University of Connecticut
Center for Public Health and Health Policy

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February 28, 2011

Commissioner Barbara C. Spear
Connecticut Insurance Department
P.O. Box 816
Hartford, CT 06142-0816

Re: Mandated Benefit Review Project 2011

Dear Commissioner Spear,

In its 2009 regular session, the Connecticut General Assembly enacted P.A. 09-179, which requires the Connecticut Insurance Department (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 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 contract. CPHHP is authorized to obtain the services of whatever other entities it needs to perform the review and analysis, both internal and outside the university.

By letter dated July 22, 2010, the co-chairs of the Insurance and Real Estate Committee requested CID to report on five proposed health insurance benefit mandates. At a date following submission of the original letter, the Committee and the CID agreed to forgo analysis of one of the proposed health benefits. Enclosed with this letter is our analysis of the remaining four mandates.

The analysis consists of five parts: a general overview and a section for each of the four proposed health benefits. Each of these five sections is written to stand on its own, because each of the proposed health benefits could be written as a separate bill in 2011 or subsequent years. With the assistance of the Department the Center and Ingenix Consulting, an actuarial consulting firm, completed the analyses.

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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Director

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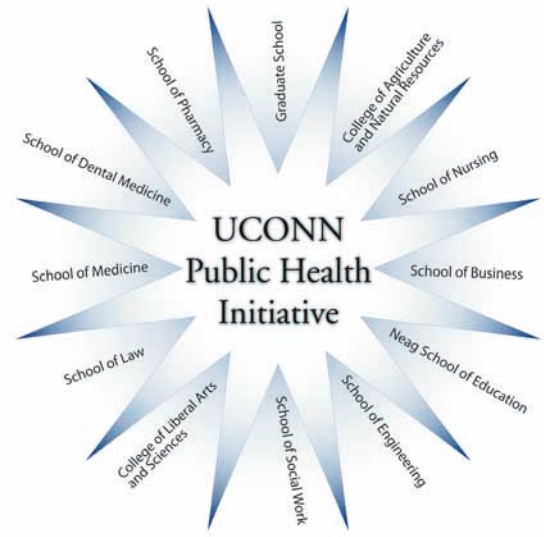
Review and Evaluation of Proposed Health Benefit Mandates in Connecticut

2011



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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 to review five proposed health benefits in a letter dated July 22, 2010. The proposed health benefits listed in the letter to be reviewed include:

- An increase in coverage for prescription eye drops (as described in SB 92, File 24, from the 2010 General Assembly session);
- An increase in coverage for magnetic resonance imaging (MRI) (as described in SB 259, File 89, from the 2010 General Assembly session);
- An increase in coverage for Parkinson's disease and multiple sclerosis (MS) in clinical trials (as described in SB 260, File 247, of the 2010 General Assembly Session);
- An expansion of coverage for neuropathic disorders associated with diabetes (later withdrawn); and
- An expansion of coverage for gastric bypass surgery.

This review has been performed in accordance with that request and with follow-up communication with the Committee. Reviews of proposed health benefits are collaborative efforts of the Connecticut Insurance Department and the University of Connecticut Center for Public Health and Health Policy, with the assistance of Ingenix Consulting. With the exception of an expansion of coverage for neuropathic disorders associated with diabetes, 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 Committee and the Connecticut Insurance Department agreed to forgo analysis of the proposed health benefit for neuropathic disorders associated with diabetes until further information related to the specific service(s) to be analyzed is available.

Brief summary of the proposed health benefits

Prescription eye drops: As defined by the bill, the proposed health benefit would provide an extra bottle of eye drops for children for use at their school or day care provider and an extra refill for children and adults who run out eye drops before the end of the month.

MRI for breast cancer screening: As defined by the bill, the proposed health benefit would require insurers to cover magnetic resonance imaging (MRI) for breast cancer screening if a mammogram shows dense breast tissue or for women who are considered at an increased breast cancer risk due to a variety of circumstances.

Routine patient care costs of clinical trials and off-label drug prescriptions for Parkinson's disease and multiple sclerosis: As defined by the bill, the proposed health benefit would require insurers to cover routine patient care costs for persons enrolled in clinical trials for Parkinson's disease and multiple sclerosis.

The bill also requires plans that cover prescription drugs to cover prescriptions of drugs that have been FDA-approved for treatment of Parkinson's disease if prescribed for treatment of multiple sclerosis and to cover prescriptions that have been FDA-approved for treatment of multiple sclerosis if prescribed for treatment of Parkinson's disease.

Gastric bypass surgery: No associated bill is referenced in the letter received from the Committee. Gastric bypass surgery is a type of bariatric surgery. Bariatric surgery is a term used for several surgical procedures for the treatment of obesity.

Estimated cost of proposed health benefits

The estimated costs shown below are based on an actuarial analysis of a sample of national claims data for group plans. The 2011 estimated medical cost in group plans of the four proposed health benefits combined is estimated to be $1.49 per member per month (PMPM). The vast majority of the incremental expense is medical cost. The medical cost of each proposed health benefit is shown below.

Mandate	**Per Member Per Month (PMPM)**
Prescription Eye Drops	$0.07
MRI Screening for Breast Cancer	$0.92
Cancer Clinical Trials	$0.00
Gastric Bypass	$0.50
Total Medical Costs	$1.49
Administrative Cost and Risk/Profit Charges	$0.32
Total Estimated 2011 Cost in Group Plans	**$1.81**

Note: Due to lack of data, estimated costs for individual health insurance policies and in self-funded plans in Connecticut is not available.

Existing health insurance coverage for the proposed health benefits

Seven health insurers and managed care organizations (MCOs) domiciled in Connecticut were surveyed regarding existing insurance coverage for the proposed health benefits in their fully insured group plans, individual policies, and self-funded plans for which they administer benefits. Four insurers/MCOs provided some information about current coverage. For the four insurers/MCOs that provided information:

	Percent of group plans with coverage			
Benefit	Insurer 1	Insurer 2	Insurer 3	Insurer 4
Prescription Eye Drops	Unknown	0	100	100
Breast MRI	100	100	100	100
Clinical Trials	Unknown	100	100	100
Gastric Bypass	Unknown	31	100	Unknown

Benefit	Percent of individual plans with coverage			
	Insurer 1	Insurer 2	Insurer 3	Insurer 4
Prescription Eye Drops	Unknown	0	N/A	N/A
Breast MRI	100	100	N/A	N/A
Clinical Trials	Unknown	100	N/A	N/A
Gastric Bypass	Unknown	0	N/A	N/A

Benefit	Percent of self-funded plans with coverage			
	Insurer 1	Insurer 2	Insurer 3	Insurer 4
Prescription eye drops	Unknown	0	100	100
Breast MRI	Unknown	100	100	100
Clinical Trials	Unknown	100	100	100
Gastric Bypass	Unknown	Not reported	Not reported	Not reported

Financial burden on insureds

Prescription eye drops: The economic analysis states that the proposed health benefit, if enacted, would relieve a relatively small financial burden related to coverage for children and potential relief from large financial burdens for adults because typically adult eye diseases are more expensive to treat and require longer term treatment than children's eye diseases in general.

MRI for breast cancer screening: The economic analysis states that in general, studies have shown breast cancer screening to be cost effective thereby saving the affected families as well as the insurers and the health care system significant expenses for cancer treatment down the road. The cost of treatment for breast cancer varies, among other things, by the type of treatment and services provided, by cancer stage and by the age at diagnosis. If the proposed health benefit results in earlier detection of breast cancer, the financial impact on insureds may be reduced.

Routine patient care costs of clinical trials and off-label drug prescriptions for Parkinson's disease and multiple sclerosis: Insurers and MCOs in Connecticut report that routine patient care costs associated with clinical trials are covered in general, thus no financial burden on insureds would be expected to be relieved as a result of the proposed health benefit. Because most insurers report that they allow off- label medication use, the cost impact for patients under this mandate would represent their cost-sharing for the off-label drug use. This cost burden impacts all income levels, except for those with extremely high incomes, albeit in different ways. A lower income family may simply have to forego the treatment in the absence of this the proposed health benefit, whereas a higher income family may have to choose between foregoing the therapy and assuming substantial financial burden.

Gastric bypass surgery: Gastric bypass surgery is a high-cost medical procedure, thus requiring insurance coverage for appropriate populations is likely to decrease financial burden for those who undergo the procedure. Financial burden may be significant even for those with insurance coverage depending on the cost sharing requirements of the health plan or policy.

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

Prescription eye drops: The actuarial reports estimates a utilization increase of ten percent in 2011 and an

expected increase over the next several years.

MRI for breast cancer screening: The actuarial report states that utilization of MRI in general has increased over the past ten years, which suggests that the proposed health benefit could contribute to continued increase in utilization. Additionally, the utilization of MRI for breast cancer screening in Connecticut is already two to three times the level of the rest of the nation. The actuarial report estimates that the proposed health benefit will double the use of MRI for breast cancer screening over the next five years.

Routine patient care costs of clinical trials and off-label drug prescriptions for Parkinson's disease and multiple sclerosis: The proposed health benefit is not expected to significantly affect the enrollment in Parkinson's disease and multiple sclerosis clinical trials, utilization of routine patient care costs associated with such clinical trials, or off-label use of FDA-approved Parkinson's disease prescriptions for treatment of multiple sclerosis and vice versa.

Gastric bypass surgery: The research on changes in utilization following the introduction of insurance coverage for bariatric surgery suggests minimal changes in utilization.

Required Coverage in Other States

Prescription eye drops: No states require coverage of prescription eye drops as defined in the bill.

MRI for breast cancer screening: Forty-nine states and the District of Columbia require coverage of screening mammograms. However, no states require coverage of screening MRIs.

Routine patient care costs of clinical trials and off-label drug prescriptions for Parkinson's disease and multiple sclerosis: No states require coverage of routine patient care costs associated with clinical trials specifically for Parkinson's disease or multiple sclerosis. Several states require coverage of routine patient care costs associated with clinical trials with "life-threatening conditions", which it is assumed would include Parkinson's disease and multiple sclerosis. No other states require coverage specifically for off-label use of FDA-approved prescriptions for multiple sclerosis for the treatment of Parkinson's disease or vice versa.

Gastric bypass surgery: The National Association of Insurance Commissioners identified Maryland, New Hampshire, Indiana, and Virginia as states with mandates either requiring inclusion of coverage or offers of coverage for the surgical treatment of morbid obesity.

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Review and Evaluation of Proposed Mandated Health Insurance Benefits in Connecticut 2011

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 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.

By letter dated July 22, 2010, the co-chairs of the Insurance and Real Estate Committee (Committee) requested CID to report on five proposed health insurance benefits by January 1, 2011. A copy of this letter is attached to this report as Appendix I. This deadline was later extended to March 1, 2011 by agreement between the CID and the co-chairs of the Committee.

Three of the proposed health benefits (dealing with coverage for breast magnetic resonance imaging, prescription eye drops and coverage for routine costs of clinical trials and off-label drugs for multiple sclerosis and Parkinson's disease) had been introduced in the legislature in prior sessions. The request from the co-chairs referenced these bills, and they form the basis of the analyses of these proposed health benefits contained in this report.. One proposed health benefit (coverage for gastric bypass surgery) did not have a reference to prior legislation, but prior bills on bariatric surgery were deemed to be germane by CID and were used to inform the analysis of this proposed health benefit. Copies of these bills are attached to this report as Appendix II. The CID deemed the fifth proposed health benefit request to be too vague to permit meaningful analysis, and by agreement with the co-chairs of the Committee, it was dropped from the request..

All of these proposed health benefits would apply to both individual and group health insurance policies sold, delivered or amended in Connecticut.

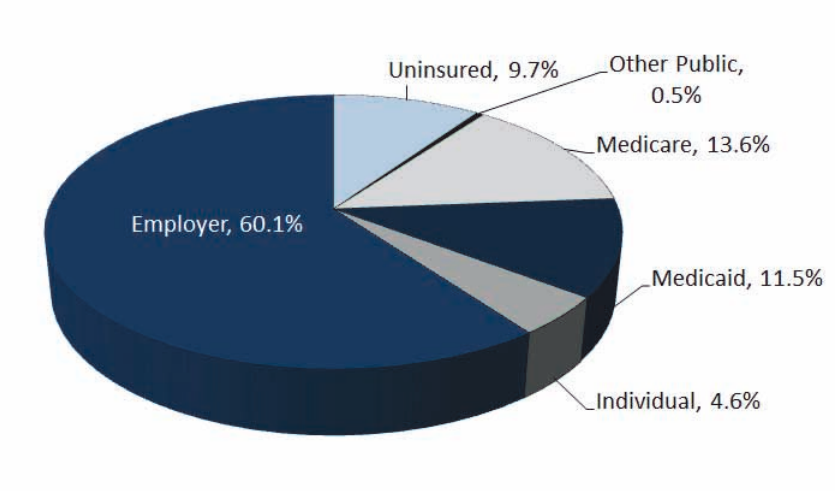
This report is comprised of five parts: the general overview and four sections. Each section reviews one of the four proposed health benefits. Each of the four sections can stand on its own, since insurance benefit mandates generally are raised separately in individual proposed legislation.

P.A. 09-179 details 25 issues to be addressed in the review of each proposed health benefit. These issues are divided into those which affect primarily the social impact of a health benefit and those which affect primarily the financial impact, although we found a good deal of overlap among the items in the two categories in the course of our research. Each section of this report addresses these issues for the respective

proposed health benefit. In addition, each section contains a background section that describes the condition, services, equipment or supplies addressed by the proposed health benefit and the segment of the general population most affected by the condition, service, equipment or supplies.

Caveat: It is important to understand that 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 regulation and are only subject to federal regulation, pursuant to the Employee Retirement Income Security Act (so-called ERISA preemption). 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 no insurance is involved. So-called ASO contracts are not considered insurance policies and therefore are not subject to state insurance regulation. The Connecticut Insurance Department has estimated that approximately 50 percent of Connecticut's workforce is covered by fully insured health plans. Therefore, only 50 percent of employees in Connecticut will be covered by any benefit mandated by statute, although it is not uncommon for some state mandated benefits to be included in ASO plans. In addition, the Department has expressed a concern that the trend is for more and more employers and organizations to opt for self-insured plans, even relatively medium or small employers. Thus, state benefit mandates may be applicable to an ever shrinking number of employees. Figures 1 and 2 show the sources of health care coverage for Connecticut residents and the types of health plans in which Connecticut residents are enrolled.

Figure 1. Health Insurance Coverage of the Connecticut Population, 2008



Source: State Health Facts, Kaiser Family Foundation.
Available at: http://www.statehealthfacts.org/profileind.jsp?ind=125&cat=3&rgn=8.

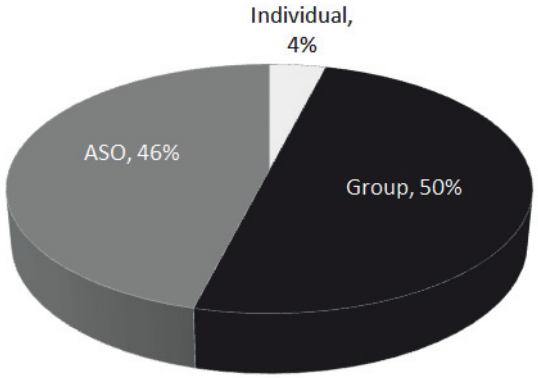
(Urban Institute and Kaiser Commission on Medicaid and the Uninsured estimates based on the Census Bureau's March 2008 and 2009 Current Population Survey (CPS: Annual Social and Economic Supplements)).

Proposed Health Benefits

The four proposed health benefits for which the Insurance Committee requested review are:

- An increase in coverage for prescription eye drops, as described in SB92, file 24 from the February 2010 session of the Connecticut General Assembly;,
- An increase in coverage for magnetic resonance imaging (MRI), as described in SB259, file 89 from the February 2010 session of the Connecticut General Assembly;
- An increase in coverage for Parkinson's disease and multiple sclerosis in clinical trials, as described in SB260, file 247 of the February 2010 session of the Connecticut General Assembly; and
- An expansion of coverage for gastric bypass surgery.

Figure 2. Types of Health Plans, Connecticut Insurers



Source: Connecticut Insurer Survey conducted October 2009, University of Connecticut, Center for Public Health and Health Policy

Process

The CPHHP performed the analysis and developed this report pursuant to a Memorandum of Agreement with the CID. The CPHHP was assisted in the development of this report by the CID and Ingenix Consulting (IC), an actuarial consulting firm. Ingenix was selected through a competitive bidding process managed by the Department.

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. IC performed the actuarial analyses and the economic and financial burden analysis. IC submitted a separate report, which formed the basis for the actuarial and financial burden analyses included in each of the individual mandate reports by CPHHP.

Methods

University of Connecticut Center for Public Health and Health Policy

CPHHP staff consulted with medical librarians at the Lyman Maynard Stowe Library at the University of Connecticut Health Center (UCHC). Medical librarians conducted literature searches under search terms particular to each proposed mandate using various resources available to them.

CPHHP staff consulted with clinical faculty and staff from the University of Connecticut School of Medicine 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 State of Connecticut website, Medicare website, other states' websites, and the websites of non-

profit and community-based organizations.

CPHHP staff also surveyed the insurance companies and managed care organizations domiciled in Connecticut as to whether their fully-insured group and individual plans currently included the proposed health benefit.

Ingenix Consulting

The CID contracted with Ingenix Consulting (IC) to provide actuarial and economic analyses of the proposed health benefits. Further details regarding the actuarial methods used to estimate the cost of the benefits and the economic methods used to estimate financial burdens may be found in the IC report, which is attached as Appendix III. We strongly recommend that this actuarial report and the financial/economic report be read in conjunction with the individual reports for a more in-depth discussion of the issues addressed in those reports.

Chapter 1

Prescription Eye Drops

Review and Evaluation of Senate Bill 92, File 24,
from the 2010 General Assembly session

Expanded coverage of
Group Hospital or Medical Insurance Coverage for
Prescription Eye Drops

Prepared by:

Sara Wakai, PhD

Brian L. Benson, MPP

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Chapter 1. Table of Contents

I. Overview

On July 22, 2010, the Chairs of the Insurance and Real Estate committee of the Connecticut General Assembly (the Committee) directed the Connecticut Insurance Department to review the proposed health benefits contained in Senate Bill 92, File Number 24, of the 2010 General Assembly session entitled, "An Act Concerning Prescription Eye Drops" (SB92). This review follows the requirements stipulated under Public Act 09-179. Reviews of required health insurance benefits are a collaborative effort of Connecticut Insurance Department and the University of Connecticut Center for Public Health and Health Policy (CPHHP).

SB92 proposed a health benefit for individual and group health insurance issued, renewed or continued in this state that provides coverage for prescription eye drops to also provides coverage for one additional bottle of eye drops once every three months for use at a child's day care center or school. In addition, for individuals of all ages, this proposed health benefit allows for refills of prescription eye drops within less than 30 days:

Specifically, Connecticut SB92 states that:

> Each individual health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 delivered, issued for delivery, amended, renewed or continued in this state, that provides coverage for prescription eye drops, shall provide coverage for:
>
> (1) A renewal of prescription eye drops when (A) the renewal is requested by the insured less than thirty days from the later of (i) the date the original prescription was distributed to the insured, or (ii) the date the last renewal of such prescription was distributed to the insured, and (B) the prescribing physician indicates on the original prescription that additional quantities are needed and the renewal requested by the insured does not exceed the number of additional quantities needed; and
>
> (2) One additional bottle of prescription eye drops when (A) such bottle is requested by the insured or the prescribing physician at the time the original prescription is filled, and (B) the prescribing physician indicates on the original prescription that such additional bottle is needed by the insured for use in a day care center or school. Such additional bottle shall be limited to one every three months.
>
> Sec. 2. of SB92 contains similar requirements for group health insurance policies.

In January of 2011, CPHHP requested information related to the proposed benefit from seven insurers and managed care organizations (MCOs) domiciled in Connecticut that cover over 90 percent of the population in fully insured group and individual health insurance plans in Connecticut (1.25 million persons). Claims data were not available at the time of actuarial analysis. The findings of this report are based on national actuarial claims data analysis and reviews of pertinent literature and other information related to the proposed health benefit.

Current coverage

One carrier confirmed coverage of prescription eye drops as described in the proposed health benefit in group insurance plan. Other carriers did not provide such coverage or were unable to access data to evaluate coverage comparable to the proposed health benefit.

Premium Impact

Group plans: Based on actuarial analysis of national claims data of group plans the medical cost is estimated to be $0.07 per member per month (PMPM) in 2011. Estimated total cost (insurance premium, administrative fees, and profit) of the proposed health benefit in 2011 in group plans is $0.10 PMPM, which is approximately 0.0 percent of estimated total costs in group plans.

Individual policies: When the medical cost of the proposed health benefit is spread to all insureds in individual policies, medical costs are estimated to be $0.05 PMPM and retention costs are estimated to be $0.03 PMPM in 2011. Thus, the total effect on insurance premiums is estimated at $0.08 PMPM in 2011.

Self-funded plans

Insurers/MCOs domiciled in Connecticut were unable to provide information regarding coverage of the services included in the proposed health benefit for the self-funded plans for which they administer benefits.

This report is intended to be read in conjunction with the General Introduction to this volume and the Ingenix Consulting Actuarial Report that is included as Appendix III.

