dollars)	
TOTAL COST CALCULATION BASED ON:	
Total Insured's (Group + Individual)	1,146,887
Group (Excluding State)	828,936
Group (State Only)	161,368

PROJECTED 2014 PMPM COST FOR GROUP COVERAGE PLANS						
	A	**B**	**C**	**D**	**E**	**F**
	Allowed Cost		Paid Cost + Retention	Allowed Cost + Retention	Paid Cost	Paid Cost
MANDATE	**Total Cost of Health Care**	**Paid Cost**	**Premium Impact**	**Overall Cost to Health Care System**	**Total Paid Cost for the State Employee Health Plan**	**Total Paid Cost for Fully Insured + State Employees**
GROUP + INDIVIDUAL	**$386,132**	**$328,741**	**$386,755**	**$444,145**		
Lung Cancer Screening	$298,597	$259,560	$305,365	$344,401		
PANDA D & T	$15,604	$12,184	$14,334	$17,754		
Fertility Preservation	$71,932	$56,997	$67,055	$81,990		
GROUP ONLY	**$266,048**	**$237,605**	**$279,535**	**$307,978**	**$46,254**	**$283,859**
Lung Cancer Screening	$206,793	$187,603	$220,709	$239,899	$36,520	$224,123
PANDA D & T	$10,532	$8,806	$10,361	$12,086	$1,714	$10,521
Fertility Preservation	$48,723	$41,195	$48,465	$55,993	$8,019	$49,215

2014 PROJECTION OF UTILIZATION RATE				
			Average Cost of Treatment	
	# of unique claimants	# of unique claimants as % of covered lives	Paid Medical Cost	Allowed Medical Cost
Diagnosis and treatment of PANDAS				
Total	**1,143**	**0.0996%**	**$128**	**$151**
Plasmapheresis	2	0.0002%	$27,528	$32,001
IVIG	4	0.0004%	$3,522	$4,357
Prophylactic Antibiotic	70	0.0061%	$1,017	$1,205
Strep Test	1,143	0.0996%	$10	$14
Fertility preservation				
Total	**170**	**0.0148%**	**$4,034**	**$5,091**
Sperm Cryopreservation	129	0.0113%	$826	$1,101
Embryo cryopreservation	36	0.0031%	$14,177	$16,240
Oocyte cryopreservation	4	0.0004%	$7,204	$8,923
Lung Cancer Screening				
Total (Screening Only No Test)	**5,179**	**0.45%**	**$257**	**$275**

PANDA Diagnosis and Treatment [1]								
Individual cost, total dollars								
Diagnosis			**Treatment**					
			Plasmapheresis		**IVIG (per treatment Protocol)**		**Prophylactic Antibiotic Use (>300days total supply)**	
Cost	**Paid Cost**	**Cost Share**	**Paid Cost**	**Cost Share**	**Paid Cost**	**Cost Share**	**Paid Cost**	**Cost Share**
Minimum	$0	$5	$1,915	$2,142	$0	$463	$26	$109
Maximum	$40	$9	$111,408	$20,092	$16,696	$1,220	$2,578	$73
Mean	$10	$3	$27,528	$4,473	$3,522	$835	$1,017	$187
Median	$8	$1	$9,051	$1,834	$2,932	$411	$734	$274
Mode	$8	$1			$3,555	$0		
25th Percentile	$6	$2	$4,095	$2,765	$1,568	$959	$401	$184
75th Percentile	$11	$4	$42,349	$897	$4,017	$1,879	$1,399	$305

Lung Cancer Screening [1]		
Individual cost, total dollars		
	Lung Cancer Screening	
Cost	Paid Cost	Cost Share
Minimum	$98	$0
Maximum	$559	$93
Mean	$257	$18
Median	$219	$10
Mode	$248	$0
25th Percentile	$111	$0
75th Percentile	$381	$18