II. Background

Prescription eye drops are a sterile solution containing a suspension of drugs which administer medicines directly onto the eye. This method of treatment is effective since most of the medicine remains in the eye and there is less risk of systemic side effects than with oral medicines. A variety of prescription eye drops are used to treat the symptoms and causes of eye conditions such as allergies, chronic dryness, eye infections and chronic disorders. In some cases, prescription eye drops can cure the eye condition; in chronic disorders they can reduce symptoms and slow disease progression.

The prescribed regimen for prescription eye drops varies by diagnosis and severity of the condition. For example, depending upon the level of infection, conjunctivitis can be treated with one drop every four hours to 2 drops every hour. The quantity of eye drops per bottle is fairly consistent across medications regardless of the prescribed dosing. As a result, there is some inherent fluctuation in how long one bottle of prescription eye drops will last for a given patient.

Medication adherence is essential to properly treat eye diseases, and patients must take the medication as prescribed even if the patient does not feel it is necessary. Conditions such as glaucoma can be treated with long acting medications that require drops only twice a day. However, drops must be administered at regular intervals to maintain proper intraocular pressure. Lack of medication adherence for these patients can increase the need for surgery and the likelihood of vision loss.

Prevalence

Allergies. The Allergy and Asthma Foundation of America estimates that 50 million Americans suffer from all types of allergies. Approximately 4 percent of allergy sufferers (2 million Americans) have eye allergies, such as allergic conjunctivitis and ocular allergies, as their primary allergies.[1] Other estimates suggest that ocular allergies affect more than 20 percent of the general population.[2] Allergic conjunctivitis is most common in children with allergic rhinitis, seasonal allergies, airborne allergies, asthma and eczema.[3]

[1] Asthma & Allergy Foundation of America. Allergy Facts and Figures. Available at: http://www.aafa.org/display.cfm?id=9&sub=30#_ftnref1. Accessed February 23, 2011.

[2] Bielory, L., Katelaris, C.H., Lightman, S., Naclerio, R.M. (2007). Treating the Ocular Component of Allergic Rhinoconjunctivitis and Related Eye Disorders. *Med Gen Med,* 9(3), 35.

[3] Gradman, J., & Wolthers, O.D. (2007). Allergic conjunctivitis in children with asthma, rhinitis and eczema in a secondary outpatient clinic.

Dry Eye Syndrome/Disease (DED). A 2009 study estimates that 1.68 million men 50 years and older (4.34 percent) suffer from DED, while 2.32 million women (7.8 percent) suffer from DED. The prevalence of DED is predicted to grow to 2.79 million men in 2030.[4] A 2003 study estimated the presence of dry eye syndrome among adults between the ages of 48 and 91 to be 14.4 percent.5 Based on these studies, approximately 12-14 percent of adults suffer from dry eye disease.

Bacterial Infections. Reports have found it difficult to identify the prevalence of bacterial eye infections.6 One common result of bacterial eye infections is conjunctivitis causing up to 50 percent of cases.7 Clinically, it is often difficult to distinguish bacterial from allergic and viral conjunctivitis. Research indicates that newborn babies are substantially at risk for bacterial eye infections. According to Ferri's Clinical Advisor 2008, conjunctivitis due to bacterial infections is found in 1.6 percent to 12 percent of all newborn babies in the United States.[8] Another report estimates that 1 in 9 (11 percent) children under 15 years old, and 1 in 5 (20 percent) children under 4 years old get conjunctivitis each year.[9]

Herpes Eye Infections. The National Eye Institute estimates that 400,000 Americans (0.15 percent) have had some form of ocular herpes, and each year 50,000 new and recurring cases are diagnosed in the United States.[10]

Glaucoma. It is estimated that the prevalence of glaucoma among adults 40 years and older in the United States is 1.9 percent, or 2.2 million persons.[11] This number is estimated to increase 50 percent to 3.6 million people in 2020 due to the rapidly aging population.[12] In addition, primary open-angle glaucoma is most prevalent in older African Americans particularly those individuals with a first degree relative diagnosed with glaucoma.[1314] A study of glaucoma prevalence among children in Olmstead County, Minnesota estimated that the incidence of childhood glaucoma in this population was 1 per 43,575 (.00229 percent) residents younger than 20 years.[15]

Table 1.1 lists common classes of prescription eye drops, names of medications, conditions or diseases treated by the medication, and frequency of medication application.[16]

Pediatric Allergy Immunology, 17(7), 524-6.

4 Schaumberg, D.A., Dana, R., Buring, J.E., & Sullivan, D.A. (2009). Prevalence of Dry Eye Disease Among US Men. *Arch Ophthalmol,* 127(6), 763-768.

5 Moss, S.E., Klein, R., & Klein, B.E., (2000). Prevalence of and Risk Factors of Dye Eye Syndrome. *Arch Ophthalmol*, 118(9), 1264-1268.

6 Chung CW, Cohen EJ. 2000. Eye Disorders: Bacterial Conjunctivitis. *Western Journal of Medicine* 173(3): 202-205.

7 Samsbursky RP. 2007. Acute Conjunctivitis. US Special Populations *Pediatrics Review* 2007(2).

8 Haddrill M. Pink Eye (Conjunctivitis) Symptoms, Remedies & Prevalence. Available at: http://www.allaboutvision.com/conditions/conjunctivitis.htm. Accessed February 25, 2010.

9 Maypole J. Second Opinion: Pinkeye. Available at: http://wondertime.go.com/learning/article/pinkeye-second-opinion.html. Accessed February 25, 201.

10 National Eye Institute. Facts About the Cornea and Corneal Disease. Available at: http://www.nei.nih.gov/health/cornealdisease/. Accessed February 23, 2011.

11 Gohdea, D.M., Balamurugan, A., Larsen, B.A., & Maylahn, C. (2005). Age-related Eye Diseases: An Emerging Challenge for Public Health Professionals. Preventing Chronic Disease Public health Research, Practice and Policy, 2(3); see also National Eye Institute. Summary of Eye Disease Prevalence Data. Available at: http://www.nei.nih.gov/eyedata/pbd5.asp. Accessed February 23, 2011.

12 *Ibid.*

13 Friedman, D.S., Jampel, H.D., Munoz, B., West, S.K. (2006). The prevalence of open-angle glaucoma among blacks and whites 73 years and older: the Salisbury Eye Evaluation Glaucoma Study. *Arch Ophthalmo*l, 124(11), 1625-30.

14 Vistamehr, S., Shelsta, H.N., Palmisano, P.C., Filardo, G., Bashford, K., Chaudhri, K., Forster, S.H., Shafranov, G., Bruce Shields, M. (2006). Glaucoma screening in a high-risk population. *Journal of Glaucoma*, 15(6), 534-40.

15 Aponte, E.P, Diehl, N., Mohney, B.G. (2010). Incidence and Clinical Characteristics of Childhood Glaucoma. *Arch Ophthalmol*, 128(4), 478-482.

16 Monthly Prescribing Guide. 2007. Thomson Healthcare, Montvale, NJ.

Table 1.1. Classes of Prescription Eye Drops

Class	Prescription Name	Condition/Disease	Frequency of application
Antihistamine eye drops	Pheniramine (Naphazoline)	Allergies	1-2 drops up to 4x/day (6 years and older)
	Ketotifen	Allergies	1 drop every 8 to 12 hours (3 years and older)
	Patanol (Olopatadine)	Allergies	1 drop twice a day at 6 to 8 hour intervals (3 years and older)
	Emedastine (Emadine)	Allergies	1 drop up to 4x/day
	Azelastine (Optivar)	Allergies	1 drop twice a day (3 years and older)
Decongestant eye drops	Tetrahydrozoline hydrochloride	Allergies	1-2 drops up to 4x/day
	Naphazoline hydrochloride (Vasocon, Allerest)	Allergies	1-2 drops of a 0.1% ophthalmic solution every 3 to 4 hours, as needed
Antihistamine/ decongestant combination eye drops	Pheniramine (Naphazoline)	Allergies	1 -2 drops up to 4x/day (6 years and older)
Nonsteroidal anti-inflammatory drug (NSAID) eye drops	Nepafenac (Nevanac)	Allergies and post-operative inflammation in cataract extraction	1 drop 3x/day 24 hours prior surgery and 2 weeks post-op. (Adults)
	Acular (Ketorolac)		1 drop 4x/day 24 hours prior surgery and 2 weeks post-op (3 years and older)
Corticosteroid eye drops	Flomex (Fluorometholone, FML)	Allergies and inflammation	1 drop 3 to 4x/day (2 years and older)
	Loteflam (Loteprednol etabonate, Lotemax, Alrex)	Allergies and post-operative inflammation	1-2 drops 4x/day. First week of treatment dosing may increase up to 1 drop/hour
	Pred Forte (Prednisone acetate, EconoPred)	Allergies and inflammation	1-2 drops 2-4x/day. First 24 to 48 hours of dosing may be increased if necessary.

Table 1.1. Classes of Prescription Eye Drops

Class	Prescription Name	Condition/Disease	Frequency of application
Mast cell stabilizers (MCS) and MCS combination eye drops	Azelastine (Astelin)	Allergies	1 drop 2x/day (3 years and older)
	Cromal (Cromolyn, Crolom)	Allergies	1-2 drops 4-6x/day at regular intervals (4 years and older)
	Emedastine (Emadine)	Allergies	1 drop up to 4x/day (3 years and older)
	Epina	Allergies	1 drop 2x/day
	Lodoxamide (Alomide)	Allergies	1-2 drops 4x/day for up to 3 months (2 years and older)
	Nedocromil (Alocril)	Allergies	1-2 drops 2x/day (3 years and older)
Mast cell stabilizers (MCS) and MCS combination eye drops	Olopatadine hydrochloride (Patanol)	Allergies	1 drop 2x/day at 6-8 hour intervals (3 years and older)
	Pemirolast (Alamast)	Allergies	1-2 drops 4x/day (3 years and older)
Artificial tears/ saline solution	Liquifilm Tears	Dry Eye Syndrome Dry Eye Disease	1-2 drops 3-4x/day
	Adsorbotear	Dry Eye Syndrome Dry Eye Disease	1-2 drops 3-4x/day
Antibiotic eye drops	Cipmox (Ciprofloxacin, Cipro, Ciplox)	Bacterial conjunctivitis and corneal ulcers	Bacterial Conjunctivitis: 1-2 drops every 2 hours while awake for 2 days than 1-2 drops every 4 hours while awake for 5 days. Corneal Ulcer: 2 drops every 15 minutes for first 6 hours, then 2 drops every 30 minutes for the rest of day 1. 2 drops every hour on day 2. 2 drops every 4 hours on days 3-14. (1 year and older)

Table 1.1. Classes of Prescription Eye Drops			
Class	Prescription Name	Condition/Disease	Frequency of application
Antibiotic eye drops	Gentamicin (Garamycin, Genoptic, Cidomycin)	Ocular bacterial infections including conjunctivitis, keratitis, keratoconjunctivitis, corneal ulcers, blepharitis, blepharoconjunctivitis, acute meibomianitis, and dacryocysititis.	1-2 drops every 4 hours to 2 drops every hour.
	Ocuflox (Ofloxacin, Floxin)	Bacterial conjunctivitis and corneal ulcers	Conjunctivitis: 1-2 drops every 2-4 hours for 2 days. 1-2 drops 4x/day for 5 days. Corneal Ulcer: 1-2 drops every 30 minutes while awake and 1-2 drops 4-6 hours after retiring for 2 days, then 1-2 drops every 1 hour while awake for 5-7 days, then 1-2 drops 4x/day for 2 days or until treatment completion. (1 year and older)
	Sulfacetamide (Sulfex, Cetamide)	External infections of the eye	1-2 drops every 2 to 3 hours for 7 to 10 days.
	Tobrex (Tobramycin)	External infections of the eye and its adnexa.	1-2 drops every 4 hours to 2 drops every hour. (Adults)
	Vigamox (Monofloxacin)	External infections of the eye	1 drop 3x/day for 7 days
	Zymar (Gatafloxin)	Bacterial conjunctivitis.	1 drop every 2 hours while awake up to 8x/day for 2 days, then 1 drop4x/day while awake for 5 days. (1 year and older)

Table 1.1. Classes of Prescription Eye Drops			
Class	Prescription Name	Condition/Disease	Frequency of application
Antiviral eye drops	Trifluridine (Viroptic)	Keratoconjunctivitis and recurrent epithelial keratitis due to herpes simplex virus	1 drop every 2 hours while awake until re-epithelialization. Max 9x/day. Following re-epitheliaization 1 drop 4x/day while awake (6 years and older)
	Trifluorothymidine	Recurrent epithelial keratitis due to herpes simplex virus	1 drop every 2 hours (8 to 9 doses/day) for 2 to 3 weeks
Glaucoma eye drops	Alphagan	Open-angle glaucoma and ocular hypertension	1 drop 3x/day every 8 hours. (2 years and older)
	Azopt	Open-angle glaucoma and ocular hypertension	1 drop 3x/day (Adults)
	Betagan (Levobunolol, AKBeta)	Open-angle glaucoma and ocular hypertension	1-2 drops 2x/day
	Betoptic (Betaxolol, Kerlone)	Open-angle glaucoma and ocular hypertension	1-2 drops 2x/day (Adults)
	Combigan	Open-angle glaucoma and ocular hypertension	1 drop 2x/day
	Dorzox (Dorzolamide, Trusopt)	Open-angle glaucoma and ocular hypertension	1 drop 2x/day every 8 hours. (2 years and older)
	Isopto	Open-angle glaucoma and ocular hypertension	1-2 drops one hour before refracting. For uveitis, 1 -2 drops up to 4x/day
	Lumigan	Open-angle glaucoma and ocular hypertension	1 drop 1x/day in evening
	Latim (Latanoprost, Xalatan)	Open-angle glaucoma and ocular hypertension	1 drop every day in pm. (Adults)
	Metipranolol (OptiPranolol)	Open-angle glaucoma and ocular hypertension	1 drop 2x/day
	Timolol (Cosopt, Timoptic, Blocadren)	Open-angle glaucoma and ocular hypertension	1 drop every day. (Adults)
	Travatan	Open-angle glaucoma and ocular hypertension	1 drop every day in pm. (Adults)
	Pilagan (Pilocarpine, Pilocar, Carpine)	Open-angle glaucoma and ocular hypertension	1 drop up to 4x/day

III. Methods

Under the direction of CPHHP, medical librarians at the Lyman Maynard Stowe Library at the University of Connecticut Health Center (UCHC) gathered published articles and other information related to medical, social, economic, and financial aspects of the proposed health benefit. Medical librarians conducted literature searches using PubMed and Scopus, UpToDate, Cochrane Systematic Review, DynaMed, Micromedex, various government websites, and a web search using Google. Some of the search keywords used include Ophthalmic Solutions, Eye drops, Artificial Tears, Antihypertensive Agents, and Antihypertension.

CPHHP staff conducted independent literature searches using the Cochrane Review, Scopus, and Google Scholar using similar search terms used by the UCHC medical librarians. Where available, articles published in peer-reviewed journals are cited to support the analysis. Other sources of information may also be cited in the absence of peer-reviewed journal articles. Content from such sources may or may not be based on scientific evidence.

CPHHP staff consulted with clinical faculty and staff from the University of Connecticut School of Pharmacy and School of Medicine on matters pertaining to medical standards of care; traditional, current and emerging practices; and evidence-based medicine related to the benefit.

Staff gathered additional information through telephone and e-mail inquiries to appropriate state, federal, municipal, and non-profit entities and from internet sources such as the State of Connecticut website, Centers for Medicare and Medicaid Services (CMS) website, other states' websites, professional organizations' websites, and non-profit and community-based organization websites.

With the assistance of the Connecticut Insurance Department (CID), CPHHP and Ingenix Consulting requested information regarding the proposed health benefit from seven insurance companies and MCOs domiciled in Connecticut. Four insurers provided information about current levels and policies of prescription eye drop coverage.

CPHHP and the CID contracted with Ingenix Consulting (IC) to provide actuarial and economic analyses of the proposed health benefit. Further details regarding the insurer/MCO information and actuarial methods used to estimate the cost of the proposed health benefit and may be found in Appendix III.

IV. Social Impact

1. The extent to which prescription eye drops is utilized by a significant portion of the population.

Connecticut's estimated population covered by fully insured group health insurance plans and individual policies with pharmacy benefits is 985,562 or 33 percent of the population under 65 years old.[17] Therefore, if the proposed health benefit was enacted, it would be available to this population. According to the IC analysis, an estimated 164 prescriptions for eye drops per 1000 privately insured children in Connecticut were covered in 2009. Additionally, an estimated 159 prescriptions for eye drops per 1000 privately insured Connecticut residents of all ages were covered in 2009. Due to difficulties in obtaining information about prescription eye drops under the definitions listed in the proposed statute, precise estimates of utilization of proposed health benefit are not available.

[17] University of Connecticut, Center for Public Health and Health Policy. 2009. Review and Evaluation of Public Act 09-188, An Act Concerning Wellness Programs and Expansion of health insurance coverage. University of Connecticut. Available at: http://publichealth.uconn.edu/images/reports/InsuranceReview09.pdf. Accessed October 8, 2010.

2. The extent to which Prescription eye drops 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.

Medicare

Medicare generally covers prescription eye drops as required by a physician or optometrist.

Part D plans cover prescription drugs including the cost of prescription eye drops needed for the treatment of eye diseases and conditions. For example, Part D plans cover Pilocarpine HCI and Xalatan, prescription eye drops used to treat glaucoma.[18] The Medicare policy regarding coverage of an additional bottle of prescription eye drops is unknown and is likely to vary among Part D plans.

Public Programs Administered by Charities

The American Optometric Association (AOA) operates a program called Vision USA. The program provides free eyeglasses and screenings to individuals who qualify. However, no mechanism is in place to offer financial assistance to individuals needing prescription eye drops.[19]

Public Programs Administered by Public Schools

School Based Health Centers (SBHCs) are free-standing medical clinics within or on school grounds. SBHCs are located in schools predominantly serving low-income minority children. Among the services is the prescribing and dispensing of medications.[20] In 2006-2007, 68 state-funded SBHC sites in 19 communities provided health services to more than 20,000 students in grades Pre-K to 12. SBHCs may provide services related to the mandate.

The Department of Public Health (DPH)

No information was found that would indicate the state Department of Public Health provides services for prescription eye drops.

Municipal Health Departments

No information was found that would indicate Connecticut municipal health departments or health districts provide services related to the proposed health benefit.

The Department of Social Services (DSS)

Medicaid covers a number of prescription eye drops used to treat eye diseases and conditions such as glaucoma. Among prescription eye drops covered are Pilocarpine, Tetrahydrazoline, and Xalatan.[21] DSS uses prior authorization for dispensing early refills of prescription drugs.

3. The extent to which insurance coverage is already available for the treatment, service or equipment, supplies or drugs, as applicable.

The extent to which insurance coverage is already available for additional bottles of prescription eye drops is dependent on several factors. State of Connecticut law does not require coverage for prescriptions in general or specifically for prescription eye drops in fully insured group plans and individual policies marketed in

[18] Medicare Plans and Formularies. Available at: http://plancompare.medicare.gov/pfdn/FormularyFinder/DrugSearch#divSearchResult. Accessed January, 24, 2011.

[19] Personal Communication. Sandi Gregson, Community Health Programs Coordinator. Vision USA. February 7, 2011.

[20] Connecticut Department of Public Health. 2009. School Based Health Centers. Available at: http://www.ct.gov/dph/cwp/view.asp?a=3138&q=387698. Accessed December 29, 2010.

[21] Department of Social Services. Drug Search. Available at: https://www.ctdssmap.com/CTPortal/Provider/Drug%20Search/tabId/51/Default.aspx. Accessed January 24, 2011.

Connecticut. One carrier confirmed coverage of prescription eye drops as described in the proposed health benefit in group insurance plan. Other carriers did not provide such coverage or were unable to access data to evaluate coverage according to the proposed health benefit. Currently, fully insured group and individual plans are not required to renew prescription eyes drops less than thirty days from the date of the original prescription to provide an additional bottle of prescription eye drops for use in day care or school settings when coverage is limited to one every three months.

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.

Coverage for prescription eye drops is generally available for persons enrolled in fully insured group health insurance plans and individual health policies that include prescription drug benefits. Currently, fully insured group and individual plans are not required to renew prescription eyes drops less than thirty days from the date of the original prescription or provide an additional bottle of prescription eye drops for use in day care or school settings. The lack of current coverage for the proposed health benefit may result in persons being unable to obtain necessary health care treatment if they are unable to purchase additional quantities out-of-pocket.

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.

As noted above, coverage for prescription eye drops services as defined in the proposed health benefit is not currently included in fully insured group health insurance plans and individual policies issued in Connecticut. Depending on the level of cost sharing for the initial prescription and personal financial resources available, the current lack of coverage may contribute to unreasonable financial hardship for the insured's family.

Prescription eye drops are generally required for treatment of common infections and serious medical conditions which could lead to loss of sight. For patients and their families, significant health and economic costs may accrue, even for those with comprehensive health benefits. Additionally, loss of work time, income and school attendance are common for patients and parents of children requiring prescription eye drops. Additional costs associated with illness and disease (e.g., travel) that are not covered by health insurance may also accrue. For some individuals and families, such costs can add to the unreasonable financial hardships beyond those attributed to medical services.

Further discussion of financial and socioeconomic effects of prescription eye drops may be found in Appendix IV: Ingenix Consulting Financial and Socioeconomic Report.

6. The level of public demand and the level of demand from providers for prescription eye drops.

At the time the Bill was under consideration, testimony was received in support of the service and insurance coverage from the public and providers. Members of the community, leaders of professional organizations, and providers advocated for renewal of prescription eye drops in less than 30 days or one additional bottle of prescription eye drops for use in day care or school settings, noting the importance for effective treatment. For example, many patients who use prescription eye drops may finish their allotted doses in less than 30 days. Frequently, patients in this situation are elderly, or have other conditions such as arthritis or Parkinson's disease which may contribute to inaccurate application of the prescription eye drops. Patients may also be on fixed incomes making purchase of an additional prescription out-of-pocket financially difficult. As a result, patients who need to stay on continuous therapy for sight threatening illnesses like glaucoma may have to suspend treatment while they wait for the subsequent refill. Treatment adherence is essential for

many patients with eye disease in order to reduce disease progression and potential blindness. In addition, some young patients require eye drops for sight threatening conditions like corneal infections or uveitis that can lead to glaucoma, cataracts and permanent vision loss. Treatment for such conditions can be long-term and require frequent applications. Since children spend a considerable amount of time in school and day care, prescription eye drops sometimes must be administered away from home. Transporting prescription eye drops via school bus, etc. can increase the likelihood that they get lost or become non-sterile rendering them unusable and necessitating a replacement bottle. Coverage for a second bottle of eye drops for use at school or day care would only be required when explicitly requested by the ordering provider and limited to once every three month.[22]

7. The level of public demand and the level of demand from providers for insurance coverage for prescription eye drops.

In Connecticut, public and provider support for coverage of this service is documented in the public testimony received during the time the Bill was under consideration for passage by the general assembly (as noted above in Question 6).

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

No information was found that would indicate other states require coverage of an additional bottle of prescription eye drops.[23] However, New York has a proposed health insurance mandate for prescription eye drops that closely parallels Connecticut's proposed health benefit. New York Senate Bill 1430 amends certain sections of the insurance law to allow for the refill of prescription eye drops when the refill is requested prior to the expiration of the period of suggested use.[24]

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

Thirty states now require a fiscal note or an additional review process for any new required health insurance benefit prior to enactment.[25] States may also review existing health insurance mandates periodically. Internet searches and telephone inquiries found no studies from state agencies and public organizations related specifically to the social impact of prescription eye drops as defined in the statute. States for which no evidence of a review was found include California, Colorado, Maryland, Maine, Massachusetts, Virginia, Wisconsin, Louisiana, New Jersey, Pennsylvania, Washington and Texas.

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

Currently, there are limited equally safe and effective alternatives to treat eye disease. Recent interest in the benefits of complementary and alternative medicine (CAM) (including acupuncture to treat glaucoma) has increased its use.[26] However, the effectiveness of most CAM treatments has not been established reliably enough for medical providers to employ them in place of traditional medications. Surgery may be necessary

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[22] Connecticut General Assembly. Report on Bills Favorably Reported By Committee. Insurance and Real Estate Committee. SB-92. February 18, 2010.

[23] NAIC Compendium of State Laws on Insurance Topics. National Association of Insurance Commissioners. A May 2010.

[24] New York State Assembly. Coverage for refills of prescription eye drops. S-1430. Available at: http://open.nysenate.gov/legislation/api/1.0/html/bill/S1430-2011#. Accessed February 25, 2011.

[25] National Conference of State Legislatures. 2009. Health insurance coverage mandates: Are they too costly? Presentation at the Louisiana Department of Insurance 2009 Annual Health Care Conference. May 28, 2009. Available at: http://www.ncsl.org/portals/1/documents/health/MandatesCauchi09.pdf. Accessed May 7, 2010.

[26] Law, S.K., Li, T. (2010). Acupuncture for glaucoma. The Cochrane Collaboration. John Wiley & Sons.

for conditions such as cataracts and detached retina. However, prescription eye drops are typically necessary after surgery for infection prevention, pain relief, and to decrease intraocular pressure.

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.

Extended coverage of prescription eye drops fulfills medical needs. Prescription eye drops are effective in treating serious chronic medical conditions, common infections, and allergies. They are frequently necessary as part of the process of recovery from injury or post-operative rehabilitation. .

In terms of social needs, prescription eye drops can facilitate or maintain levels of functioning that allow individuals to live independently including being able to go to work and school. In addition, research has shown an association between decreased quality of life and eye disease due in part to interference with reading, night driving, working at a computer screen, eye discomfort and blurred vision.[27]

One of the roles of health insurance is to cover unexpected health care costs. Adequate supply of prescription eye drops as defined in the proposed health benefit are required for medication adherence and effective treatment As such, the proposed services are consistent with the role of health insurance and 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.

It is possible that the basic structure of the proposed health benefit could be replicated for other types of prescription services, e.g., ointments that may need to be applied during day care or school hours, or inhalers that may be necessary for swift administration of asthma drugs. These prescriptions are also susceptible to being misplaced requiring an early refill.

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

The impact of the proposed health benefit on the availability of other benefits currently offered is expected to be minimal because it is a low cost benefit.

Insurers and MCOs may cut costs by eliminating or restricting access to, or placing limits on other non-mandated benefits currently offered. However, the availability of any benefit to be restricted may be limited. Existing benefits may be administratively costly to restrict and insurers may be contractually obligated to provide them. Additionally, many of the benefits that could be targets for elimination are included in plans for competitive advantage.

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.

There are several reasons for health insurance premium increases, including medical cost inflation, an aging population and an aging workforce, and required benefits or "mandates." Employers contemplating a shift to self-funded plans are likely to weigh these and other factors. Employers also may shift to plans with higher coinsurance amounts to keep premiums at a more affordable level ("benefit buy down"). Benefit buy down can result in employees not taking up coverage and thus being uninsured or not accessing care when it is needed because of high deductibles.

Coverage under self-funded plans is unknown.

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[27] Friedman, N.J. (2010). Impact of dry eye disease and treatment on quality of life. *Current Opinion in Ophthalmology*, 21, 310-316.

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

As a self-funded entity, the state employee health insurance or health benefits plan is exempt from state health insurance mandates under the federal Employee Retirement Income Security Act (ERISA). If the state voluntarily provided the services included in the proposed health benefit under review, the social impact of the benefit for the approximately 134, 344 covered lives in the state employee plans and 30,000 state retirees not enrolled in Medicare 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.

The actuarial analysis estimates the costs of the services included in the proposed health benefits would be $0.10 PMPM in the fully-insured group population. In terms of financial impact to the state employee health insurance or health benefits plan, there is little reason to expect that the PMPM estimate would vary significantly from the fully insured group population estimate.

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

Prescription eye drops, when used appropriately are generally safe and effective for a variety of medical conditions. In children cyclosporine eye drops, at one percent or two percent concentration, were found to be safe and effective for long-term treatment of vernal keratoconjunctivitis, a chronic and potentially sight-threatening disease.[28] In addition, topical apraclonidine 0.5 percent has been found to be safe and effective for short-term treatment in a pediatric glaucoma sample, both perioperative and postoperative.[29] The findings were based on a retrospective chart review of 115 eyes of 75 pediatric glaucoma patients who received apraclonidine 0.5 percent drops for a total of 179 sessions. The average age of the patients was 5.3 months (range, 0.1 month to 17 years). Nonthreatening side effects were noted in eight percent of children (e.g. topical allergy, lethargy, and decreased appetite).

In adult patients, the use of a fixed combination therapy with the carbonic anhydrase inhibitor dorzolaminde hydrochloride 2 percent and the beta blocker timolol maleate 0.5 percent was found to be safe and efficacious, and well tolerated.[30] In addition to the medical benefits, combining the two medications was also found to be convenient for patients since fewer doses were required contributing to increased adherence and reduced effects of "washout" when instilling multiple drops. In addition, the use of topical corticosteroids combined with the appropriate antibiotic in the treatment of bacterial keratitis can be effective in limiting permanent corneal damage in adults.[31]

However, the use of some prescription eye drops poses possible serious side effects, toxicity, and drug interactions. For example, brimonidine, a medication to lower intraocular pressure, has been prescribed to treat children although it is not licensed for this use. Only a few case reports and small retrospective studies have investigated its safety and efficacy in this population. Findings indicate potentially fatal systemic side effects including: bradycardia, hypotension, hypotonia, apnea, dyspnea, hypoventilation, cyanosis and lethargy. Although there are no concrete guidelines, extreme caution should be taken when treating children

[28] Pucci, N., Caputo, R., Mori, F, De Libero, C., Di Grande, L., Massai, C., Bernardini, R., Novembre, E. (2010). Long-term safety and efficacy of topical cyclosporine in 156 children with vernal keratoconjunctivitis. *International Journal of Immunopathology Pharmacology*, 23, 3, 865-71.

[29] Wright, T.M., & Freedman, S.F. (2009). Exposure to topical apraclonidine in children with glaucoma. *Journal of Glaucoma.* 18(5), 395-398.

[30] Bell, N.P., Ramos, J.L., & Feldman, R.M. (2010). Safety, tolerability, and efficacy of fixed combination therapy with dorzolamide hydrochloride 2% and timolol maleate 0.5% in glaucoma and ocular hypertension. *Clinical Ophthalmology*, 4, 1331-1346.

[31] Hindman, H.B., Patel, S.B., & Jun, A.S. (2009). Rational for adjuctive topical corticosteroids in bacterial keratitis. *Arch Ophthalmol*, 127, 1, 97-102.

weighing less than 20 kg and those younger than six years of age.[32] In addition, in a study investigating the risk of cataract development among patients with juvenile idiopathic arthritis (JIA)- associated uveitis treated with topical corticosteroids, findings indicate an increased risk of cataract formation independent of active uveitis or presence of posterior synechiae. However, chronic use of topical corticosteroids dosed at three or fewer drops daily seemed to be associated with a lower risk of cataract development relative to eyes receiving higher dose over follow-up in the suppression of uveitis.[33] Research has found that beta-blockers used to treat glaucoma in adults may be inappropriate for patients with cardiopulmonary disease.[34] In addition, prostaglandin analogues, also used to treat glaucoma, should not be used with patients with lightly pigmented irises (irises could change color) and patients with a history of uveitis or recent intraocular surgery.[35]

IV. Financial Impact

1. The extent to which the proposed 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 proposed health benefit is not expected to materially alter the availability or cost of prescription eye drops over the next five years. In general, prescription eye drops are a low cost and infrequently needed health service. The additional cost of a refill in less than 30 days, or a second bottle every three months to be used in a day care or school setting, is not expected to have any additional effect on the unit cost of treatment. The costs of the services are likely to increase (or decrease) at the same rates as other medical services.

2. The extent to which the proposed health benefit may increase the appropriate or inappropriate use of Prescription eye drops over the next five years.

For those individuals whose insurance plans would not otherwise cover additional bottles of prescription eye drops, the proposed health benefit may increase appropriate use of the service. For those who are covered by self-funded plans, who use out-of-pocket funds, or who receive additional bottles of prescription eye drops from other sources, a mandated benefit may not increase appropriate use. Prescription eye drops are formulated to address specific medical needs and inappropriate use is not expected to occur as a result of the proposed health benefit.

3. The extent to which prescription eye drops may serve as an alternative for more expensive or less expensive treatment, service or equipment, supplies or drugs, as applicable.

Medically necessary prescription eye drops are required for treatment to be effective for children and adults diagnosed with eye disease or infections. Such treatment does not serve as an alternative for any other treatment, service or equipment, supplies or drugs. Lack of any medically necessary care often leads to complications (disease progression and loss of sight) and more extensive treatment (surgery, laser treatment), that is more expensive than the care forgone at the earlier treatment opportunity.

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

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[32] Fudemberg, S.J., Batiste, C., Jay Katz, L. (2008). Efficacy, safety and current application of brimonidine. *Expert Opinion Drug Safety.* 7(6), 795-799.

[33] Thorne, J.E., Woreta, F.A., Dunn, J.P., & Jabs, D.A. (2010). Risk of cataract development among children with juvenile idiopathic arthritis-related uveitis treated with topical corticosteroids. *Ophthalmology*, 117, 7,1436-1441.

[34] Fudemberg, S.J., Bastiste, C. & Katz, L.J. (2008). Efficacy, safety, and current applications of brimonidine. *Expert Opinion Drug Safety,* 7(6), 795-799.

[35] *Ibid.*

It is anticipated that insurers and MCOs would employ the same utilization management methods and cost controls that are implemented with other covered benefits. The legislation does not prohibit insurers and MCOs from employing utilization management, prior authorization, or other utilization tools at their discretion.

5. The extent to which insurance coverage for an additional bottle of prescription eye drops may be reasonably expected to increase or decrease the insurance premiums and administrative expenses for policyholders.

Insurance premiums include medical cost and retention costs. Medical cost accounts for medical services. Retention costs include administrative cost and profit (for for-profit insurers/MCOs) or contribution to surplus (for not-for-profit insurers/MCOs). For further discussion, please see Appendix III, Ingenix Consulting Actuarial Report, page 10-11.

Group plans: When the medical cost of the proposed health benefit is spread to all insureds in group plans, medical costs are estimated to be $0.07 PMPM and retention costs are estimated to be $0.03 PMPM in 2011. Thus, the total effect on insurance premiums is estimated at $0.10 PMPM in 2011. Insurance coverage for the proposed health benefit could reasonably be expected to increase group health insurance premiums accordingly, that is, $1.20 per year per insured.

Individual policies: When the medical cost of the proposed health benefit is spread to all insureds in individual policies, medical costs are estimated to be $0.05 PMPM and retention costs are estimated to be $0.03 PMPM in 2011. Thus, the total effect on insurance premiums is estimated at $0.08 PMPM in 2011. Insurance coverage for the proposed health benefit could reasonably be expected to increase individual health insurance premiums accordingly, that is, $0.96 per year per insured.

For further information, please see the Appendix III: Ingenix Consulting Actuarial Report.

6. The extent to which an additional bottle of prescription eye drops are 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.

An additional bottle of prescription eye drops as defined in the proposed health benefit provide for medication tailored for individual patient needs as directed by the prescribing physician. At present there are limited equally safe and effective alternatives to treat eye disease. Recent interest in the benefits of complementary and alternative medicine (CAM) (including acupuncture to treat glaucoma) has increased its use.[36] However, the effectiveness of most CAM treatments has not been established reliably enough for medical providers to employ them in place of traditional medications. Surgery may be necessary for conditions such as cataracts and detached retina. However, prescribed eye drops are typically necessary after surgery for infection prevention, pain relief, and to decrease intraocular pressure.

7. The impact of insurance coverage for prescription eye drops 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.

The total cost of health care is understood to be the funds flowing into the medical system, which are the medical costs of insurance premiums and cost sharing. Actuarial analysis shows a projected cost in 2011 of $2,405,871 for expanded coverage of prescription eye drops for Connecticut residents covered by fully-insured group health insurance plans. Of the total cost, $1,122,740 is for insurer/MCO paid medical costs

[36] Law, S.K., Li, T. (2010). Acupuncture for glaucoma. The Cochrane Collaboration. John Wiley & Sons.

and $1,283,131 represents cost-sharing paid out-of-pocket by patients for the additional eye drops. Cost sharing represents 53.3 percent of the predicted increase in the total cost of health care.

In many cases the consistent application of prescription eye drops may prevent disease progression and loss of sight resulting in reduced medical complications and their associated costs.

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

No published literature was found regarding the impact of proposed health benefit of coverage for prescription eye drops as defined in the statute on the cost of health care for small employers. Although small employers may be more sensitive to premium increases than other employers, the estimated low cost of the proposed health benefit ($0.10 PMPM) on insurance premiums in fully-insured group plans suggests little differences in effects among different sized employers.

For further information regarding the differential effect of the proposed health benefit on small group vs. large group insurance, please see Appendix III: Ingenix Consulting Actuarial Report, page 22-23.

9. The impact of the proposed 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.

Cost-shifting between private and public payers of health care coverage generally occurs when formerly privately insured persons, after enrolling in a public program or becoming un- or underinsured, require and are provided health care services. Cost-shifting also occurs when a formerly publicly-funded service becomes the responsibility of private payers, which can result following enactment of a health insurance mandate.

Most persons formerly covered under private payers lose such coverage due to a change in employer, change in employment status, or when private payers discontinue offering health care coverage as an employee benefit or require employee contributions to premiums that are not affordable. Due to the low incidence of prescription eye drops in Connecticut and in the insured population, the proposed health benefit is not estimated to have an impact on cost-shifting between private and public payers.

If enacted, medical costs of the proposed health benefit are estimated to be $0.07 PMPM and retention costs are estimated to be $0.03 PMPM in 2011. Thus, the total effect on insurance premiums is estimated at $0.10 PMPM in 2011. Insurance coverage for the proposed health benefit could reasonably be expected to increase group health insurance premiums accordingly, that is, $1.20 per year per insured.

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. Actuarial analysis shows a projected cost in 2011 of $2,874,311 for expanded coverage of prescription eye drops for Connecticut residents covered by fully-insured group insurance plans. Of the overall cost, $1,122,740 is for paid medical costs, $1,283,131 for cost sharing, and $468,440 for retention. Cost sharing paid out-of-pocket accounts for 44.6 percent of the overall cost increase.

For further information, please see Appendix III, Ingenix Consulting Actuarial Report.

Chapter 2

An Increase in Coverage for Magnetic Resonance Imaging

Review and evaluation of

Senate Bill 259, file 89

2010 February Session

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Chapter 2. Table of Contents

I. Overview

Pursuant to Public Act 09-179, An Act Concerning Reviews of Health Insurance Benefits Mandated in this State, the chairs of the Committee on Insurance and Real Estate of the Connecticut General Assembly directed the Connecticut Insurance Department to review the proposed health insurance benefit mandates contained in their letter of July 22, 2010 (attached as Appendix I). This report is a part of that review and was conducted following the requirements stipulated under Public Act 09-179. The review is a collaborative effort of the Connecticut Insurance Department and the University of Connecticut Center for Public Health and Health Policy.

Senate Bill 259, file 89, from the 2010 February Session (SB259) would require both individual and group health insurance policies to provide benefits for magnetic resonance imaging (MRI) of an entire breast or breasts, in addition to annual mammograms, in certain circumstances.

Specifically, SB259 section 2 would amend CGSA sec. 38a-530 as follows:

> (a) (1) Each group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-42 469 delivered, issued for delivery, renewed, amended or continued in this state [on or after October 1, 2001,] shall provide benefits for mammographic examinations to any woman covered under the policy which are at least equal to the following minimum requirements: [(1)] (A) A baseline mammogram for any woman who is thirty-five to thirty-nine years of age, inclusive; and [(2)] (B) a mammogram every year for any woman who is forty years of age or older.
>
> (2) Such policy shall provide additional benefits for comprehensive ultrasound screening **and magnetic resonance imaging**, of an entire breast or breasts if a mammogram demonstrates heterogeneous or dense breast tissue based on the Breast Imaging Reporting and Data System established by the American College of Radiology or if a woman is believed to be at increased risk for breast cancer due to family history or prior personal history of breast cancer, positive genetic testing or other indications as determined by a woman's physician or advanced practice registered nurse.
>
> (b) Benefits under this section shall be subject to any policy provisions that apply to other services covered by such policy.
>
> (c) On and after October 1, 2009, each mammography report provided to a patient shall include information about breast density, based on the Breast Imaging Reporting and Data System established by the American College of Radiology. Where applicable, such report shall include the following notice: "If your mammogram demonstrates that you have dense breast tissue, which could hide small abnormalities, you might benefit from supplementary screening tests, which can include a breast ultrasound screening or a breast MRI examination, or both, depending on your individual risk factors. A report of your mammography results, which contains information about your breast density, has been sent to your physician's office and you should contact your physician if you have any questions or concerns about this report.".

(Bracketed language would be deleted from and underlined language would be added to the Connecticut General Statutes by this bill.)

Section 1 of SB259 contains essentially the same provisions for individual health insurance policies. SB259 is attached to this report as Appendix II.

N.B. Based on the existing language of CGSA sections 503 and 530, it is assumed for purposes of this report that SB259 would mandate coverage of breast MRIs when used for screening purposes where there are no signs or symptoms of disease, rather than when used for diagnostic purposes after an abnormality has been found or when used in concert with various treatments after breast cancer has been diagnosed. Health insurance policies generally already cover MRIs in the latter two circumstances.

In January 2011, CPHHP and Ingenix Consulting (IC) requested information related to the proposed mandated benefit from seven insurers and managed care organizations (MCOs) domiciled in Connecticut that cover approximately 90 percent of the population in fully-insured group and individual health insurance plans in Connecticut (1.25 million persons). Based on the survey responses, a review of the legislative history, reviews of pertinent literature and the Ingenix Consulting report, this review found the following:.

Current coverage

Connecticut-domiciled insurers/MCOs reported that 100 percent of their fully insured policies have coverage for breast MRI in at least some circumstances. Two carriers reported that their policies covered breast MRI, subject to their medical necessity guidelines, which generally follow the guidelines of the American Cancer Society. One of these two carriers allows coverage for screening MRIs when the patient has a personal history of breast cancer or has dense breasts. See Social Impact question number 3 below for a more detailed discussion.

Premium impact

Group plans: On a 2011 basis, the medical cost of this proposed mandate is estimated to be $0.92 per member, per month (PMPM). Estimated total cost to insurers (medical cost, administrative fees, and profit) of the mandated services on a 2011 basis in group plans is $1.10 PMPM, which is 0.3 percent of estimated total premium costs in group plans. The Affordable Care Act prohibits cost sharing for preventive services after 2010, so estimated cost sharing is $0.00 PMPM.