Fertility Preservation [1]						
Individual cost, total dollars						
	Sperm Cryopreservation		Embryo Cryopreservation		Oocyte Cryopreservation	
Cost	Paid Cost	Cost Share	Paid Cost	Cost Share	Paid Cost	Cost Share
Minimum	$0	$0	$5,990	$0	$2,413	$74
Maximum	$7,783	$2,140	$25,501	$3,078	$24,085	$6,094
Mean	$826	$287	$14,177	$2,063	$7,204	$1,751
Median	$291	$147	$13,716	$1,970	$6,705	$1,033
Mode	$0	$0				
25th Percentile	$124	$31	$12,847	$934	$4,601	$552
75th Percentile	$1,089	$407	$14,609	$2,558	$15,397	$2,160

[1] Please note that it is not appropriate to calculate an allowed amount as Paid Cost plus Cost Share using the summary statistics from tables.\

COST OF MANDATED HEALTH CARE BENEFIT ON COST OF HEALTH CARE BY EMPLOYER SIZE

PMPM COST SMALL GROUP (< 100 EMPLOYEES) COVERAGE						
			= A - B		=C + D	
	A	B	C	D	E	G
Mandate	Allowed Cost	Cost Share	Paid Cost	Retention	Paid Cost + Retention	% of Premium
Lung Cancer Screening	0.2495	0.0232	0.2263	0.0418	0.2681	0.049%
PANDA D&T	0.0127	0.0021	0.0106	0.0020	0.0126	0.002%
Fertility Preservation	0.0588	0.0091	0.0497	0.0092	0.0589	0.011%

PMPM COST LARGE GROUP(100+ EMPLOYEES) COVERAGE						
			= A - B		=C + D	
	A	B	C	D	E	G
Mandate	Allowed Cost	Cost Share	Paid Cost	Retention	Paid Cost + Retention	% of Premium
Lung Cancer Screening	0.2495	0.0232	0.2263	0.0385	0.2648	0.048%
PANDA D&T	0.0127	0.0021	0.0106	0.0018	0.0124	0.002%
Fertility Preservation	0.0588	0.0091	0.0497	0.0085	0.0582	0.011%

Appendix V

Glossary of Terms and Acronyms

Glossary of Terms and Acronyms

Term	Definition
AAAAI	American Academy of Allergy, Asthma and Immunology
AACAP	American Academy of Child and Adolescent Psychiatry
AAN	American Academy of Neurology
AAP	American Academy of Pediatrics
AATS	American Association for Thoracic Surgery
ACA	Patient Protection and Affordable Care Act
ACCP	American College of Chest Physicians
ACR	American College of Radiologists
ACS	American Cancer Society
Acute pharyngitis	A sore throat.
Administrative services only (ASO) contract	A contract between an insurance company or third party administrator (TPA) and a self-funded plan according to which the insurance company or TPA performs administrative services only and does not assume any risk. The services usually include claims processing but may include other services as well, such as actuarial analysis, utilization review, and so forth.
AHA	American Heart Association
ALA	American Lung Association
Allowed costs	All payments to health care providers, whether paid by the carrier or the policyholder.
Assisted Reproductive Technology (ART)	In general, a procedure, such as IVF, which involves surgically removing eggs from a woman's ovaries, combining them with sperm in a laboratory, and returning the fertilized eggs to the woman's body or donating them to another woman. They do not include treatments in which only sperm are handled (i.e., intrauterine—or artificial—insemination) or procedures in which a woman takes medicine only to stimulate egg production without the intention of having eggs retrieved.
Amoxicillin	An antibiotic that is used to treat bacterial infection by killing bacteria.
Antibiotics	A drug that is used to kill harmful bacteria and to cure infections.
Anti-strep titers	A measure of anti-bodies produced by the immune system to fight off a strep infection.
APA	American Psychiatric Association

Term	Definition
Artificial insemination	The introduction of semen into part of the female reproductive tract (as the cervical opening, uterus, or fallopian tube) by other than natural means; may include intracytoplasmic injection (ICI) and intrauterine injection (IUI).
Asbestos	A naturally occurring mineral, utilized worldwide for its durability and heat resistant qualities, which can easily enter the respiratory system and damage sensitive tissue causing damage that can result in asbestosis, mesothelioma, and lung cancer.
ASCO	American Society for Clinical Oncology
Asymptomatic	The state of presenting no symptoms of disease.
ATS	American Thoracic Society
Azithromycin	A macrolide antibiotic used to treat bacterial infection.
Benzathine Penicillin G	An antibiotic drug used to treat or prevent various infections caused by gram-positive bacteria such as streptococcus.
Carcinoma in situ	An early-stage tumor where in the case of cancer, tumor cells are still confined to the originating site and have neither metastasized nor invaded neighboring cells.
Centers for Medicare & Medicaid Services (CMS)	The federal agency responsible for financing and overseeing Medicare and Medicaid services. CMS is part of the U.S. Department of Health and Human Services and was formerly known as the Health Care Financing Administration.
Chemotherapy	The use of chemical agents in the treatment or control of disease or mental disorder.
Children's Health Insurance Program (CHIP)	A program created by the federal government to provide a "safety net" and preventive-care level of health coverage for children. The program is funded through a combination of federal and state funds and administered by the states in conformance with federal requirements. Also referred to as State Children's Health Insurance Program (SCHIP).
CID	Connecticut Insurance Department.
Clinical trials	Trials to evaluate the effectiveness and safety of medications or medical devices by monitoring their effects on groups of people.
Cognitive behavioral therapy (CBT)	A form of psychotherapy that involves the therapist and patient examining and modifying the specific patterns of beliefs and behavior held by the patient to produce lasting emotional and behavioral change.

Term	Definition
Coinsurance	An insurance provision that limits the amount of coverage for services to a certain percentage, commonly 80 percent. The rest of the cost is paid by the member out-of-pocket.
Comorbidity	The co-occurring presence of two or more medical conditions.
Control group	A set of items or people that serves as a standard or reference for comparison with an experimental group.
Conversion	The conversion of coverage from a group policy to an individual policy. The chance to convert may be offered to subscribers who lose their group coverage (e.g., through job loss or death of a working spouse) and who are ineligible for coverage under another group policy.
Co-payment	The amount that a member must pay out-of-pocket for medical services. It is usually a fixed amount, such as $10, $15 or $25 per service.
Cost-sharing	Payment by a member of some portion of the cost of services. Usual forms of cost-sharing include deductibles, coinsurance, and co-payments.
Cost-shifting	Shifting the obligation to pay the cost of medical care from one payer to another.
CPHHP	Center for Public Health and Health Policy (University of Connecticut)
CPT code	Current Procedural Terminology code
Cryoprotectant	A substance used to protect against the deleterious effects of subjection to freezing temperatures. Some cryoprotectants include glycerol, dimethyl sulfoxide, and raffinose.
Cytotoxin	A substance (as a toxin or antibody) having a toxic effect on cells.
Deductible	That portion of a subscriber's (or member's) health care expenses that must be paid out-of-pocket before the insurance coverage applies ($100 to $1500 depending on type of plan). Deductibles are common in insurance plans and PPOs, uncommon in HMOs, and they may apply only to the out-of-network portion of a point-of-service plan or only to one portion of the plan coverage (e.g., just to pharmacy services).
Direct access	Access to specialists without requiring a referral from a primary care provider. In an HMO that uses the direct access model, a member may self-refer to a specialist rather than having to seek an authorization. In such HMOs, the co-payment for care received from a specialist may be higher than the co-pay for care received from a primary care provider.
DPH	Connecticut Department of Public Health.
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, 5th Edition

Term	Definition
DSS	Department of Social Services
EAGLE	Environment and Genetics in Lung Cancer Etiology
Embryo	Early stage of development of an organism in the egg or the uterus, during which its essential form and its organs and tissues develop. In humans, the organism is called an embryo for the first seven or eight weeks after conception, after which it is called a fetus.
Employee Retirement Income Security Act (ERISA)	The Employee Retirement Income Security Act of 1974 (ERISA) is a federal law that sets minimum standards for most voluntarily established pension and health plans in private industry to provide protection for individuals in these plans.
Extraterritorial	Applies outside of the territorial boundaries.
False positive	A test result that wrongly indicates the presence of a disease or other condition the test is designed to reveal.
fluoxetine	An SSRI used to treat OCD symptoms.
fluvoxamine	An SSRI used to treat OCD and social anxiety disorder symptoms.
Follicle Stimulating Hormone (FSH)	A pituitary hormone responsible for stimulating follicular cells in the ovary to grow, stimulating egg development and the production of estrogen.
Gamete	A mature male or female germ cell usually possessing a haploid chromosome set and capable of initiating formation of a new diploid individual by fusion with a gamete of the opposite sex— also called a sex cell.
Gonadal Shielding	A specially designed contact or shadow shield used to protect the gonadal area of a patient from the primary radiation beam during radiographic procedures.
Gonadal Suppression	A technique used to suppress ovarian function through the usage of gonadotropin-releasing hormones (GnRH).
Gonadotoxic	Having a deleterious effect on the gonads.
Gonadotropin-Releasing Hormone (GnRH) Agonist	A hormone drug used in ovarian suppression, that initially stimulates and then subsequently decreases the secretion of follicle stimulating (FSH) and luteinizing hormones (LH) from the pituitary gland.
Gonadotropin-Releasing Hormone (GnRH) Antagonist	A hormone drug that directly decreases FSH and LH secretion from the pituitary gland.