Individual policies: On a 2011 basis, medical cost is estimated to be $0.62 PMPM. Estimated total cost (medical cost, administrative fees, and profit) of the mandated services in 2011 in individual plans is $0.80 PMPM, which is 0.3 percent of estimated total premiums in individual plans. The Affordable Care Act prohibits cost sharing for preventive services after 2010, so estimated cost sharing is $0.00 PMPM.

Self-insured plans

Information received from five insurers/MCOs domiciled in Connecticut indicates that 100 percent of members in self-funded plans of three of the insurers/MCOs have coverage for the proposed mandated benefit. The other two insurers/MCOs were unable to provide information on their self-funded plans within the time frame of the survey.

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

II. Background

Breast cancer is the most common cancer diagnosed in women in the United States.[37] According to the Connecticut Department of Public Health (CTDPH), it is also the most commonly diagnosed cancer in women in Connecticut.[38] In 2004, there were 2706 diagnoses of new malignant breast cancers in Connecticut. Breast cancer is the second-leading cause of cancer deaths in women in Connecticut, with 552 deaths in 2004.[39]

Women at average risk of developing breast cancer have approximately a 12 percent chance of developing breast cancer over their lifetimes.[40] The risk of developing breast cancer increases with age. Women aged 30-39 have a one in 233 chance of developing breast cancer in the next ten years. Women aged 60-69 have a one in 29 chance. According to the CTDPH, three out of four new cancers in 2004 were found in women over 50 years of age.

Risk

Certain women are at higher than average risk of developing breast cancer. Genetic testing for certain gene mutations; a family history of breast cancer in first or second degree relatives, especially before age 40; and a woman's own clinical history are used to identify such women.

Women who have certain genetic mutations, such as the BRCA1 or BRCA2 genes, are at very high risk. The American Cancer Society reports that women with the BRCA1 gene mutation have a 65 percent risk of developing breast cancer by age 70. Women with the BRCA2 gene mutation have a 45 percent risk. Women from certain cancer-prone families can have a risk as high as 85 percent.[41] The prevalence of such mutations ranges from 1/500 to 1/1000 in the general population, but women of Ashkenazic Jewish descent have a 1/50 prevalence.

Women in families with a significant history of breast cancer among first and second degree relatives are at increased risk of having a gene that carries a high rate of risk of breast cancer. A woman from a family with a known BRCA mutation is at high risk even if she has not been tested for the mutation. However, a woman from such a family who tests negative for the mutation is at no greater risk than the average woman for developing breast cancer A woman from a high risk family where there is no known gene mutation is at high risk even if she is tested and no mutation is found.

Certain clinical factors are associated with increased risk. Women who have had radiation of the chest to treat Hodgkin's disease, if done between the ages of 10 and 30, have a significant risk of developing breast cancer 15-30 years after treatment, although this may not be true of women treated after 1974 with newer radiotherapy methods. Women who have had certain types of noninvasive cancers or atypical hyperplasia can be at 4-10 times greater risk of developing invasive breast cancer. Breast density can also increase a woman's risk of breast cancer. The ACS guidelines cite studies that found a four- to six-fold increase in risk between women with the most dense breasts and those with the least dense breasts.[42]

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[37] American Cancer Society. 2011. American Cancer Society Guidelines for Breast Screening with MRI as an adjunct to Mammography. *CA Cancer J Clin* 57(1);75-89.

[38] Connecticut Department of Public Health. 2007. Breast Cancer in Connecticut Available at: http://www.ct.gov/dph/cwp/view.asp?a=3134&q=396512. Accessed on February 24, 2011.

[39] *Ibid.*

[40] National Cancer Institute. 2010. Probability of Breast Cancer in American Women. Available at: http://www.cancer.gov/cancertopics/factsheet/detection/probability-breast-cancer. Accessed on February 24, 2011.

[41] Saslow D, Boetes C, Burke W *et al.* 2007. American Cancer Society Guidelines for Breast Screening with MRI as an Adjunct to Mammography. *CA Cancer J Clin* 57(2);75-89. Downloaded from caonline.americancancersoc.org on February 9, 2011.

[42] *Ibid.* p. 78-79.

There are two decision-making models that assist physicians in estimating the likelihood that a particular woman has a BRCA mutation: BRCAPRO and BOADICEA. BOADICEA also can estimate a woman's risk of developing breast cancer.[43] The ACS guidelines for use of MRIs as a screening tool are based on the level of risk for a particular woman as determined by these or similar models.

Screening modalities

Screening and early diagnosis have been shown to reduce morbidity and mortality from breast cancer among women between the ages of 40 and 74.[44, 45] Five year survival rates for breast cancer are highest when it is detected at the earliest stages, before it has spread beyond the breast.[46] Regular mammograms and clinical breast examination by a trained health care provider are the most effective ways to detect breast cancer early.[47]

However, mammograms are not perfect. Screening mammograms can miss up to 20 percent of breast cancers that are present at the time of screening.[48] Such false-negative results occur most often as a result of dense breast tissue. Dense tissue and tumors have a similar appearance on a mammogram, making it harder to detect a tumor. Dense tissue is more common among young women than among older women, because breast tissue generally becomes more fatty and less dense as women age. Mammograms can also result in false-positive reports, which can result in unnecessary follow-up procedures such as biopsies for what turn out to be benign abnormalities. On balance, such risks are deemed to be outweighed by the benefits of early detection.

Breast ultrasound uses high frequency sound waves to develop a picture of the breast tissue. It is noninvasive and does not use radiation. It is most often used as a diagnostic aid when a mammogram or clinical breast exam has detected an abnormality. Some studies have shown that screening women with very dense breasts using both mammogram and ultrasound can find more cancers than screening with mammography alone.[49]

Magnetic resonance imaging (MRI) uses magnetic fields and radio waves to produce very detailed cross-sectional pictures of the body. Contrast MRIs use a contrast agent injected into a vein either before or during the MRI to provide enhanced detail. MRI is used primarily as a diagnostic tool or as an adjunct to treatment for diagnosed breast cancer, but it can also detect some cancers that are missed on mammograms, especially in dense breast tissue. However, it has a higher rate of false-positive results than mammography, leading to more follow-up procedures and biopsies than are needed. MRIs of the breast are most accurate when performed on a breast MRI machine, as opposed to an MRI machine designed for chest or abdominal scanning. Not all hospitals or imaging centers have such specialized equipment.[50]

All three imaging technologies require physicians and technicians specially trained in their use and

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[43] *Ibid,* p. 77.

[44] Swayampakula AK, Dillis C and Abraham J. 2008. Role of MRI in screening, diagnosis and management of breast can*cer. Expert Rev Anticancer Ther.* 8(5);811-817.

[45] National Cancer Institute. 2011. Fact Sheet: Mammograms. Available at: http://www.cancer.gov/cancertopics/factsheet/detection/mammograms. Accessed on February 24, 2011.

[46] Connecticut Department of Public Health. 2001. Connecticut Women's Health. P. 67. Available at: http://www.ct.gov/dph/LIB/dph/state_health_planning/PDF/CTWomensHealth_Chp1_10.pdf. Accessed on February 24, 2011.

[47] National Cancer Institute. 2011. Fact Sheet: Mammograms. Available at: http://www.cancer.gov/cancertopics/factsheet/detection/mammograms. Accessed on February 24, 2011.

[48] *Ibid.*

[49] American Cancer Society. 2010. Mammograms and other imaging procedures. Available at: http://www.cancer.org/Healthy/FindCancerEarly/ExamandTestDescriptions/MammogramsandOtherBreastImagingProcedures/mammograms-and-other-breast-imaging-procedures. Accessed on February 24, 2011.

[50] *Ibid.*

interpretation.[51]

Screening Recommendations

Mammography, coupled with regular clinical breast exams, is the primary screening method recommended by the National Cancer Institute,[52] the CDC,[53] and the American Cancer Society[54] to detect cancer in the breast. However, both the American Cancer Society and the American College of Radiology recommend the use of MRIs as an adjunct to mammograms for the screening of women at very high risk for developing breast cancer. It is felt that this level risk of breast cancer outweighs the higher risk of false positives that MRI entails for such women.

American Cancer Society (ACS) guidelines for breast MRI.[55]

Annual MRI screening in addition to annual mammogram screening is recommended for women at high risk of developing breast cancer. These are women who:

- Have a known BRCA gene mutation,
- Are a first degree relative of a known BRCA carrier, but have themselves not been tested,
- Have a life-time risk equal to 20-25 percent or greater of developing breast cancer, as defined by BRCAPRO or other models that are largely dependent on family history,
- Have had radiation to the chest between the ages of 10 and 30 years,
- Have Li-Fraumeni syndrome or are a first degree relative, or
- Have Cowden and Bannayan-Riley-Ruvalcaba syndromes or are a first degree relative

The ACS has found insufficient evidence to recommend for or against MRI screening for women who have a moderate risk of developing breast cancer. These are women who:

- Have a lifetime risk between 15 and 20 percent, as defined by BRCAPRO or other models largely dependent on family history,
- Have had lobular carcinoma in situ (LCIS) or atypical lobular hyperplasia (ALH),
- Have had atypical ductal hyperplasia (ADH),
- Have heterogeneously or extremely dense breast on mammography, or
- Have a personal history of breast cancer, including ductal carcinoma in situ (DCIS)
- ACS recommends against MRI screening for women at average risk (less than 15 percent lifetime risk) of developing breast cancer.

American College of Radiology (ACR) guidelines for breast MRI.[56]

ACR recommends MRI as an adjunct to clinical history, physical examination results and the results of

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[51] *Ibid.*

[52] National Cancer Institute. 2011. Fact Sheet: Mammograms. Available at: http://www.cancer.gov/cancertopics/factsheet/detection/mammograms. Accessed on February 24, 2011.

[53] Centers for Disease Control and Prevention. 2011. Breast Cancer Screening. Available at: http://www.cdc.gov/cancer/breast/basic_info/screening.htm. Accessed on February 24, 2011.

[54] Smith R, Cokkinides V and Brawley O. 2009. Cancer screening in the United States, 2009: a review of current American Cancer Society guidelines and issues in cancer screening. *CA Cancer J Clin* 59(1);27-41.

[55] Saslow D, Boetes C, Burke W *et al.* 2007. American Cancer Society Guidelines for Breast Screening with MRI as an Adjunct to Mammography. *CA Cancer J Clin* 57(1);75-89. Downloaded from caonline.americancancersoc.org on February 9, 2011.

[56] American College of Radiology. 2008. ACR Practice Guideline for the Performance of Contrast-Enhanced Magnetic Resonance Imaging (MRI) of the Breast. Available at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/breast/mri_breast.aspx. Accessed on February 24, 2011.

mammography for screening high risk patients:

- Those with a 20 percent lifetime risk of cancer,
- A genetic predisposition to breast cancer based either on genetic testing or family history, or
- A history of mantle radiation for Hodgkin's disease.
- ACR recommends using MRI to screen the other breast for cancer when a new breast malignancy has been found in one breast.
- ACR also recommends using MRI for patients with silicone or saline implants, or free injections of silicone or other materials, for whom mammography is difficult. MRI can also be used to determine the integrity of implants.
- ACR does not recommend using MRI to screen for breast cancer in the general population of asymptomatic, average-risk women.
- ACR recommends that screening MRI be used in addition to and not in place of screening mammography, because some cancers are detected better by mammography than by MRI. It also recommends that MRI not be used in lieu of biopsy to evaluate suspicious findings of mammography, clinical exam or sonography.

III. Methods

Under the direction of CPHHP, medical librarians at the Lyman Maynard Stowe Library at the University of Connecticut Health Center (UCHC) gathered published articles and other information related to medical, social, economic, and financial aspects of the proposed mandated benefit. Medical librarians conducted literature searches using UptoDate, DynaMed, Cochrane Database, EMedicine and web searches using Google and Bing. General search terms used included MRI, magnetic resonance imaging, screening, breast cancer and breast neoplasm.

CPHHP staff conducted independent literature searches using similar search terms used by the UCHC medical librarians. Where available, articles published in peer-reviewed journals are cited to support the analysis. Other sources of information may also be cited in the absence of peer-reviewed journal articles. Content from such sources may or may not be based on scientific evidence.

CPHHP staff consulted with clinical faculty from the University of Connecticut School of Medicine on matters pertaining to medical standards of care, traditional, current and emerging practices, and evidence-based medicine related to the benefit.

Staff gathered additional information through telephone and e-mail inquiries to appropriate state, federal, municipal, and non-profit entities and from internet sources such as the State of Connecticut website, Centers for Medicare and Medicaid (CMS) website, other states' websites, professional organizations' websites, and non-profit and community-based organization websites.

With the assistance of the Connecticut Insurance Department (CID), CPHHP and Ingenix Consulting surveyed the insurance companies and MCOs domiciled in Connecticut as to whether their fully-insured group and individual plans currently included the proposed mandated benefit. Five insurers/MCOs responded. Three insurers/MCOs also provided information about coverage for this service in the self-insured plans they administer.

CPHHP and the CID contracted with Ingenix Consulting (IC) 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 may be found in the IC report, which is attached as Appendix III.

IV. Social Impact

1. The extent to which the treatment, service or equipment, supplies or drugs, as applicable, is utilized by a significant portion of the population.

Connecticut has approximately 628,717 women between the ages of 40-64, and approximately 127,176 women between the ages of 35-59. Roughly 46.6 percent of Connecticut's population is covered by fully insured group and individual health policies.[57] . About 40 percent of women nationally have dense breast tissue, which decreases with age.[58] An estimated 2 percent of women are at high risk of developing breast cancer due to genetic or family history of breast cancer.[59]

2. The extent to which the treatment, service or equipment, supplies or drugs, as applicable, is 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 distinguishes between screening mammograms given to a person without signs or symptoms of breast disease, and diagnostic mammograms performed subsequent to a suspicious screening mammogram or when there are signs or symptoms of disease. Medicare covers one screening mammogram per year for all women age 40 and over, and one baseline mammogram between the ages of 35-39. Medicare does not cover screening mammograms for men or for women under 35. A screening mammogram is not subject to the Part B deductible but is subject to coinsurance. Diagnostic mammograms are also covered, and are subject to the deductible.

Medicare covers breast MRIs only for the following purposes:

- Where diagnosis is inconclusive,
- To evaluate post-operative patients when scar tissue cannot be differentiated from tumors,
- Where there are positive axillary nodes with no known primary site,
- Where there is a rupture of a breast implant, or
- To determine the extent of a known malignancy prior to treatment.[60]
- Medicare does not cover screening MRIs.

Medicaid

Medicaid coverage of MRIs for breast cancer screening closely parallels the coverage provided by Medicare.

Connecticut Department of Public Health

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[57] University of Connecticut, Center for Public Health and Health Policy. 2009. Review and Evaluation of Public Act 09-188, An Act Concerning Wellness Programs and Expansion of Health Insurance Coverage. Available at: http://publichealth.uconn.edu/images/reports/InsuranceReview09.pdf.

[58] Ingenix Consulting Report, Appendix III, p. 6.

[59] National Cancer Institute. 2009. Fact Sheet: BRCA1 and BRCA2: Cancer Risk and Genetic Testing. Available at: http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA. Accessed on February 24, 2011.

[60] Centers for Medicare and Medicaid Services. 2008. Local Coverage Determination for BREAST Imaging, Connecticut. LCD ID number: L26890. Available at https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=26890&ContrTypeId=8&ver=52&ContrNum=13101&CoverageSelection=Local&ArticleType=All&PolicyType=Final&s=Connecticut&KeyWord=Breast+Imaging&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAA&. Accessed on February 20, 2011.

The Connecticut Department of Public Health funds the Breast and Cervical Cancer Early Detection Program, which provides breast and cervical cancer screening services for certain women between 40 and 65 years of age who are at or below 200 percent of the federal poverty level.[61] This program provides, among other services, screening and diagnostic mammograms and breast ultrasounds through contracted health providers around the state. No information was found that would indicate the state Department of Public Health provides services for MRI breast cancer screenings.

3. The extent to which insurance coverage is already available for the treatment, service or equipment, supplies or drugs, as applicable.

Survey responses from five Connecticut-domiciled insurers/MCOs indicate that 100 percent of fully insured health benefit policies currently provide coverage for screening breast MRI based on medical necessity. One insurer/MCO limits coverage of screening MRIs to the circumstances recommended in the American Cancer Society guidelines. One insurer/MCO allows screening MRIs in accordance with the ACS guidelines and in addition covers screening MRIs for women with a personal history of breast cancer and women with dense breasts. The other three insurers/MCOs did not indicate any limits on the coverage of screening MRIs.

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.

Breast MRIs can cost as much as $2,000.[62] If insurance coverage is not available, this cost may deter women from obtaining MRIs for cancer screening purposes. For women at high risk of developing breast cancer, for whom a screening MRI is recommended as an adjunct to a screening mammogram, this cost could result in the inability to obtain such screening.

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.

Assuming an average annual cost of $2,000,[63] the cost of a screening breast MRI can cost an average of 4 percent of a family's income for families earning $50,000 annually, if there is no insurance for it.

6. The level of public demand and the level of demand from providers for the treatment, service or equipment, supplies or drugs, as applicable.

With the exception of women who are at very high risk for breast cancer (greater than 20-25 percent risk), neither the American Cancer Society nor the American College of Radiologists recommends that MRI be used routinely for breast cancer screening.

7. 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.

The Connecticut State Medical Society and the Radiological Society of Connecticut testified in favor of SB259 in 2010.

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

Forty-nine states and the District of Columbia mandate insurance coverage of screening mammograms.

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[61] Connecticut Department of Public Health. 2010. The Connecticut Breast and Cervical Cancer Early Detection Program. Available at: http://www.ct.gov/dph/cwp/view.asp?a=3124&q=388824. Accessed on February 21, 2011.

[62] Ingenix Consulting Report, Appendix III, p.17

[63] Ingenix Consulting Report. Appendix III, p. 17

According to the National Association of Insurance Commissioners, none of them mandate coverage of breast MRIs.[64]

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

The Connecticut Department of Public Health does not include breast MRI in its Breast and Cervical Cancer Early Detection Program.

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

Mammography and ultrasound are alternative breast cancer screening technologies. Both are effective in detecting breast lesions in the majority of women, and are widely accepted in the medical community. However, they are less effective than MRIs in detecting certain types of cancers and in detecting cancers in women with dense breast tissue.[65]

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 mandate deals with a technology for the diagnosis of breast cancer, which is a medical disease. It therefore addresses a medical need and is consistent with the role of health insurance and 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.

This mandate may have implications for other types of screening technologies that are new and that are recommended primarily for special patient populations.

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

As insurance costs rise, employers may choose to reduce benefit levels rather than drop coverage altogether. This can be done by increasing member cost-sharing through higher deductible or increased co-pays and/or coinsurance levels. When this happens, members sometimes forgo needed services because of the out-of-pocket cost. As a result of the Affordable Care Act, deductibles and co-pays would not be applicable to this proposed mandated benefit, but the additional cost could cause an increase in member cost for other covered services that are not preventive in nature. For further discussion, see the IC report at page 24.

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.

Five insurers/MCOs domiciled in Connecticut submitted responses to our survey. Three of the five insurers/MCOs indicated that 100 percent of their self-funded policies provide coverage for breast MRIs, presumably with the same medical necessity requirements as their fully insured plans. In general, these medical necessity requirements follow the guidelines of the American Cancer Society. The remaining carriers replied that they could not estimate how many self-funded plans provided such coverage.

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

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[64] National Association of Insurance Commissioners. 2009. Compendium of State Laws on Insurance Topics.

[65] Saslow D, Boetes C, Burke W *et al.* 2007. American Cancer Society Guidelines for Breast Screening with MRI as an Adjunct to Mammography. *CA Cancer J Clin* 57(1);84. Downloaded from caonline.americancancersoc.org on February 9, 2011

Assuming that the State plans would comply with this proposed mandated health benefit, the total annual cost for this mandate in 2011 is estimated to be $1,814,247.[66] This estimate includes both active employees and those retirees who are not covered by Medicare (n.b., the cost may be somewhat lower for the retiree plans, since the density of breast tissue decreases with age and therefore the fewer women will meet the requirements of the mandate). This has been calculated by multiplying the 2011 PMPM cost by 12 to get an annual cost per insured life, and then multiplying that product by 133,334 covered lives for the active employee plans and 30,000 covered lives under the retiree medical plans that are not eligible for Medicare, as reported by the State Comptroller's office.[67]

Caveat: This estimate is calculated using weighted averages for all claims paid by Connecticut-domiciled insurers and managed care organizations in the State. The actual cost of this proposed mandate to the State plans may be higher or lower, based on the actual benefit design of the State plans and the demographics of the covered lives (e.g., level of cost-sharing, average age of members, etc.).

Retention costs are not included in this estimate because the State is now self-funded and the traditional elements of retention do not apply. State costs for administration of the plans would be in addition to the above amount

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.