Term	Definition
Group Coverage	A type of health insurance in which members receive coverage through an insurance contract that covers an entire group, usually an employment-based group. Employees usually have the option of covering other members of their families as well.
Guillain-Barre's Syndrome	A syndrome in which the body's immune system attacks its nerves, and eventually causes paralysis.
Habit Reversal Training (HRT)	A behavioral intervention that attempts to help patients control tics by helping them chose to do something that satisfies the urge to tic other than perform the usual tic.
Haloperidol	A drug used to treat Tourette's Disorder.
Health Maintenance Organization (HMO)	A type of managed care plan that acts as both insurer and provider of a comprehensive set of health care services to an enrolled population. Services are furnished through a network of providers.
HRSA	Health Resources and Services Administration
IDSA	Infectious Disease Society of America
Immune response	The body's recognition and defense mechanism against bacteria, viruses, and other substances that appear to be foreign and harmful.
Immune-based therapies	Also referred to as immunotherapy, a form of treatment that uses biologic agents to enhance or stimulate normal immune function.
In Vitro Fertilization (IVF)	An ART technique, the fertilization of an egg in a laboratory dish or test tube. Specifically, a mixture usually in a laboratory dish of sperm with eggs which have been obtained from an ovary that is followed by introduction of one or more of the resulting fertilized eggs into a female's uterus.
Infusions	The therapeutic introduction of fluid other than blood into a vein.
Intracervical Injection (ICI)	Also referred to as Intracervical Insemination, a procedure which involves placing sperm inside a woman's cervix to facilitate fertilization.
Intracytoplasmic Sperm Injection (ICSI)	The injection by a micro-needle of a single sperm into an egg that has been obtained from an ovary followed by transfer of the egg to an incubator where fertilization takes place and then by introduction of the fertilized egg into a female's uterus.
Intramuscular injection	An injection of a substance into a muscle.
Intrauterine Injection (IUI)	Also referred to as Intrauterine Insemination, a procedure which involves placing sperm inside a woman's uterus to facilitate fertilization.

Term	Definition
Intravenous Immunoglobulin (IVIG)	An immune based therapy, whereby a blood product containing immunoglobulin is administered intravenously.
Ionized radiation	High-energy radiation capable of producing ionization in substances through which it passes. It includes nonparticulate radiation, such as x-rays, and radiation produced by energetic charged particles, such as alpha and beta rays, and by neutrons, as from a nuclear reaction.
LCS	Lung cancer screening
LDCT	Low-Dose Computed Tomography
Lung nodule	An abnormal mass of tissue in the lung, which may be pre-cancerous.
Luteinizing Hormone (LH)	The hormone that triggers ovulation and stimulates the corpus luteum to secrete progesterone.
Managed care	Managed care is a system of health care delivery that tries to control the cost of health care services while regulating access to those services and maintaining or improving their quality. A managed care organization typically has a panel of contracted providers that does not include all available providers, some type of limitations on benefits if subscribes use non-contracted providers (unless authorized to do so), and some type of authorization system.
Managed Care Organization (MCO)	An organization that delivers health care services using a managed care approach. Some people prefer managed care organization to health maintenance organization because it encompasses plans that do not conform to the strict definition of an HMO. Managed care organizations include preferred provider organizations, point-of-service plans, integrated delivery systems, open-panel HMOs, and closed-panel HMOs.
Mandated benefits	Health benefits that a health coverage provider is required by law to provide. The federal government and many states mandate the coverage of specified benefits by certain health coverage providers. Common examples include in vitro fertilization, defined days of inpatient mental health or substance abuse treatment, and other special-condition treatments.
Medical cost ratio	The ratio between the total cost of delivering medical care and the total amount of money taken in by the insurer in the form of premium.
Medical trend	The change in the cost of medical care driven by changes in utilization and unit costs of covered services.
Member	An individual covered under a managed care plan. Members include subscribers and dependents.

Term	Definition
Member month	One month of coverage for one member. For example, if a plan had 10,000 members in January and 12,000 members in February, the total member months for the year to date as of March 1 would be 22,000.
Metastasis	Cancer resulting from the spread of the primary tumor or the process of cancer spreading from the primary tumor to distant locations in the body.
Millisieverts (mSv)	Millisieverts (mSv) is the most commonly accepted, international system of units used to measure the amount or "dose" of ionizing radiation received by people.
NAIC	National Association of Insurance Commissioners
NCCN	National Comprehensive Cancer Network
NELSON	A large ongoing lung cancer screening trial being conducted in the Netherlands and Belgium.
Neuropsychology	A science concerned with the integration of psychological observations on behavior and the mind with neurological observations on the brain and nervous system.
NIMH	National Institutes of Mental Health
NLST	National Lung Screening Trial
OCD	Obsessive-Compulsive Disorder
Off-label	A drug prescribed, or a medical device used, by a physician for a purpose other than that for which it has been specifically approved (as by the United States Food and Drug Administration).
OHCA	Connecticut Office of Health Care Access
Oocyte	Also referred to as a female gametocyte, an egg before maturation.
Oophoropexy	Used in female cancer patients receiving pelvic irradiation, the transposition of the ovaries outside of the radiation field.
Ovarian Hyperstimulation Syndrome	A disorder that causes the ovaries to become swollen or painful. May occur as a result of taking hormonal medications that stimulate the development of eggs in a woman's ovaries.
Paid medical costs	The portion of allowed costs paid by the carrier.
PANDAS	Pediatric Neuropsychiatric Disorder Associated with Streptococcal Infections

Term	Definition
PANDAS/PANS Advisory Council	An advisory council established by Public Act 13-187 "An Act Concerning a School Nurse Advisory Council and an Advisory Council on PANDAS" to advise the Commissioner of Public Health on research, diagnosis, treatment and education relating to PANDAS/PANS.
PANS	Pediatric Acute-Onset Neuropsychiatric Syndrome
Paroxetine	Drug used to treat OCD symptoms.
Pelvic Irradiation Therapy	Radiation administered to the pelvic region for therapeutic purposes.
Pelvic Shielding	A structure, device, or part that serves as a protective cover or barrier (e.g. a lead shield to protect against X-rays) for the pelvic region.
Penicillin	A medicine that is used to kill harmful bacteria.
Per member per month (PMPM)	Cost for each enrolled member each month.
Pimozide	A drug used to treat Tourette's Disorder.
Placebo	[An injection] given to a patient like a drug but that has no physical effect on the patient.
Plasma exchange	A blood treatment procedure used to treat several autoimmune diseases.
Plasma volume	The total volume of blood plasma.
PLCO	Prostate, Lung, Colorectal, and Ovarian Cancer Screening Program
Premium Rate	The amount of money that a group or an individual must pay to a health plan for coverage. The payment is usually in the form of a monthly fee.
Preventive Care	Health care that is aimed at preventing complications of existing diseases or preventing the occurrence of diseases.
Prophylactic antimicrobial therapy	Administration of antibiotics in absence of a known infection, as a measure to prevent future infection.
Prostate specific antigen	A protease that is secreted by the epithelial cells of the prostate and is used in the diagnosis of prostate cancer since its concentration in the blood serum tends to be proportional to the clinical stage of the disease.
Radiation therapy	Also referred to as radiotherapy, a technique used for the treatment of disease by means of radiation.
Radon	A radioactive gas that seeps from certain soils and rocks (such as granite) into the atmosphere and can accumulate in poorly ventilated spaces which could increase the risk of lung cancer.