Magnetic resonance imaging has become widely used in the United States. Magnetic fields are generally considered to be nonhazardous to the human body, but precautions must be taken to prevent injuries from ferromagnetic objects that may be within the range of the magnet.[68]

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 use of magnetic resonance imaging for breast cancer screening nearly doubled between 2006 and 2008 in Connecticut, with a concomitant doubling in allowed and paid medical costs.[69] The IC actuarial report estimates that it is likely to double again over the next five years, as a result of this mandate and the Affordable Care Act's prohibition on patient cost-sharing for preventive services.[70]

The IC actuarial report estimates that this mandate will double the 2011 estimated medical costs for screening breast MRIs, adding $0.92 PMPM to the estimated 2011 medical cost for this service. By 2015, the mandate will increase the 2011 estimated medical cost for screening breast MRIs by an estimated $1.61 PMPM. This assumes a 5 percent annual increase for medical inflation and a 10 percent annual increase in utilization.[71]

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

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66 Ingenix Consulting Report, Appendix 4. Appendix III

67 Conversation with Scott Anderson, State Comptroller's office, September 14, 2010

68 Schenck JF. 2000. Safety of strong, static magnetic fields. *Journal of Magnetic Resonance Imaging*. 12(1);2-19.

69 Ingenix Consulting Report, Appendix III, pp.6 and 32

70 *Ibid.*

71 Ingenix Consulting Report, Appendix III, p. 36

years.

The IC actuarial report estimates that this mandate would double the use of screening breast MRIs initially and would increase the use of screening breast MRIs by 10 percent annually thereafter over the next five years.

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.

Breast MRI is not viewed as an alternative to mammography and breast ultrasound, but as an adjunct to these screening technologies. The cost of a mammogram is approximately $100-200, and the cost of a sonogram is approximately $100. The cost of a breast MRI is approximately $2,000.[72]

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

The proposed mandate is limited to breast MRI that is prescribed by a licensed health care provider. It is also limited as to the circumstances under which it may apply. In addition, all other terms of the policy apply, so that insurers/MCOs can negotiate allowed costs with MRI providers to help control unit costs and utilization review can be exercised by the carriers to avoid inappropriate use of the benefit. However, the proposed limits are less restrictive than the American Cancer Society guidelines and the current policies of some of the insurers/MCOs. The language of the proposed mandate may also hinder the efforts of the insurers/MCOs to exercise utilization review.

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. Medical cost accounts for medical services. Retention costs include administrative cost and profit (for for-profit insurers/MCOs) or contribution to surplus (for not-for-profit insurers/MCOs). (For further discussion, please see Appendix III, Ingenix Consulting Actuarial Report, page 10.)

Since the majority of Connecticut insurers/MCOs reported that they currently cover at least some level of screening breast MRIs in their fully insured policies, the figures below represent the estimated incremental cost that would be added to premiums by this mandate, over and above the current cost of breast MRIs that are embedded in current premiums. Thus the figures below do not represent the full estimated cost of benefits for screening breast MRIs in fully insured policies. (The IC actuarial report estimates the current medical cost of screening breast MRIs in group policies to be $0.92 PMPM on a 2011 basis. The PMPM figures below would be in addition to this amount.)

Group plans: When the medical cost of the proposed mandate is spread to all insureds in group plans, the medical costs of the mandate are estimated to be $0.92 PMPM and retention costs are estimated to be $0.18 PMPM on a 2011 basis. Thus the total effect on insurance premiums is estimated at $1.10 PMPM on a 2011 basis, which is 0.3 percent of premium.

Individual plans: When the medical cost of the proposed mandate is spread to all insureds in individual plans, the medical costs of the mandate are estimated to be $0.62 PMPM and retention costs are estimated to be $0.19 PMPM on a 2011 basis. Thus the total effect on insurance premiums is estimated at $0.80 PMPM on a 2011 basis, which is 0.3 percent of premium.

[72] Ingenix Consulting Report, Appendix III, p. 17

For further information, please see Appendix III: Ingenix Consulting Actuarial Report.

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.

MRI ($2000) is considerably more expensive than either mammography ($100-200) or ultrasound ($100). All three technologies are deemed to be safe and effective. MRI can detect some cancers, especially in dense breast tissue, somewhat better, but it also has a higher incidence of false positives which can lead to unnecessary follow-up procedures and biopsies.[73]

7. 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.

The total cost of health care is understood to be the funds flowing into the medical system, which are the medical costs portion of insurance premiums and the cost sharing of the insureds. The Ingenix Consulting actuarial analysis estimates an impact on a 2011 basis of $14,756,010 for coverage of screening breast MRIs for Connecticut residents covered by fully-insured group and individual health insurance.

The cost of such MRIs may be offset by lower treatment costs for breast cancers that are found at an earlier stage.

8. 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.

According to the actuarial report, this proposed mandate is expected to have roughly the same effect on the allowed cost of small group plans as it does on large group plans.[74] However, the small group market is more sensitive to the cost of health insurance and may be somewhat more likely to drop coverage as a result of cost increases generally.

Ingenix also found that small groups tend to shift more cost to the insured in the form of higher co-pays, deductibles, and coinsurance, and to require employees to pay a larger share of the premium than large plans do. Therefore, the cost burden of the mandates is likely to be somewhat greater for those whose insurance is provided through a small group employer.

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 estimated annual impact of this proposed mandate on the overall cost of health care delivery in the state is $17,834,328.[75] It is not expected to result in cost-shifting between private and public payers of health care coverage.

This estimated impact assumes that the State of Connecticut plans continue to comply with this mandate even though these plans are now self-funded and therefore are not required to include it.

[73] Saslow D, Boetes C, Burke W *et al.* 2007. American Cancer Society Guidelines for Breast Screening with MRI as an Adjunct to Mammography. *CA Cancer J Clin* 57(1);75-89. Downloaded from caonline.americancancersoc.org on February 9, 2011

[74] Ingenix Consulting report, Appendix III, p. 22

[75] Ingenix Consulting report, Appendix III

Chapter 3

Parkinson's Disease and Multiple Sclerosis: Routine Patient Care Costs for Clinical Trials and Off-Label Drug Prescriptions

Review and Evaluation of
Connecticut 2010 General Assembly
Senate Bill 260, File No. 247

An Act Concerning Health Insurance Coverage
for Routine Patient Care Costs
for Certain Clinical Trial Patients

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Chapter 3. Table of Contents

I. Overview

On July 22, 2010, the Chairs of the Insurance and Real Estate Committee of the Connecticut General Assembly (the Committee) directed the Connecticut Insurance Department to review the proposed health benefits contained in Senate Bill 260, File 247, from the 2010 General Assembly session, entitled, "**An Act Concerning Health Insurance Coverage for Routine Patient Care Costs for Certain Clinical Trial Patients.**" This review follows the requirements stipulated under Public Act 09-179. Reviews of required health insurance benefits are a collaborative effort of Connecticut Insurance Department and the University of Connecticut Center for Public Health and Health Policy (CPHHP).

The analysis is based on Senate Bill 260, File Number 247, of the 2010 General Assembly session (SB260), which would amend CGSA § 38a-504a-g; CGSA § 38a-542a-g; CGSA § 38a-492b; and CGSA § 38a-518b to require fully insured group plans and individual insurance policies to cover routine costs of clinical trials for Parkinson's Disease and multiple sclerosis, as well as cancer, and for those plans that cover prescription drugs, it would also require coverage of off-label prescription drugs for Parkinson's Disease and multiple sclerosis. The full text SB260 is attached to this report as Appendix II. As directed by the Committee, this review includes analysis of the social and financial impact of required coverage for benefits associated with Parkinson's disease (PD) and multiple sclerosis (MS). Coverage of routine patient care costs for persons enrolled in cancer clinical trials and off-label drug prescriptions for cancer patients is existing law in Connecticut and analyses of the social and financial impact of required coverage for these benefits was completed in January 2011.[76]

For off-label drug prescriptions for Parkinson's disease and multiple sclerosis, the proposed health benefit would require coverage only for off-label use of MS-approved drugs for treatment of Parkinson's disease and off-label use of Parkinson's disease-approved drugs for treatment of MS rather than all off-label prescriptions.

In January 2011, CPHHP requested information related to the proposed benefit from seven insurers and managed care organizations (MCOs) domiciled in Connecticut that cover approximately 90 percent of the population in fully-insured group and individual health insurance plans in Connecticut (1.25 million persons). The insurers/MCOs were unable to differentiate claims for routine patient care costs associated with Parkinson's disease and Multiple Sclerosis clinical trials from claims for patient care costs for care not associated with a clinical trial in their claims databases. The insurers/MCOs report that routine patient care costs are generally covered for patients enrolled in clinical trials, consistent with standards of care. For off-label prescriptions, insurers/MCOs stated in general that claims for such services are covered in most circumstances in accordance with common managed care practices used for pharmacy benefits. Some prescription drugs require prior authorization. Additionally, the insurers/MCOs state a patient's diagnosis is not included in claims for prescription drugs thus information technology systems in place for pharmacy benefits cannot be used to identify off-label prescriptions.

Premium impact

CID contracted with Ingenix Consulting (IC) for actuarial and economic analysis of the proposed health benefits. IC analysis estimates that the costs to both fully insured group plans and individual health insurance policies for both off-label prescriptions of MS and PD prescription drugs and the routine patient care costs of clinical trials for PD or MS would be *de minimis*.

[76] Center for Public Health and Health Policy. 2011. Connecticut Mandated Health Insurance Benefits Reviews, 2010. University of Connecticut. Available at: http://www.ct.gov/cid/cwp/view.asp?Q=447304&A=1254. Accessed February 18, 2011.

Self funded plans

For the same reasons insurers/MCOs were unable to provide claims data for fully insured plans and individual policies, they were unable to provide information regarding coverage of the services included in the proposed health benefit for the self-funded plans for which they administer benefits.

This report is intended to be read in conjunction with the Ingenix Consulting Actuarial Report which is included as Appendix III.

II. Background

Parkinson's Disease

Parkinson's disease (PD) is a slowly progressing, degenerative disease that is characterized by a chemical imbalance in the brain that leads to tremors and difficulty with walking, movement, and coordination.[77] The disease is chronic and progressive and is primarily contracted based on heredity.[78] The primary symptoms of PD include the following:[79]

- Rigidity - stiffness when the arm, leg, or neck is moved back and forth.
- Resting tremor - tremor (involuntary movement from contracting muscles) that is most prominent at rest.
- Bradykinesia - slowness in initiating movement.
- Loss of postural reflexes - poor posture and balance that may cause falls; gait or balance problems.

PD occurs when nerve cells in the brain that produce dopamine are slowly destroyed. Dopamine is a neurotransmitter that helps to relay brain signals to the rest of the body. The loss of dopamine leads to loss of muscle function. The cause of deteriorating nerve cells in PD is unknown; however, research suggests specific genetic mutations likely play a role either by genetic inheritance or environmental exposure.[80]

PD is a form of Parkinsonism. Like PD, Parkinsonism is characterized by symptoms commonly associated with PD including tremors, changes in movement, rigidity, and postural instability. The primary difference is that the cause of Parkinsonism is not related to dopamine. Parkinsonism may be caused by, but not limited to, environmental factors, metabolic disorders, and non-neurological disorders.[81]

Diagnosis of PD requires a complete neurological exam in conjunction with a review of the patient's medical history. Accurate diagnosis largely depends on the skill of the physician performing the evaluation. Some laboratory and diagnostic tests may be used to rule out other possible conditions; however a physician may need to observe the patient over time to determine presence of PD symptoms.[82] The five stages of PD as it progresses throughout the life of a diagnosis are: [83,84]

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[77] National Institutes of Health. 2010. US National Library of Medicine. Parkinson's Disease. Available at: http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001762. Accessed February 15, 2011.

[78] NY Presbyterian Hospital. 2010. Parkinson's disease. Available at: http://nyp.org/health/parkinson-disease.html. Accessed January 31, 2011.

[79] *Ibid.*

[80] Bekris LM, Mata IF, Zabetian CP. 2010. The genetics of Parkinson disease. *Journal of Geriatric Psychiatry and Neurology* 23(4): 228-42.

[81] Tuite PJ, Krawczewski K. 2007. Parkinsonism: a review-of-systems approach to diagnosis. Seminars in Neurology 27(2): 113-22.

[82] Mayo Clinic Staff. Parkinson's Disease. May Clinic. Available at: http://www.mayoclinic.com/health/parkinsons-disease/DS00295/DSECTION=tests-and-diagnosis. Accessed February 15, 2011.

[83] Glass J. 2010. The five stages of Parkinson's Disease. Web MD. Available at: http://www.webmd.com/parkinsons-disease/parkinsons-stages. Accessed February 15, 2011.

[84] Massachusetts General Hospital. Unified Parkinson's Disease Rating Scale. Available at: http://neurosurgery.mgh.harvard.edu/functional/pdstages.htm. Accessed February 15, 2011.

- **Stage One**: Mild symptoms, inconvenience completing day-to-day tasks, poor posture, and loss of balance.
- **Stage Two**: Symptoms are bilateral affecting limbs on both sides of the body, problems walking.
- **Stage Three**: Severe symptoms, inability to walk straight or stand straight, noticeable slowing of physical activity.
- **Stage Four**: Patients cannot live on their own, rigidity and bradykinesia are visible, usually unable to complete day-to-day tasks.
- **Stage Five**: Unable to take care of him or herself and may not be able to stand or walk; usually requires constant one-on-one nursing care.

Approximately 1.5 million people in the United States have Parkinson's disease and 50,000 new cases are diagnosed each year in the United States.[85] While onset typically occurs after age 50 and most diagnoses occur around age 60, onset occurs in some patients under age 40.[86] Parkinson's disease ranks among the most common late-life neurodegenerative diseases, affecting approximately 1.5 to 2.0 percent of the population older than age 60 years.[87]

A study of Medicare beneficiaries over a 10-year span determined that whites have a higher prevalence and incidence of PD than blacks or Asians and found no relationship between prevalence and urban/rural residency. [88] Prevalence of the disease is highest in the Midwest and Northeast regions.[89] Given the prevalence of PD in these regions the likelihood of environmental factors as contributory to the disease is likely.

While there is no cure for PD, several medications are available to treat and manage the disease. Levodopa is the most commonly prescribed and most effective medicine for controlling the symptoms of Parkinson's disease, particularly bradykinesia and rigidity. When released into the brain Levodopa can be converted into dopamine. Other medications are also available that conserve dopamine in the brain or mimic its function. Pharmacological intervention is frequently effective; however fifteen percent of patients are typically unresponsive to prescription drugs. For these individuals, surgical procedures are available.[90]

Deep brain stimulation may be used to treat PD and is more commonly used for advanced stages of the disease. The procedure involves implanting an electrode within parts of the brain that control movement. The electrode is regulated by a pace-maker like device implanted in the upper chest that is connected through a wire placed under the skin to the electrode. This procedure has proven effectiveness in controlling involuntary movements (dyskinesia) and tremors.[91]

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[85] Cleveland Clinic. 2006. Parkinson's Disease, Incidence. Available at: http://my.clevelandclinic.org/disorders/Parkinsons_Disease/hic_Parkinsons_Disease_Incidence.aspx. Accessed February 15, 2011.

[86] *Ibid.*

[87] Sweeney S. 2010. Parkinson's disease. Cleveland Clinic Center for Continuing Education. Available at: http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/neurology/parkinsons-disease/#s0015. Accessed February 10, 2011.

[88] Wright Willis A, Evanoff BA, Lian M, *et al.* 2010. Geographic and ethnic variation in Parkinson disease: a population-based study of US Medicare beneficiaries. *Neuroepidemiology* 34(3): 143-51.

[89] *Ibid.*

[90] Cleveland Clinic. 2006. Parkinson's Disease, Medications. Available at: http://my.clevelandclinic.org/disorders/Parkinsons_Disease/hic_Medications_for_Parkinsons_Disease.aspx. Accessed February 15, 2011.

[91] Mayo Clinic Staff. Parkinson's Disease. May Clinic. Available at: http://www.mayoclinic.com/health/parkinsons-disease/DS00295/DSECTION=treatments-and-drugs. Accessed February 15, 2011.

The direct medical costs of treatment for persons with PD is considerable. A study concluded the annual direct costs were $23,101 per patient with PD versus $11,247 for controls.[92] The researchers added $25,326 in indirect costs, and multiplying by 645,000 cases of PD in the United States, projected an annual cost of $23 billion for the United States.[93]

Multiple Sclerosis

Multiple Sclerosis (MS) is a chronic, sometimes debilitating autoimmune disorder that affects the brain and spinal cord (central nervous system). The primary characteristic of the disease is the damage to protective coverings (myelin sheaths) that surround nerve cells. Nerve damage is caused by inflammation that occurs when the body's immune cells attack the nervous system. Episodes of inflammation can occur along any area of the brain, optic nerve, and spinal cord.[94] Persons diagnosed with MS suffer from a range of symptoms including numbness in the limbs, paralysis, or loss of vision. Specific symptoms and onset are unpredictable and vary between individuals.[95]

The root cause of MS is unknown. Environmental, immunological, and genetic factors are all being explored. MS affects women more than men.[96] The overall incidence rate of MS is 3.6 cases per 100,000 person-years in women and 2.0 in men. During the last half of the 20th Century, the female-to-male ratio in MS incidence steadily increased.[97] Risk factors linked to MS include vitamin D deficiency, low lifetime UV radiation, and residing in northern climes.[98] However, the significance of these factors as a cause of MS requires further analysis. Other risk factors include being female, between the ages of 20 to 40, having a family history of MS, being white, and having other autoimmune or neurological disorders. Those with a family member stricken with MS have a one to three percent chance of contracting the disease.

Diagnosis of MS requires administration of a set of diagnostic tests that require evaluation by a neurologist who specializes in MS. Nearly 10 percent of people diagnosed with MS have some other condition that mimics MS. A neurological exam, magnetic resonance imaging (MRI) screenings, spinal taps, and blood studies may all contribute to a MS diagnosis. Despite the availability of various tests and diagnostic tools, in large part, a correct diagnosis depends on correct interpretation of the results.[99]

There are four types of MS:[100]

- ***Relapsing-remitting MS*** (RRMS). RRMS is characterized by relapse (flare-ups of symptoms) followed by remission (periods of recovery). Symptoms may vary from mild to severe, and relapses and remissions may last for days or months. More than 80 percent of people who have MS begin with relapsing-remitting cycles.
- ***Secondary-progressive MS*** (SPMS). SPMS often develops in people who have relapsing-

[92] Huse DM, Schulman K, Orsini L, *et al.* 2005. Burden of illness in Parkinson's disease. *Movement Disorders* 20(11): 1449-54.

[93] *Ibid.*

[94] National Institutes of Health. 2010. US National Library of Medicine. Multiple Sclerosis. Available at: http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001747. Accessed February 15, 2011.

[95] National Multiple Sclerosis Society. 2011. Symptoms of MS. Available at: http://www.nationalmssociety.org/about-multiple-sclerosis/what-we-know-about-ms/symptoms/index.aspx. Accessed January 31, 2011.

[96] Mayo Clinic Staff. 2010. Multiple Sclerosis Risk Factors. Mayo Clinic. Available at: http://www.mayoclinic.com/health/multiple-sclerosis/DS00188/DSECTION=risk-factors. Accessed January 31, 2011.

[97] Alonso A, Hernan M. 2008. Temporal terns in the incidences of multiple sclerosis: a systematic review. *Neurology* 71: 129-135.

[98] Krokki O, Bloigu R, Reunanen M. 2010.Increaseing incidence of Multiple Sclerosis of women in Northern Finland. *Multiple Sclerosis* 17(2):133-8.

[99] Cleveland Clinic. 2007. Multiple Sclerosis Diagnosis. Available at: http://my.clevelandclinic.org/disorders/multiple_sclerosis/hic_how_is_multiple_sclerosis_diagnosed.aspx. Accessed January 31, 2011.

[100] Mayo Clinic. 2011. Multiple Sclerosis. Available at: http://www.mayoclinic.org/multiple-sclerosis/types.html. Accessed January 31, 2011.

remitting MS. In SPMS, relapses and partial recoveries occur, but the disability doesn't fade away between cycles. Instead, it progressively worsens until a steady progression of disability replaces the cycles of attacks.

- ***Primary-progressive MS*** (PPMS). PPMS progresses slowly and steadily from its onset. There are no periods of remission and symptoms generally do not decrease in intensity. About 15 percent of people who have MS have PPMS.
- ***Progressive-relapsing MS*** (PRMS). In this relatively rare type of MS, people experience both steadily worsening symptoms and attacks during periods of remission.

There is no cure for MS and treatment is limited. The available primary treatments modify the disease course and treat exacerbations, attacks and flare-ups. Disease-modifying medications are intended for long term management of the disease through retarding the natural course of MS. They do not directly treat exacerbations. There are currently eight disease-modifying agents on the market approved by the FDA: Avonex, Betaseron, Copaxone, Extavia, Gilenya, Novantrone, Rebif, and Tysabri.[101] Most of these drugs are used to treat relapsing-remitting MS. Not all of these eight drugs are FDA approved to treat each of the four types of MS discussed above.

Corticosteroids are the most common treatment of MS to reduce inflammation that intensifies during a relapse or attack, known as an exacerbation. Several corticosteroids are FDA-approved for treatment of MS exacerbations. Plasmapheresis or plasma exchange is a procedure that mechanically separates blood cells from plasma and is also used to treat MS exacerbations. Plasma exchange is usually limited to cases of severe relapse in patients who are not responding to intravenous steroids and it is not effective for all types of MS.[102]

Progress is being made through the use of stem cell research in reversing the disease's course; however, further randomized trials are needed.[103]

The cost of the treatment can be considerable. Annual prescription drug costs per patient for the disease-modifying agents range from $20,000-$48,000.[104,105]

Routine Patient Care Costs for Clinical Trial Patients

Clinical trials are research studies that allow physicians and scientists to investigate ways to improve the health and care of patients through finding better ways to prevent, diagnose, or treat a disease or condition. A clinical trial is one of the final stages of a long and careful research process to determine whether promising approaches to prevention, diagnosis, and treatment are safe and effective. For cancer, Parkinson's disease and MS patients and their families and physicians, decisions on therapy are largely based on what is known about treatment outcomes for other patients. In general, the most accurate data are derived from the experience of a large group of patients treated in a standard manner, such as those enrolled in clinical trials.

A vast catalog of clinical trials is currently underway; most clinical trials are investigating cancer and by comparison, relatively few are investigating Parkinson's disease and MS. Investigators are researching many

[101] National Multiple Sclerosis Society. 2010. Disease Modifying Drugs Available at: http://www.nationalmssociety.org/about-multiple-sclerosis/what-we-know-about-ms/treatments/download.aspx?id=45. Accessed January 31, 2011.

[102] Cortese I, Chaudhry V, So YT, *et al.* 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(3): 294-300.

[103] Ballantyne C. 2009. Stem cell therapy helps patients with multiple sclerosis, small study shows. Scientific American. Available at: http://www.scientificamerican.com/blog/post.cfm?id=stem-cell-therapy-helps-patients-wi-2009-01-30 . Accessed January 31, 2011.

[104] Personal communication. James O. Donaldson, MD. February 14, 2011.

[105] von Schaper E. 2010. Novartis Gilenya MS pill to cost $48,000 per year. Bloomberg. Available at: http://www.bloomberg.com/news/2010-09-30/novartis-gilenya-ms-pill-to-cost-48-000-a-year-update1-.html. Accessed February 10, 2011.

different types of treatments, drugs, prevention strategies, detection methods, and quality of life of patients in attempts to improve prevention of disease, increase rates of survival, improve treatment methods and reduce side effects of treatment. The United States National Institutes of Health currently documents 17,463 cancer clinical trials in the United States; 1060 in Connecticut.

There are several different types of clinical trials. Treatment trials test new treatments, e.g., a new drug, new approaches to surgery or radiation therapy, new combinations of treatments, or novel methods. Prevention trials test new approaches, such as medicines, vitamins, minerals, or other supplements that may lower the risk of a disease. Screening trials test the best way to detect disease, especially in its early stages. Quality of Life trials (also called Supportive Care trials) explore ways to improve comfort and quality of life for patients.[106]

There are also several different phases of clinical trials. Phase I trials test the maximum tolerated dose and side effects of a new drug. Phase I trials also evaluate the frequency and determine how a new drug should be given (by mouth, injected into the blood, or injected into the muscle). A Phase I trial usually enrolls only a small number of patients with advanced disease. Phase II trials continue to test the safety of the drug, and begin to evaluate how well the new drug works and usually focus on a particular type or subtype of disease (e.g., RRMS or melanoma). Phase III trials test a new drug, a new combination of drugs, or a new surgical procedure in comparison to standard therapy to evaluate response to treatment, survival, and quality of life. Phase III trials often enroll 400-1000 people and may be conducted at many doctors' offices, clinics, and hospitals nationwide. A successful Phase III trial results in submission to the Food and Drug Administration (FDA) for approval. Upon FDA approval, the drug or treatment is made available for commercial use in patients with the specifically tested type of disease (e.g., RRMS or breast cancer). Phase IV trials evaluate the side effects, risks, and benefits of a drug over a longer period of time and involve thousands of people—far more than Phase III trials.

While enrolled in a clinical trial, patients continue to receive the routine health care (such as doctor visits, hospital stays, clinical laboratory tests, x-rays, recommended treatment, drugs, etc.) that they would receive whether or not they were participating in a clinical trial. A common clinical trial design is delivery of the investigational treatment in addition to "standard of care" services; often, the "standard of care" services are included in routine health care costs.[107] Due to their own financial constraints and the high cost of health care and existing treatments, clinical trial sponsors generally do not cover routine patient care costs for trial participants. Insurance coverage of medically necessary routine patient care costs for persons enrolled in cancer, Parkinson's disease, and MS clinical trials may be a factor in the decision to enroll in a clinical trial, which can affect the survival, health outcome, quality of life and recovery time of patients, and affect the progress of medical research on the whole.

Off-label Use of Prescription Drugs

"Off label drug prescription" or off-label use of a drug refers to the use of an FDA-approved drug for a treatment that is not listed on its FDA-approved label. It does not refer to the use of investigational drugs that have not yet received FDA approval.[108] Off-label use may refer to an approved drug that is:

- Used for a different disease or medical condition,
- Given in a different way (such as by a different route), or

[106] National Cancer Institute. Clinical Trials. United States National Institutes of Health. Available at: http://www.cancer.gov/clinicaltrials. Accessed September 23, 2010.

[107] Personal communication. Biree Andemariam, MD. July 14, 2010.

[108] National Cancer Institute. 2004. Understanding the Approval Process for New Cancer Treatments. Available at: http://newscenter.cancer.gov/clinicaltrials/learning/approval-process-for-cancer-drugs/allpages/print#Anchor-Wha-26668. Accessed on January 8, 2011.

– Given in a different dose than on the approved label.[109]

FDA approval is required prior to marketing new drugs. FDA approval is based on the results of clinical trials submitted to the FDA as part of the approval process and is often very narrow in its application. The FDA considers the marketing of an approved drug for unapproved use to be an unapproved new drug with respect to that use [FD&C Act §§ 505(a), 30l(d), 21 U.S.C. 355(a), 33 1(d)], and the marketing of a drug for an unapproved use to be misbranding because the label does not include the new use or adequate directions for the unapproved use.[110]

The drug manufacturer is not required to seek FDA approval for new uses of an approved drug. It simply may not market or recommend the drug for a use for which it is not approved. The FDA does allow manufacturers to provide reprints of articles from peer-reviewed journals supporting an off-label use of an approved drug in some circumstances, provided the manufacturer does not promote the use of its drug for that off-label use.[111]

Regardless, the FDA does not regulate the practice of medicine; once a drug is approved by the FDA as safe and effective, a licensed physician may prescribe it for any purpose for which it is deemed to be medically appropriate.[112]

Drug Compendia

Of the three compendia listed in the proposed health benefit, only the American Society of Hospital Pharmacists' American Hospital Formulary Service Drug Information (AHFS-DI) is still in existence. The U. S. Pharmacopoeia Drug Information Guide for the Health Professional (USP DI) and the American Medical Association's Drug Evaluations (AMA DE) are no longer in use. The content of the U.S. Pharmacopeia was included in DrugPoints, a successor compendium.[113] In 2008 CMS added three new compendia, Clinical Pharmacology, DRUGDEX, and the National Comprehensive Cancer Network Drugs and Biologics Compendium, to its list of approved compendia for Medicare.[114] CMS requires approved compendia to have a publicly transparent process for evaluating therapies and for identifying conflicts of interest. In addition, compendia approved after 2010 must explicitly identify the indications that are not medically accepted as well as the indications that are medically accepted for a particular drug.[115]

Prescription Drugs and Off-label Use for Parkinson's Disease

There are several drugs that are FDA-approved and used for treatment of PD. Under the proposed health benefit, coverage would be required if these drugs were prescribed for use by a person with MS. The off-label use of an FDA-approved drug for Parkinson's disease in the treatment of MS is expected to be a very rare occurrence.[116]

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[109] American Cancer Society. Off-label Drug Use. Available at: http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Chemotherapy/off-label-drug-use. Accessed on January 8, 2011.

[110] U.S. Department of Health and Human Services, Food and Drug Administration. 2009. Good reprint practices for the distribution of medical journal articles and medical or scientific reference publications on unapproved new uses of approved drugs and approved or cleared medical devices. Available at: http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0053-gdl.pdf. Accessed on January 8, 2011.

[111] *Ibid.*

[112] American Cancer Society. Off-label Drug Use. Available at: http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Chemotherapy/off-label-drug-use. Accessed on January 8, 2011.

[113] Abernethy A, Raman G, Balk E, *et al.* 2009. Systematic review: reliability of compendia methods for off-label oncology indications. *Annals of Internal Medicine* 150(5):336.

[114] *Ibid.*

[115] Centers for Medicare and Medicaid. 2008. Thompson Micromedex Drugdex Compendium Revision Request - CAG00391. Available at: http://www.cms.gov/mcd/ncpc_view_document.asp?id=16. Accessed on January 8, 2011.

[116] Personal communication. James Donaldson, MD.

Table 3.1. Commonly Used FDA-approved Drugs for Parkinson's Disease		
Brand name	Class	Generic name/Active ingredient
Sinemet®	Central nervous system agent + Decaroxylase inhibitor	Levodopa Carbidopa
Stalevo®	Central nervous system agent + Decaroxylase inhibitor + catechol-O-methyltransferase (COMT) inhibitor	Levodopa Carbidopa Entacapone
Comtan®	COMT inhibitor	Entacapone
Tasmar®	COMT inhibitor	Tolcapone
Mirapex®	Dopamine agonist	Pramipexole
Requip®	Dopamine agonist	Ropinirole
Azilect®	Monoamine oxidase (MAO) type B inhibitors	Rasagline
Eldepryl®	Monoamine oxidase (MAO) type B inhibitors	Selegiline

The proposed health benefit, as written, does not require coverage for all off-label prescriptions for persons with PD. The off-label use of MS drugs for treatment of Parkinson's disease and the off-label use of Parkinson's disease drugs for treatment of MS is expected to be rare.[117] In contrast, several potential Parkinson's treatments are FDA-approved for treatment of conditions other than MS, for example:[118]

- Abilify (aripiprazole) – Currently in use as an antipsychotic. In phase IV trial for treating psychosis associated with Parkinson's.
- Keppra (levetiracetam) – Currently in use as an antiepileptic. In phase IV clinical trial for treatment of levodopa-induced dyskinesia.
- Zonegran (zonisamide) – Currently in use as an antiepileptic. A phase III study in Japan of its use in Parkinson's found it improved all main Parkinson disease symptoms including tremor and dyskinesias. Approval as a PD treatment is being applied for in Japan.
- Namenda (memantine hydrochloride) - Currently used for moderate to severe Alzheimer's. In phase IV trial for treatment of cognitive impairment and dementia in Parkinson's Disease.
- DynaCirc (isradipine) - Currently prescribed for high blood pressure and stroke. Pre-clinical research with mice found it might offer neuroprotection for dopamine neurons. Currently in a phase I trial to determine safety of higher doses.
- Minocycline – Currently in use as an antibiotic. A phase II futility trial for possible neuroprotective benefits (NET-PD) recommended further study.
- PD-02 (Creatine) – A dietary supplement used by athletes to improve performance. Since it plays a role in mitochondrial energy production, and there is evidence of mitochondrial dysfunction in Parkinson's disease, it is thought creatine might provide neuroprotection. Currently in a phase III trial.

Prescription Drugs and Off-label Use for Multiple Sclerosis

Currently, eight FDA-approved disease modifying agents are available for MS: Avonex, Betaseron,

[117] *Ibid.*

[118] Parkinson Pipeline Project Database. 2007. Questions and answers about "off-label use of prescription drugs. Available at: http://www.pdpipeline.org/database/offlabel_QA.htm. Accessed February 4, 2010.

Copaxone, Extavia, Gilenya, Novantrone, Rebif, and Tysabri.[119] Most of these drugs are used to treat relapsing-remitting MS. Not all of these eight drugs are FDA-approved to treat each of the four types of MS discussed above and some physicians may prescribe these drugs off-label for patients with less common types of MS. Additionally, there are several drugs used to treat symptoms related to MS. Table 3.2[120] lists the drugs on the market that are FDA-approved for treatment of MS and could conceivably be required to be covered for off-label use for persons with Parkinson's disease should the proposed health benefit be enacted.

Table 3.2. Commonly Used FDA-approved Drugs for Multiple Sclerosis

Brand name	FDA-approved use	Year Approved	Generic name/ Active ingredient
Disease Modifying Agents[121]			
Avonex®	Relapsing forms of MS	1996	Interferon beta-1a
Betaseron®	Relapsing forms of MS	1993	Interferon beta-1b
Extavia®	Relapsing forms of MS	2009	Interferon beta-1b
Copaxone®	Relapsing-remitting MS	1996	Glatiramer
Gilenya®	Relapsing forms of MS	2010	Fingolimod
Novantrone®	Worsening relapsing-remitting MS, progressive-relapsing MS or secondary-progressive MS	2000	Mitoxantrone
Rebif®	Relapsing forms of MS	2002	Interferon beta-1a
Tysabri®	Monotherapy[122] for relapsing forms of MS	2006	Natalizumab
Symptoms Related to MS[123]			
Ampyra®	Walking difficulties associated with MS	2010	Dalfampridine
H.P. Acthar Gel®	Acute exacerbations of MS	1952	Adrenocorticotropic Hormone / Corticotropin
Solu-Medrol®	Acute exacerbations of MS	1959	Methylprednisolone
Celestone Soluspan®	Acute exacerbations of MS	1965	Betamethasone
Dexamethasone (generic drug)	Acute exacerbations of MS	various	Dexamethasone
Lioresal®	Spasticity associated with MS	1992	Baclofen

In treating symptoms of MS, physicians may prescribe off-label drugs.[124] Naltrexone was approved by the FDA in 1984 for opiate addiction and in 1995 for alcohol abuse. Studies show that low dose Naltrexone

[119] National Multiple Sclerosis Society. 2010. Disease Modifying Drugs Available at: http://www.nationalmssociety.org/about-multiple-sclerosis/what-we-know-about-ms/treatments/download.aspx?id=45. Accessed January 31, 2011.

[120] There may be other prescription drugs that are FDA-approved for treatment of MS that are not listed.

[121] National Multiple Sclerosis Society. 2010. The MS Disease Modifying Medications. General Information. Available at: http://www.nationalmssociety.org/about-multiple-sclerosis/what-we-know-about-ms/treatments/download.aspx?id=45. Accessed February 10, 2011.

[122] Monotherapy refers to use of drugs not in combination with any other disease-modifying medications.

[123] National Multiple Sclerosis Society. 2010. Medications used in MS. Available at: http://www.nationalmssociety.org/about-multiple-sclerosis/what-we-know-about-ms/treatments/medications/index.aspx. Accessed February 10, 2011.

[124] Multiple Sclerosis Association of America. 2010. MS Symptoms Management. Available at: http://www.msassociation.org/about_multiple_sclerosis/medications/types/symptom.asp. Accessed January 31, 2011.

(LDN) may be an effective treatment for MS. A recent clinical trial found that LDN is a relatively safe therapeutic option in RRMS and SPMS while recommending additional long-term clinical trials.[125] Modafinil (brand name, Provigil), is a FDA-approved drug for the treatment of narcolepsy, obstructive sleep apnea/hypopnea syndrome, and shift-work sleep disorder, but was found to relieve MS fatigue in some studies. A literature review shows that use of modafinil for the treatment of MS-related fatigue has demonstrated benefit in uncontrolled studies but has conflicting results from two controlled studies.[126]

In summary, the proposed health benefit, as written, would not require coverage for all drugs prescribed on an off-label basis; it would require coverage of FDA-approved drugs for MS for persons diagnosed with Parkinson's disease and coverage of FDA-approved drugs for PD for persons diagnosed with MS.

III. Methods

Under the direction of CPHHP, medical librarians at the Lyman Maynard Stowe Library at the University of Connecticut Health Center (UCHC) gathered published articles and other information related to medical, social, economic, and financial aspects of the proposed health benefit. Medical librarians conducted literature searches using PubMed, Scopus, UpToDate, DynaMed, Cochrane Database, EMedicine, Micromedex, and a web search using Google and Bing. Search terms included health knowledge, attitudes, practice; health care costs; health care disparities; health insurance; reimbursement; insurance coverage; cost effectiveness analysis; clinical trials, economics, legislation, jurisprudence; Parkinson's disease; Multiple Sclerosis; biomedical research; demography; research support; insurance benefits; off-label; drug labeling; cancer; neoplasm; social impact.

CPHHP staff conducted independent literature searches using the Cochrane Review, Scopus, and Google Scholar under the search terms of Parkinson's disease; Multiple Sclerosis; clinical trials; routine patient care costs; and off-label prescription drugs. Where available, articles published in peer-reviewed journals are cited to support the analysis. Other sources of information may also be cited in the absence of peer-reviewed journal articles. Content from such sources may or may not be based on scientific evidence.

CPHHP staff consulted with clinical faculty and staff from the University of Connecticut School of Medicine and School of Pharmacy on matters pertaining to medical standards of care; traditional, current and emerging practices; and evidence-based medicine related to the proposed health benefit.

Staff gathered additional information through telephone and e-mail inquiries to appropriate state, federal, municipal, and non-profit entities and from internet sources such as the State of Connecticut website, Centers for Medicare and Medicaid Services (CMS) website, other states' websites, professional organizations' websites, and non-profit and community-based organization websites.

CPHHP requested information related to the proposed increase in coverage from seven insurance companies and MCOs domiciled in Connecticut. Insurers/MCOs provided information about current coverage of services included in the proposed health benefit. The insurers/MCOs were unable to provide claims data for off-label prescriptions or for routine patient care costs associated with Parkinson's disease and Multiple Sclerosis clinical trials for their fully insured group and individual plan participants or for the self-insured plans they administer. Claims paid for routine patient care costs for persons enrolled in clinical trials cannot be isolated and claims paid for off-label prescriptions are indistinguishable from claims paid for drugs

[125] Sharafaddinzadeh N, Moghtaderi A, Kashipazha D, *et al.* 2010. The effect of low-dose naltrexone on quality of life of patients with multiple sclerosis: a randomized placebo-controlled trial. Multiple Sclerosis 16(8): 964-9.

[126] Brown JN, Howard CA, Kemp DW. 2010. Modafinil for the treatment of multiple sclerosis-related fatigue. *The Annals of Pharmacotherapy* 44(6):1098-103. Mohamed N. Hassan, MD, PhD. February 18, 2011.

prescribed as approved by the FDA.

CPHHP and the CID contracted with Ingenix Consulting (IC) to provide actuarial and economic analyses of the proposed health benefit. Further details regarding the insurer/MCO information request and actuarial methods used to estimate the cost of the benefit may be found in Appendix III.

IV. Social Impact

1. The extent to which the services included in the proposed health benefit are utilized by a significant portion of the population.

According to the U.S. National Institutes of Health, 698 clinical trials for MS are underway in the United States; 271 of which are seeking new volunteers. In Connecticut, 47 clinical trials are underway for MS; 12 are seeking new patients. For Parkinson's Disease, 783 clinical trials are underway in the U.S.; 277 are seeking new patients. In Connecticut, 77 clinical trials are underway for Parkinson's Disease; 21 of which are seeking new patients.

An actuarial analysis of existing health insurance mandates in Connecticut estimated that 0.023 percent of all insureds in Connecticut had a diagnosis code for participation in a clinical trial, which would be approximately 320 persons.[127] The diagnosis code includes participation in any clinical trial (not specifically a Parkinson's Disease or multiple sclerosis clinical trial). The vast majority of clinical trials occurring in the United States and in Connecticut are related to cancer; there are ten times as many cancer clinical trials underway in Connecticut as there are for PD and MS combined.[128] For further information, please see Appendix III, Ingenix Consulting Actuarial Report, page 18.

Off-label drug use is well-documented in the medical literature and very common in certain settings, such as oncology, pediatrics, and HIV/AIDS care. The extent to which off-label drug use of Parkinson's disease drugs for treatment of MS and vice versa occurs is unknown. Due to the low prevalence of Parkinson's disease and MS in the fully-insured group and individual policy population, utilization of off-label prescription drugs as defined in the bill is expected to be low.

2. The extent to which the services included in the proposed health benefit 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.

Medicare

Routine patient care costs—In 2000, Medicare policy changed to include coverage of routine patient care costs of clinical trials.[129] Medicare pays for routine health care costs for beneficiaries enrolled in most treatment clinical trials that are funded by federal agencies, including office visits, tests, hospital stays, surgery, tests and treatments for side effects.[130] Medicare does not pay for some clinical trial treatments, tests that collect information only for the trial, and coinsurance and deductibles.[131] The trial must evaluate

[127] University of Connecticut Center for Public Health and Health Policy. 2011. Connecticut Mandated Insurance Benefits Reviews, 2010, Volume IV. Available at: http://www.ct.gov/cid/cwp/view.asp?a=1254&q=447304. Accessed February 10, 2011.

[128] National Cancer Institute. 2010. Studies related to cancer in the United States. United States National Institutes of Health. Available at: http://clinicaltrials.gov/ct2/results?term=Cancer&cntry1=NA%3AUS. Accessed September 22, 2010.

[129] Unger JM, Coltman CA, Crowley JJ, *et al.* 2006. Impact of the year 2000 Medicare policy change on older patient enrollment to cancer clinical trials. *Journal of Clinical Oncology* 24(1): 141-4.

[130] U.S. Department of Health Aid and Human Services. 2001. Medicare and Clinical Trials. Available at: http://www.medicare.gov/Publications/Pubs/pdf/ct.pdf. Accessed January 21, 2010.

[131] National Cancer Institute. 2009. Clinical trials and insurance coverage. National Institutes of Health.

an item or service that falls within a Medicare benefit category and must be designed to treat or diagnose a disease. No information was found specifically regarding routine patient care costs associated with clinical trials for Parkinson's Disease or multiple sclerosis.