Term	Definition
Rheumatic fever	A disease especially of young people that is characterized by fever, inflammation and pain in and around the joints, and inflammation of the membranes surrounding the heart and the heart valves.
Self-funded plan	In a self-funded plan, the risk for medical cost is assumed by the plan sponsor (usually an employer), rather than an insurance company or managed care organization. Under the Employee Retirement Income Security Act, employer-sponsored self-funded health benefits plan are exempt from state health benefit mandates. They are also exempt from premium taxes. Self-funded plans often contract with insurance companies or third-party administrators to administer benefits.
Self-insured plans	See self-funded plan.
Selective serotonin reuptake inhibitors (SSRIs)	A drug that increases the amount of serotonin, a natural substance in the brain that helps maintain mental balance.
Sertaline	Drug used to treat OCD symptoms.
Sputum cytology	A screening technique that determines the presence of a pulmonary system malignancy. It is used most frequently in patients who have an abnormal chest x-ray, productive cough, and nothing visible on bronchoscopy. A positive test indicates malignancy, but a negative test means only that, if a tumor exists, it is not shedding cells.
State of domicile	The state in which an insurance company or MCO is licensed as its primary location.
Strep infection	An infection caused by a pathogenic bacteria of one of several species of the genus streptococcus or their toxins.
Strep test	A test that determines the presence of a strep throat infection. Can be performed as a throat culture, where a sterile swab is rubbed over the back of the throat and tonsils to get a sample of the secretions and the sample is then cultured in a laboratory for the presence of bacteria; results may be available in less than two days. A Rapid Antigen test may also be performed with a swab sample that can detect strep bacteria in minutes by looking for substances (antigens) in the throat.
Subscriber	The individual or member who has the health plan coverage in virtue of being eligible on his or her own behalf rather than as a dependent.
Sydenham's Chorea	A movement disorder that occurs with rheumatic fever.
Termination date	The day that health plan coverage ceases to be in effect.
Tic disorder	A condition that involves quick, involuntary movements or vocal outbursts.

Term	Definition
Tourette's Disorder	Also referred to as Tourette's syndrome, a chronic tic disorder that starts in childhood. It involves unwanted repetitive movements and vocalizations (tics). For instance, one may repeatedly blink one's eyes, shrug one's shoulders or jerk one's head. In some cases, one might unintentionally blurt out offensive words.
Tumor	An abnormal benign or malignant new growth of tissue that possesses no physiological function and arises from uncontrolled usually rapid cellular proliferation.
Ultrasound	The diagnostic or therapeutic use of sound vibrations above the range of human hearing and especially a noninvasive technique involving the formation of a two-dimensional image used for the examination and measurement of internal body structures and the detection of bodily abnormalities.
USPSTF	United States Preventive Services Task Force
Vitrification	An ultra-rapid method of freezing eggs and embryos that may offer certain advantages compared to traditional types of cryopreservation.

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- U.S. Dept. of Labor Health Plans and Benefits website
- U.S. Environmental Protection Agency
- U.S. National Library of Medicine
- U.S. Occupational Safety and Health Administration (OSHA)
- University of Maryland Medical Center

Acknowledgements

The report authors would like to acknowledge the following people and organization who generously gave their time and effort making this report possible.

- Nicholas Bennett, MD, PhD
- Evelyn Breck Morgen, MSLS, AHIP
- Kathleen Crea, MLS
- Jessica Kilham, MLS
- Lisa Pepin, RN
- Maureen Rescildo, RN
- Diane Ravech, MPA
- Juan C. Salazar, MD, MPH
- Colleen Shea, CPC
- Paul Verrastro, MPA
- Hongjie Wang, MA, MLS
- Jeffrey Wasser, MD
- Kathryn Wheeler, BS, PharmD, BCPS
- Christian Andresen, Marylou Gonsalves, and Dawn Sorosiak from the Connecticut Department of Public Health.

Insurers and managed care organizations in Connecticut responding to the survey.

We would also like to acknowledge Beth Cook, James Perras, and Paul Lombardo of the Connecticut Insurance Department for their guidance and assistance in completing this report.

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