Medicare generally covers routine patient care costs of clinical trials funded by one of the following federal agencies:

- National Institutes of Health (NIH)
- Centers for Disease Control and Prevention (CDC)
- Agency for Healthcare Research and Quality (AHRQ),
- Health Care Financing Administration (HCFA)
- Department of Defense (DOD)
- Department of Veterans Affairs (VA).[132]

Off-label drug prescriptions—Part B: Prior to 1993, Medicare and many commercial insurers did not pay for drugs prescribed off-label, deeming such use to be experimental or investigational. In 1993, Congress directed CMS to pay for drugs and biologics for off-label uses if they were included in the same compendia that are listed in the Connecticut law or were supported by clinical evidence in peer-reviewed medical literature appearing in publications which have been identified for this purpose by the Secretary.[133] It also empowered the Secretary of Health and Human Services to revise the list of compendia provided the included compendia have a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.

Part D: Medicare contractors are required to provide coverage for accepted off-label uses published in the recognized compendia. However, they have discretion over coverage of off-label uses that are only referenced in peer-reviewed literature.[134] To receive coverage for an off-label drug, the beneficiary or provider must submit evidence in support of the prescribed use to the drug plan.[135]

Public Programs Administered by Charities

The National MS Society does not offer health care insurance, and does not have the means to provide all the people who need it with financial assistance. Some financial assistance is available to those who qualify. The MS Society also answers financial and insurance questions from the public and funds research on the causes of MS and its potential prevention and treatment.[136]

The National Parkinson's Foundation does not provide direct financial assistance, but does help individuals with Parkinson's Disease with financial planning and with strategies for coping with the disease.[137]

Available at: http://www.cancer.gov/clinicaltrials/education/insurance-coverage/page3. Accessed February 7, 2011.

[132] *Ibid.*

[133] Social Security Administration. Compilation of Social Security Laws. Part E – Miscellaneous Provisions, Definitions. 42USC sec 1861(t)(2). Available at: http://www.ssa.gov/OP_Home/ssact/title18/1861.htm. Accessed on January 8, 2011.

[134] Centers for Medicaid and Medicare Services: 2010. Medicare Benefit Policy Manual; Chapter 15 Covered medical and other health services. Sec. 50.4.5 Off-label use of drugs and biologicals in anticancer chemotherapeutic regimen. Available at: http://www.cms.gov/manuals/Downloads/bp102c15.pdf. Accessed on January 10, 2011.

[135] Center for Medicare Advocacy, Medicare Coverage for Off-label Drug Use. Available at: https://www.medicareadvocacy.org/InfoByTopic/PartDandPrescDrugs/10_09.16.OffLabelDrugCoverage.htm. Accessed February 24, 2010.

[136] National MS Society. 2010. "Financial Assistance". Available at: http://www.nationalmssociety.org/chapters/ctn/programs--services/services/financial-assistance-program/index.aspx. Accessed February 7, 2011.

[137] National Parkinson Foundation. 2010. About Us. Available at: http://www.parkinson.org/About-Us/Contact-Us/helpline.aspx. Accessed February 7, 2011.

The Parkinson's and MS charities may also help with transportation and lodging, which are particularly important needs for clinical trials participants and their families. Clinical trials participants often must travel long distances to participate in a specific clinical trial during treatment and for follow-up, thus financial assistance for travel and lodging for patients and their families can offset significant financial burdens not covered by health insurance or the clinical trial sponsor.

The Partnership for Prescription Assistance (PPA) program is organized by drug companies, health care providers, patient advocacy organizations, and community groups. PPA helps people who lack prescription coverage find assistance programs. There are over 475 public and private patient assistance programs, including more than 200 programs offered by drug companies.[138] For eligible patients, PPA programs may be available that provide off-label prescription drugs for persons with MS.

Public Programs Administered by Public Schools

No information was found that would indicate Connecticut public schools provide services related to the proposed health benefit. While some schools may provide the types of routine health care services covered by the mandate for students, it is unlikely provision of such care occurs for students in clinical trials.

The Department of Public Health (DPH)

No information was found that would indicate the Connecticut Department of Public Health provides or funds routine patient care costs associated with clinical trials or off-label drug prescriptions for persons with Parkinson's disease or multiple sclerosis as defined in the bill. A search of the DPH website found no references to Parkinson's disease or multiple sclerosis.

Municipal Health Departments

No information was found that would indicate Connecticut municipal health departments or health districts provide or fund services related to the proposed health benefit.

The Department of Social Services (DSS)

Medicaid covers medical services based on medical necessity, thus it is expected that routine patient care costs associated with multiple sclerosis and Parkinson's disease clinical trials would be covered.

No information was found related to Medicaid off-label drug prescription coverage for persons with Parkinson's disease or multiple sclerosis specifically as defined in the bill. The Social Security Act provides for coverage of off-label drugs in title 19, section 1927(g)(1)(b)(i) and (k)(6). It allows such drugs to be subject to prior authorization and to be excluded from formularies by the states if the excluded drug does not have a clinical advantage over other drugs which are included in the formulary (section 1927(d) and if coverage can be requested under prior authorization.

3. The extent to which insurance coverage is already available for services included in the proposed health benefit.

The extent to which insurance coverage for the services included in the proposed health benefit is already available is not precisely known because utilization of these services is not easily identified in insurer/MCO data systems. In general, coverage of routine patient care costs associated with clinical trials is a common practice; it is assumed to occur in clinical trials for PD and MS. Not all health insurance plans include pharmacy benefits. Off-label prescription drug use is a common medical practice, however no information specific to off-label prescription drug coverage for Parkinson's disease and multiple sclerosis as limited in the

[138] American Cancer Society. 2010. Prescription Drug Assistance Programs. Available at: http://www.cancer.org/Treatment/FindingandPayingforTreatment/ManagingInsuranceIssues/PrescriptionDrugAssistancePrograms/prescription-drug-assistance-programs-if-you-need-financial-help. Accessed January 10, 2011.

proposed bill was found and medical experts assert that there is no clear rationale for use of PD-approved drugs in treatment of MS or for use of MS-approved drugs in treatment of PD.[139]

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.

Lack of coverage for routine patient care costs for persons enrolled in Parkinson's disease and MS clinical trials or for off-label drug prescriptions would not necessarily result in persons being unable to obtain necessary health care treatment. Coverage of standard of care treatment services for Parkinson's disease and MS is expected to be included in most fully insured group plans and individual health insurance policies. Lack of coverage for off-label prescriptions and routine patient care costs associated with clinical trials may limit access to the full range of desired health care treatment options for some persons with Parkinson's disease or MS who are interested in enrolling in clinical trials or utilizing certain prescriptions not approved for the disease or condition that afflicts them.

The uninsured and underinsured represent the largest population groups in Connecticut that may be unable to obtain necessary health care treatment. While Connecticut residents who are uninsured and underinsured may obtain treatment through the health care safety net or from providers on a no- or low- cost basis, they may be more likely receive a delayed diagnosis and require more intensive treatment because the disease may have progressed further than for an individual with health insurance coverage.

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.

There is a range of costs for routine patient care costs associated with Parkinson's disease and Multiple Sclerosis clinical trials; several factors contribute such as the type of clinical trial, type and severity of potential side effects of treatment and location of facility. Prescription drugs can be high cost medical expenses in general; prescription drugs for treatment of MS are generally high cost; $20,000-$40,000 per year.[140] The retail cost of a recently approved brand-name drug for treatment of MS is reported to be $48,000 annually.[141] Financial hardships may be experienced due to routine patient care costs or prescription drugs for those without insurance coverage for the proposed health benefits.

Depending on the severity of disease and progression at time of diagnosis, a diagnosis of Parkinson's disease or Multiple Sclerosis often results in significant health and economic costs for the individual and their family, even for those with comprehensive health benefits. In such cases, lost work time and income are common, as well as other costs associated with treatment (e.g., travel) that are not covered by health insurance.

In clinical trials, the costs of the treatment under investigation do not generally result in financial hardships for the patient or their families because investigational treatments are provided free-of-charge by the sponsoring organization or with minimal cost to the participant/patient.

6. The level of public demand and the level of demand from providers for services included in the proposed health benefit.

Routine patient care costs of clinical trials—Because clinical trials may provide patients with debilitating diseases/conditions unique opportunities for finding effective treatment, it is expected that the proposed

[139] Personal communication. James Donaldson, MD; and Mohamed N. Hassan, MD, PhD. February 18, 2011.

[140] Personal communication. James Donaldson, MD.

[141] von Schaper E. 2010. Novartis Gilenya MS pill to cost $48,000 per year. Bloomberg. Available at: http://www.bloomberg.com/news/2010-09-30/novartis-gilenya-ms-pill-to-cost-48-000-a-year-update1-.html. Accessed February 10, 2011.

benefit might enjoy broad public and provider support. However, public demand is tempered due to lack of awareness of the availability of clinical trials and widespread misconceptions about clinical trials among lay persons (e.g., fear of getting a placebo instead of actual treatment, being a "guinea pig").[142] Provider demand, while assumed to be generally strong due to the scientific background of health care practitioners, may be moderated due to structural barriers in the way the practice of medicine is organized, such as lack of time, staff, or funding to enroll patients and lack of strong connections with research institutions where clinical trials occur.

Off-label drug prescriptions—For cancer, approximately half of anti-cancer chemotherapy drugs are prescribed off-label according to the American Society of Clinical Oncology.[143] The percentage of off-label use of FDA-approved prescription drugs for MS and Parkinson's disease is unknown. It is estimated that some public and provider demand for coverage of off-label prescriptions for MS and Parkinson's disease is likely as evidenced by widespread use of the practice in general; no specific studies or information about public and provider demand for use of FDA-approved MS drugs for treatment of Parkinson's disease or for use of FDA-approved PD drugs for treatment of MS were found.

7. The level of public demand and the level of demand from providers for insurance coverage for the services included in the proposed health benefit.

Medicare policy changed in 2000 to include coverage of routine patient care costs associated with clinical trials. It is likely that public and provider demand for Medicare coverage for the benefit contributed to the change in policy. For off-label prescriptions for Parkinson's disease and MS, no information published in peer-reviewed literature was found that would indicate the level of public or provider demand for insurance coverage of the services. For cancer, at least one professional organization advocates for third-party payers to be required to cover off-label indications for anti-cancer drugs if such indications are listed in the compendia or supported in peer-reviewed medical literature.[144]

Several members of the public and providers testified in favor of insurance coverage for the proposed health benefits during the time the bill was under consideration by the Connecticut General Assembly.[145]

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

Routine patient care costs for clinical trials—No information was found regarding other states' coverage of routine patient care costs related specifically to multiple sclerosis and Parkinson's disease clinical trials. Different organizations report divergent numbers of states with required coverage of routine patient care costs related to clinical trials as follows:

The National Cancer Institute (NCI) reports that Washington DC and 25 states including Connecticut require coverage for patient care costs for patients enrolled in cancer clinical trials only.[146] The NCI also reports eight states with required coverage for patient care costs for patients in clinical trials for cancer or for

[142] National Parkinson's disease and Multiple Sclerosis Institute. 2005. Doctors, patients face different barriers to clinical trials. U.S. National Institutes of Health. Available at: http://www.Parkinson's disease and Multiple Sclerosis.gov/clinicaltrials/developments/doctors-barriers0401. Accessed September 27, 2010.

[143] American Society of Clinical Oncology. 2006. Reimbursement for cancer treatment: coverage of off-label drug indications. *Journal of Clinical Oncology* 24:3206-3208.

[144] American Society of Clinical Oncology. ASCO's position. Available at: http://www.asco.org/ASCOv2/Public+Policy/Policy+Issues/Off-Label+Drug+Indications/ASCO's+Position. Accessed on January 8, 2011.

[145] Connecticut General Assembly. Joint Favorable Report. An Act Concerning Health Insurance Coverage for Routine Patient Care Costs for Clinical Trial Patients. Insurance and Real Estate Committee. SB-260. March 16, 2010.

[146] U.S. National Institutes of Health. National Cancer Institute. States That Require Health Plans to Cover Patient Care Costs in Clinical Trials. Available at: http://www.cancer.gov/clinicaltrials/education/laws. Accessed December 1, 2010.

other life-threatening conditions. It is assumed that routine patient care costs in clinical trials for Parkinson's disease and MS contemplated by the bill under review would be covered in these eight states. The states that do not limit mandated coverage of patient care costs to cancer clinical trials include Colorado, Maine, Maryland, New Hampshire, North Carolina, Oregon, Texas, and West Virginia. Specifically, in Colorado, patient care costs are covered for clinical trials for patients with a disabling, progressive, or life-threatening condition. Maine's statute for patient care costs in clinical trials requires coverage for a life-threatening or serious illness for which no standard treatment is effective. Maryland requires coverage of patient care costs for phase II, III, and IV clinical trials for life threatening conditions for which there are no clearly superior non-investigational alternative. New Hampshire requires coverage for cancer or other life-threatening conditions. North Carolina requires coverage for patients with a life-threatening condition in a Phase II, III, or IV clinical trial. Oregon requires coverage of routine patient care costs in all clinical trials. Texas requires coverage for clinical trials conducted to prevent, detect, or treat a life-threatening condition. West Virginia requires coverage for clinical trials for cancer or treatment of any other life-threatening condition.

The National Association of Insurance Commissioners lists eight states, including Connecticut, that require coverage of routine patient care costs for persons enrolled in clinical trials; however, only two states, New Hampshire and West Virginia do not limit coverage to cancer clinical trials.[147]

The Council for Affordable Health Insurance lists 28 states with insurance mandates for "Clinical Trial(Cancer)" but does not provide information about clinical trials for any other specific diseases/ conditions or types of services that must be covered.[148]

Off-label prescriptions—The National Association of Insurance Commissioners lists 33 states that mandate insurance coverage for off-label prescription drugs.[149] Seventeen states (including Connecticut) limit the mandated service to cancer treatments. Three states with mandates for cancer treatments also have mandates for off-label drugs for HIV/AIDS. Sixteen states have insurance mandates for off-label prescriptions that are not tied to specific diseases or conditions. It is assumed that off-label prescribing for Parkinson's disease and MS contemplated by the bill under review would be covered in these states. Most states require that the drug be recognized for the use for which it is prescribed by at least one standard medical reference compendia or a medically recognized peer-reviewed journal. Only Connecticut and Nevada specify the compendia to be used. Please see Table 3.3 for further details.

Table 3.3 States with Statutes for Off-label Prescriptions Not Tied to Specific Diseases or Conditions

Alabama	Insurance policy may not exclude coverage on the grounds that the drug is being used for other purposes than approved by the FDA if the drug treatment is recognized in at least one standard reference compendium.
California	Shall not limit or exclude prescription coverage because a drug is prescribed for a different use than approved by the FDA if it meets one of the following conditions: 1) the drug is prescribed for a life threatening condition, 2) the drug is medically necessary to treat a chronic and seriously debilitating condition and the drug is on the insurer's formulary, or 3) the drug usage is recognized by one of the listed standard medical reference compendia.

[147] NAIC Compendium of State Laws on Insurance Topics. National Association of Insurance Commissioners. August 2008.

[148] Craig Bunce V, Wieske JP. 2010. Health insurance mandates in the states 2010. Council for Affordable Health Insurance. Available at: http://www.cahi.org/cahi_contents/resources/pdf/MandatesintheStates2010.pdf. Accessed February 10, 2011.

[149] NAIC Compendium of State Laws on Insurance Topics. National Association of Insurance Commissioners. August 2008.

Table 3.3 States with Statutes for Off-label Prescriptions Not Tied to Specific Diseases or Conditions	
Georgia	Shall not limit or exclude prescription coverage because a drug is prescribed for a different use than approved by the FDA, if it meets one of the following conditions: 1) the drug is prescribed for a life threatening condition, 2) the drug is medically necessary to treat the condition and the drug is on the insurer's formulary, or 3) the drug usage is recognized by one of the listed standard medical reference compendia.
Indiana	Insurance policy that includes prescription coverage may not exclude coverage on the grounds that the drug is being used for other purposes than approved by the FDA if the drug treatment is recognized in at least one standard reference compendium or the use is found to be safe and effective in formal clinical studies and the results are published in a peer-reviewed medical journal
Maryland	A policy or contract that provides coverage for prescription drugs may not exclude coverage of a drug for an off-label use of the drug if the drug is recognized for treatment in any of the standard reference compendia or in the medical literature.
Michigan	If provide coverage for prescription drugs, shall provide coverage for off-label use of a federal FDA approved drug when the drug is prescribed for a life threatening condition or a chronic and seriously debilitating condition, if the use is recognized in one of the listed sources.
New Hampshire	If provide coverage for prescription drugs, shall not exclude drug for other indication than approved by FDA if recommended in medical literature.
New Jersey	If provide coverage for prescription drugs, shall provide benefits for expenses incurred in prescribing drugs for treatment for which they have not been approved by the FDA, if the drug is recognized as being medically appropriate for the specific treatment in a listed reference compendia. Off-label drug use is legal when prescribed in a medically appropriate way.
North Dakota	Contracts that cover prescription drugs shall provide benefits for expenses incurred in prescribing drugs for treatment for which they have not been approved by the FDA if the drug is recognized as being medically appropriate for the specific treatment in listed reference compendia.
Ohio	No policy that provides coverage for prescription drugs shall limit or exclude coverage for any drug approved by the FDA on the basis that the drug has not been approved by the United States food and drug administration for the treatment of the particular indication for which the drug has been prescribed, provided the drug has been recognized as safe and effective for treatment of that indication in one or more of the standard medical reference compendia listed.
Oregon	No policy or contract providing coverage for a prescription drugs shall exclude coverage of that drug for a particular indication solely on the grounds that the indication has not been approved by the FDA if the Health Resources Commission determines that the drug is recognized as effective for the treatment of that indication.
South Dakota	If cover prescription drugs shall cover drugs used to treat cancer or other life threatening illness even if they have not been approved by the FDA for that indication if the drug is recognized in medical literature or one of the standard reference compendia.

Table 3.3 States with Statutes for Off-label Prescriptions Not Tied to Specific Diseases or Conditions	
Tennessee	If cover prescription drugs, shall cover off-label drug use when it is prescribed in a medically appropriate way, and medical literature or standard reference compendia recognize the use.
Texas	If cover prescription drugs, shall cover off-label drugs used to treat a patient for a covered chronic, disabling or life-threatening illness if recognized for treatment of the illness in a reference compendium or peer-received literature.
Virginia	If cover prescription drugs, may not exclude coverage on the grounds that the drug is being used for other purposes than approved by the FDA if the drug treatment is recognized in at least one standard reference compendium.
Washington	May not exclude coverage on the grounds that the drug is being used for other purposes than approved by the FDA if the drug treatment is recognized in at least one standard reference compendium.

The Council for Affordable Health Insurance lists 36 states with insurance mandates for "Off Label Drug Use" but does not provide information about specific diseases/conditions required to be covered.[150]

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

CPHHP staff found no studies from state agencies and public organizations related to the social impact of the services included in the proposed health benefit. Several states have reviewed existing mandates or proposed health benefits related to clinical trials or off-label drug prescriptions related to cancer or in general; however, no reports reviewed the benefits in relation to MS or Parkinson's disease.

Records searched included those of states that have or had an established process for studying mandated health insurance benefits, with a relatively large number of mandated health benefits, or located in the Northeast. States searched included Arkansas, California, Colorado, Indiana, Louisiana, Maine, Maryland, Massachusetts, Minnesota, New Jersey, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Texas, Virginia, Washington, and Wisconsin.

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

Routine patient care costs for clinical trials—The proposed benefit covers routine health care costs which include a wide range of treatments, procedures, drugs, tests and imaging. In light of a comprehensive and undefined set of services included in the mandated benefit, identification and review of all potential alternatives is not attempted.

Off-label prescriptions—Off-label prescriptions are themselves considered an alternative treatment, thus the alternatives may be standard of care treatments (primarily drugs that are FDA-approved for treatment of MS and Parkinson's disease) that are ineffective for or not tolerated by a particular patient. Cancer drugs are prescribed off label because effective treatment options for cancer are often limited, prognoses are often grim,

[150] Craig Bunce V, Wieske JP. 2010.

and submission of FDA applications for every combination of agent and cancer is impractical.[151] The same is generally true for off-label prescriptions for MS and Parkinson's disease.

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.

Coverage for routine patient care costs associated with Parkinson's disease and multiple sclerosis clinical trials fulfills a medical need that might not otherwise be met. Currently approved treatment options and disease management strategies for Parkinson's disease and multiple sclerosis are not always successful or may produce intolerable side effects. Parkinson's disease and multiple sclerosis clinical trials attempt to identify treatments and disease management methods that are more effective than those currently available while giving persons with advanced Parkinson's disease and multiple sclerosis treatment opportunities that they would otherwise not be able to access. Required insurance coverage for routine patient care costs associated with Parkinson's disease and multiple sclerosis clinical trials may also serve broad social needs because it may allow the sponsors of clinical trials to reach a larger population of subjects. As such, progress towards more effective Parkinson's disease and multiple sclerosis treatments with fewer side effects are facilitated, contributing to the public good.

The use of off-label prescription drugs is a medical treatment and meets medical needs.

As medical needs, coverage of routine patient care costs associated with Parkinson's disease and MS clinical trials and the off-label use of prescriptions are consistent with the role of health insurance and the concept of managed care. One of the roles of health insurance is to provide coverage in the case of serious illness or disease. Parkinson's disease and MS are serious, debilitating diseases. The proposed health benefit is further consistent with the concept of managed care in that the bill includes clauses that allow managed care practices to be implemented in provision of coverage, including subjecting routine patient care costs to the terms conditions, restrictions, exclusions and limitations of the contract or certificate of insurance, including, for example, medical necessity of health care services and limitations on out-of-network care. Prior authorization is a frequently employed managed care tool for costly services, such as some prescription drugs. The proposed benefit does not disallow the use of prior authorization in off-label prescriptions for Parkinson's disease and MS.

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.

Clinical trials are one of the primary methods of medical research that involve human subjects. Thus, it is possible that the basic structure of the proposed health benefit (i.e., required coverage for routine health care costs for clinical trials enrollees) could be replicated for non-Parkinson's disease and non-MS clinical trials (e.g., clinical trials related to mental health, diabetes, or heart disease.) If denials of insurance coverage for routine patient care costs for patients participating in non-Parkinson's disease and non-MS clinical trials commonly occur or restrict access to care for a particular constituency, it is possible that mandated coverage could be proposed where currently it does not exist.

By the same token, this proposed health benefit may have implications for off-label drugs prescribed for other medical conditions.

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

Insurers and MCOs may cut costs by eliminating or restricting access to, or placing limits on other non-

[151] Abernethy AP, Raman G, Balk EM, *et al.* 2009. Systematic review: reliability of compendia methods for off-label oncology indications. *Annals of Internal Medicine* 150(5): 336-43.

mandated benefits currently offered. However, the availability of any benefit to be restricted may be limited. Existing benefits may be administratively costly to restrict and insurers may be contractually obligated to provide them. Additionally, many of the benefits that could be targets for elimination are included in plans for competitive advantage.

In general, FDA-approved drugs for treatment of MS are substantially more expensive in comparison to FDA-approved drugs for treatment of Parkinson's disease. Although no evidence of widespread use of off-label use of MS-approved drugs for treatment of Parkinson's disease was found, should the practice become more widely utilized, some effect on the availability of other benefits currently offered is conceivable. In contrast, FDA-approved drugs for treatment of Parkinson's disease are generally less expensive, thus the impact of the availability and utilization of such drugs by persons with MS would be expected to have less effect on benefits currently offered, particularly if the PD drugs were used as substitutes for the more expensive MS drugs.

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.

Due to the low number of persons in the fully-insured population with Parkinson's disease and MS and the even lower number of persons participating in Parkinson's disease and MS clinical trials, it is not anticipated that employers would shift to self-funded plans as a result of this health benefit in isolation. Current use of FDA-approved MS drugs for treatment of Parkinson's disease and vice versa is expected to be very low, and the proposed coverage would only apply for plans that provide coverage for prescribed drugs.

There are several reasons for health insurance premium increases, including medical cost inflation, an aging population and an aging workforce, and required benefits or "mandates." Employers contemplating a shift to self-funded plans are likely to weigh these and other factors. Employers also may shift to plans with higher coinsurance amounts to keep premiums at a more affordable level ("benefit buy down"). Benefit buy down can result in employees not taking up coverage and thus being uninsured or not accessing care when it is needed because of high deductibles.

Current coverage of the proposed health benefit in self-funded plans in Connecticut is unknown. A Maryland analysis of existing mandated benefits conducted in 2008 found that "significantly more than half but not all employers with self-funded plans provide benefits" that covered patient costs for clinical trials and "half" of employers with self-funded plans provide benefits for off-label prescriptions.[152] If coverage for the mandated benefit in self-funded plans in Connecticut is similar to that in Maryland, it is likely that the proposed health benefit, if enacted, would have little direct effect on employers shifting to self-funded plans.

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

As a self-funded entity, the state employee health insurance or health benefits plan is exempt from state health insurance mandates under the federal Employee Retirement Income Security Act (ERISA). If the state voluntarily provided the services included in the proposed health benefit under review, the social impact of the benefit for the approximately 134,344 covered lives in state employee plans and 30,000 state retirees not enrolled in Medicare[153] 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.

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[152] Maryland Health Care Commission. 2008. Study of Mandated Health Insurance Services: A Comparative Evaluation. Available at: http://mhcc.maryland.gov/health_insurance/mandated_1207.pdf. Accessed December 1, 2010.

[153] Personal communication. Scott Anderson, State of Connecticut Comptroller's Office. September 14, 2010.

The actuarial analysis estimates the costs of the services included in the proposed health benefits would be *de minimis* in the fully-insured population. In terms of financial impact to the state employee health insurance or health benefits plan, it is expected that the costs would also be *de minimis*.

16. The extent to which credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community determines that the services included in the proposed health benefit are safe and effective.

Routine patient care costs for clinical trials—The proposed health benefit covers routine health care costs which include a wide range of treatments, procedures, drugs, tests and imaging. In light of a comprehensive and necessarily undefined set of services included in the mandated benefit, review of the safety and effectiveness of the services included is not attempted.

Off-label prescriptions—The safety and effectiveness of prescription drugs must be proven for the diseases/conditions for which they are FDA approved to treat. Review of the safety and effectiveness of all FDA-approved drugs for Parkinson's disease and MS and their off-label uses is beyond the scope of this analysis. There are many benefits as well as many risks associated with prescription drug use; drugs approved for Parkinson's disease and MS are not exempt from these concerns, particularly when off-label use is employed. Cancer drugs are prescribed off label because FDA-approved treatment options for a specific type of tumor or stage of cancer may be limited or have been attempted and proven ineffective and prognoses may be grim. The same is generally true for off-label prescriptions for MS and Parkinson's disease.

The widespread and accepted practice of off-label prescribing in medicine is well-documented in the literature. The use of drug compendia is an effective mechanism for ensuring that patients have access to the safest and most effective drugs or drugs that produce fewer side effects when evidence becomes available to support specific off-label uses.[154]

One of the primary safety issues concerning off-label prescriptions is related to the drug label. One of the most reliable and easy-to-find sources of information on drugs is the drug label, but drug labels do not contain information regarding off-label use of the drug. Lack of information on off-label drug use and outcomes may put patients at a higher risk for medication errors, side effects, and unwanted drug reactions or interactions with other drugs.[155]

A reason to attempt to restrict or control widespread off-label use of approved drugs is that it may remove the financial incentive for pharmaceutical manufacturers to conduct clinical trials that would establish the efficacy and effectiveness of the drug for those off-label uses.[156]

The proposed health benefit excludes coverage of experimental or investigational drugs that are not FDA-approved; an important consideration related to safety and effectiveness.

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[154] Abernethy AP, Raman G, Balk EM, *et al.* 2009. Systematic review: reliability of compendia methods for off-label oncology indications. *Annals of Internal Medicine* 150(5): 336-43

[155] American Cancer Society. 2010. Off-label drug use: what problems are caused by off-label drug use? Available at: http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Chemotherapy/off-label-drug-use. Accessed on January 10, 2011.

[156] Ratner M, Gura T. 2008. Off-label or off-limits? *Nature Biotechnology* 26(8);871.

IV. Financial Impact

1. The extent to which the mandated health benefit may increase or decrease the cost of services included in the proposed health benefit over the next five years.

Routine patient care costs for clinical trials—For MS and Parkinson's disease clinical trials, University of Connecticut Health Center (UCHC) medical librarians and CPHHP researchers identified no studies related to increasing or decreasing costs of routine patient care costs. For cancer, UCHC medical librarians identified a study of the incremental treatments costs in cancer clinical trials. The study found that over a 2.5-year period, direct care costs were 6.5 percent higher for trial participants than nonparticipants.[157] The study found that incremental costs were higher for patients who died and who were in early phase studies and concluded that the additional treatment costs for government-sponsored cancer clinical trials appear minimal.[158] It is possible that similar financial impact is experienced in MS and Parkinson's disease clinical trials.

Off label prescriptions—Because off-label prescribing of FDA-approved MS drugs for treating Parkinson's disease patients and vice versa is expected to occur very rarely, the proposed health benefit is expected to have little to no impact on the cost of treatment.

2. The extent to which the mandated health benefit may increase the appropriate or inappropriate use of services included in the proposed health benefit over the next five years.

Routine patient care costs for clinical trials—For those persons whose insurance plans would not otherwise cover routine patient care costs associated with Parkinson's disease or multiple sclerosis clinical trials, the proposed health benefit may increase participation in such trials and appropriate use of the service. For those who are covered by self-funded plans, who use out-of-pocket funds, or who receive routine patient care costs associated with Parkinson's disease and Multiple Sclerosis clinical trials from other sources, a mandated benefit may not increase participation or appropriate use.

Inappropriate use is not expected to occur, due to the specific and restricted nature of the development of and highly restricted enrollment procedures for clinical trials. Additionally, the legislation requiring the coverage references eligibility guidelines for Parkinson's disease and multiple sclerosis clinical trials.

Off label prescriptions—If the off-label use of MS drugs for treatment of Parkinson's disease and vice versa are considered appropriate treatments, then the proposed health benefit could be expected to increase appropriate use of such drugs. However, professional opinion lends little support to the appropriateness of these approaches and a dearth of literature was found on the topic.

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.

Routine patient care costs for clinical trials—The proposed health benefit covers routine health care costs which include a wide range of treatments, procedures, drugs, tests and imaging. In light of a comprehensive and undefined set of services included in the mandated benefit, it is not possible to identify and review all applicable alternatives and whether such alternatives might be more or less expensive.

Off label prescriptions—Prescription drugs used to treat MS are generally more costly than many other prescription drugs, thus if levels of MS drug utilization increased through increases in utilization by persons

[157] Goldman DP, Berry SH, McCabe MS, *et al.* 2003. Incremental treatment costs in national cancer institute-sponsored clinical trials. *Journal of the American Medical Association* 289(22): 2970-7.

[158] *Ibid.*

with Parkinson's disease, the mandated benefit would be expected to increase costs of their treatment. Professional opinion suggests that the widespread use of MS drugs for persons with Parkinson's disease would be highly unlikely due to the lack of clinical effectiveness and absence of quality of life benefit of use of MS drugs by persons with Parkinson's disease.[159] FDA-approved drugs for Parkinson's disease are generally far less expensive than FDA-approved drugs for MS, therefore little effect on costs of treatment would be anticipated through their off-label use. As is the case for off-label use of MS approved drugs among patients with Parkinson's disease, there appears to be no evidence of any clinical effectiveness or quality of life improvements through off-label use of Parkinson's disease approved drugs among persons with MS.

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

It is anticipated that insurers and MCOs would employ the same utilization management methods and cost controls that are implemented for other covered benefits as appropriate for the services included in the proposed health benefit. The legislation does not prohibit insurers and MCOs from employing utilization management, prior authorization, or other utilization tools at their discretion. The legislation also defines eligibility guidelines for Parkinson's disease and Multiple Sclerosis clinical trials and "routine patient care costs." Utilization and cost impact is limited due to the low prevalence of the diseases in the population and the small number of beneficiaries enrolled in Parkinson's disease and Multiple Sclerosis clinical trials.

5. The extent to which insurance coverage for the services included in the proposed health benefit may be reasonably expected to increase or decrease the insurance premiums and administrative expenses for policyholders.

The design of many clinical research trials is to provide an additional treatment or drug in addition to the standard recommended treatment for the patient's disease or condition. In effect, the "routine patient care costs" for trial participants is the standard recommended treatment. The cost of such "routine" treatment is not insignificant; Parkinson's disease and particularly multiple sclerosis are high cost diseases to treat and for which to provide continuity of care. Connecticut does not require health insurance coverage for Parkinson's disease and Multiple Sclerosis treatment, however, it is expected that such coverage is included in the vast majority of policies issued in Connecticut, thus it is not anticipated that required coverage of routine patient care costs associated with Parkinson's disease and Multiple Sclerosis clinical trials would have a significant effect on health insurance premiums and administrative expenses for policyholders.

The off-label prescribing portion of the proposed health benefit is limited to coverage for FDA-approved drugs for a limited set of diseases prescribed by a licensed health care provider for the treatment of MS and Parkinson's disease. It is also limited as to the circumstances under which it may be prescribed: it must be recognized as appropriate for treatment of MS or Parkinson's disease in one of three named reference compendia (two of which no longer exist).

Actuarial analysis found a very low prevalence of Parkinson's disease and MS in the Connecticut population; a small number of enrollees in Parkinson's disease and multiple sclerosis clinical trials in Connecticut; and low expected frequency of off-label prescribing for Parkinson's disease and MS as limited by the language included in the bill. The actuarial report estimated the costs of services included in the proposed health benefit to be *de minimis*. For further discussion, please see Appendix III: Ingenix Consulting Actuarial Report, page 18.

6. The extent to which the services included in the proposed health benefit are more or less expensive than an existing treatment, service or equipment, supplies or drugs, as applicable, that is

[159] Personal communication. Mohamed N. Hassan, MD, PhD.

determined to be equally safe and effective by credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community.

Routine patient care costs for clinical trials—The proposed health benefit covers routine health care costs which include a wide range of treatments, procedures, drugs, tests and imaging. In light of a comprehensive and undefined set of services included in the mandated benefit, it is not possible to identify and review all applicable alternatives and whether such alternatives might be more or less expensive.

Off label prescriptions—Medical librarians and CPHHP researchers found no peer-reviewed medical literature that discusses the safety, effectiveness and cost-effectiveness of the use of FDA-approved MS drugs for the treatment of Parkinson's disease or the use of FDA-approved Parkinson's disease drugs for the treatment of MS.

7. The impact of insurance coverage for the services included in the proposed health benefit 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.

The total cost of health care is understood to be the funds flowing into the medical system, which are the medical costs of insurance premiums and cost sharing. Actuarial analysis estimates the costs of the services included in the proposed health benefit to be *de minimis*. For further information, please see Appendix III: Ingenix Consulting Actuarial Report, page 7-8.

The services included in the proposed health benefit are related to treatment of established disease, thus no disease prevention or early detection economic benefits are anticipated. Some economic benefit may be realized by patients and their employers if the services included in the proposed health benefit allow those with Parkinson's disease or MS to return to work or foster improved on-the-job productivity.

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

No published literature was found regarding the effect of mandated coverage for off-label prescriptions and routine patient care costs associated with Parkinson's disease and MS clinical trials on the cost of health care for small employers. Because Connecticut insurers/MCOs are expected to provide coverage for treatment of Parkinson's disease and Multiple Sclerosis and "routine patient care costs" for trial participants is the standard recommended treatment, it is unlikely that the proposed health benefit, if enacted, would result in different effects among different types of employers.

For further information regarding the differential effect of the proposed health benefits on small group versus large group insurance, please see Appendix III: Ingenix Consulting Actuarial Report, page 22-23.

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.

Cost-shifting between private and public payers of health care coverage generally occurs when formerly privately insured persons, after enrolling in a public program or becoming un- or underinsured, require and are provided health care services. Cost-shifting also occurs when a formerly publicly-funded service becomes the responsibility of private payers, which can result following enactment of a health insurance mandate.

Most persons formerly covered under private payers lose such coverage due to a change in employer, change in employment status, or when private payers discontinue offering health care coverage as an employee benefit or require employee contributions to premiums that are not affordable. Because this proposed benefit is expected to have little financial impact on utilization or costs if enacted, it is unlikely it would have

any impact on cost-shifting between private and public payers of health care coverage.

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. For reasons described throughout this review and in the actuarial report, the estimated cost of the proposed health benefit, if enacted, is expected to be *de minimis*.

For further information, please see Appendix III, Ingenix Consulting Actuarial Report.

Chapter 4

Gastric Bypass

"An expansion of coverage for gastric bypass surgery."

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Chapter 4. Table of Contents

I. Overview

On July 22, 2010, the Chairs of the Insurance and Real Estate Committee of the Connecticut General Assembly (the Committee) directed the Connecticut Insurance Department to review "an expansion of coverage for gastric bypass surgery." This review follows the requirements stipulated under Public Act 09-179. Reviews of required health insurance benefits are a collaborative effort of Connecticut Insurance Department and the University of Connecticut Center for Public Health and Health Policy (CPHHP).

CPHHP did not receive additional language from the Committee with regard to the intended coverage parameters for gastric bypass surgery. Based on a review of previous bills considered by the Committee, the interpretation used for this review is that "coverage for gastric bypass surgery" refers to gastric bypass for the surgical treatment of clinically severe obesity not the use of gastric bypass as an experimental treatment for reversing Type 2 Diabetes (T2DB) in overweight and slightly obese individuals.

To evaluate the proposed mandate, in January 2011, CPHHP distributed and received responses to a survey requesting related policy documents and data for the proportion of members with policy exclusions, coverage, claims, and utilization review related to bariatric surgery and gastric bypass. Four out of seven Connecticut-domiciled insurers and managed care organizations (MCOs) responded.

CPHHP also contracted with Ingenix Consulting (IC) for actuarial and economic analysis of the proposed health benefits. IC analysis estimates the costs for both fully insured group plans and individual health insurance policies. The estimates are based on the potential cost increase in bariatric surgery claims, rather than gastric bypass alone. The cost estimates are also dependent on the assumption that the level of coverage and eligibility parameters required by the mandate are consistent with the average level of coverage available under existing private health plans that do provide coverage. For example, if a proposed mandate sets a coinsurance or maximum benefit level that exceeds the current standard of care among plans with coverage, the expected cost would be greater than that presented in this report. Similarly, if the state requirements for determining eligibility extend eligibility to a larger population than covered among plans with coverage, the expected cost would also be greater than that presented in this report.

Overall, the IC projected increase in cost to Connecticut's health care system for a bariatric surgery mandate implemented in 2011 is $10,320,213. This amount includes a $8,019,571 increase in total medical claims, $1,819,468 in retention (administrative expenses plus profit/reserves) and $481,174 in cost sharing. On average, out-of-pocket cost sharing is expected to comprise 4.7 percent of the increase.

Current coverage

Available data does not provide a definitive estimate regarding coverage for bariatric surgery in Connecticut. Coverage for bariatric surgery is included under certain circumstances under Medicaid and Medicare whereas the coverage for members of fully insured group and individual plans varied from 0 to 100 percent, according to Connecticut insurers/MCOs (carriers). Some policies exclude coverage for treatment of obesity, including bariatric surgery. The coverage available to individuals also varies in terms of deductibles, coinsurance, maximum benefits, and the health conditions required to determine bariatric surgery as medically necessary.

Premium impact

Insurance premiums are comprised of carrier paid medical claims and retention. Retention includes administrative expenses and profit/reserves. The estimated increase projected for covering bariatric surgery in 2011 represents less than 0.2 percent of the average total monthly premium paid.

Group plans: Ingenix Consulting projects an average increase in premiums of $0.61 per member per month (PMPM) for employers with fully insured group plans of which $0.50 PMPM is for paid medical costs and $0.11 PMPM for retention.

Individual policies: The projected increase for individual health plans is $0.44 PMPM of which $0.34 PMPM is for paid medical costs and $0.10 PMPM is for retention.

There is some evidence that improvement or resolution of comorbidities in bariatric surgery patients lead to a decrease in related pharmaceutical and medical care. Over time, these cost-savings may reduce the burden of the surgery cost provided that the cumulative savings are not outpaced by the need for routine nutritional therapy, follow up care or treatment of surgery complications. Some studies suggest a return on investment for bariatric surgery within two to nine years, depending on the type of surgery and whether it is performed laparoscopically.

Self-funded plans

The Ingenix Consulting report suggests that on average self-funded plans in the U.S. cover bariatric surgery. Surveys of self-funded employers in other states generally report some level of coverage for bariatric surgery, especially among labor pools and the largest of employers. The responses from the survey of Connecticut-domiciled insurers/MCOs did not indicate the level of coverage available for the self-funded plans they administer.

This report is intended to be read in conjunction with the General Overview and the Ingenix Consulting Actuarial Report, which is included as Appendix III.

II. Background

Body Mass Index

The standard international classification system for adult weight status uses a weight-for-height index, referred to as the Body Mass Index (BMI). The BMI calculation is defined as the weight in kilograms divided by the square of the height in meters of an adult. BMI scores are classified as underweight, normal range, overweight, or obesity (Table 4.1). Obesity is further classified into Class I, Class II, and Class III.[160] Class III obesity, also labeled extreme obesity, refers to individuals who are about 100 or more pounds overweight. For example, a person with extreme obesity and a height of 5 foot 8 inches (the average height of the U.S. adult male)[161] would weigh over 263 pounds whereas a normal weight person of the same height would way between 122 and 164 pounds. Although limitations exist when using BMI as a marker for overweight and obesity, BMI is strongly associated with body fat mass and health outcomes and is used in conjunction with waist circumference measurements during medical assessments.[162] BMI is also the predominant measure used in national health surveillance surveys.

[160] World Health Organization. BMI classification. Available at: http://apps.who.int/bmi/index.jsp?introPage=intro_3.html. Accessed February 23, 2011.

[161] Centers for Disease Control and Prevention. Body measurements. 2009. Available at: http://www.cdc.gov/nchs/fastats/bodymeas.htm. Accessed February 23, 2011.

[162] Obesity Education Initiative. 1998. Clinical guidelines to the identification, evaluation, and treatment of overweight and obesity in adults. Available at: http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.pdf. Accessed February 23, 2011.

Table 4.1. International Classification for adult weight status using BMI		
Classification	BMI	Weight (lbs) for 5'8" height*
Underweight	<18.5	<121.7
Normal range	18.5-24.9	121.7
Overweight	25-29.9	164.4
Obesity	≥30	197.3
Class I	30.0-34.9	197.3
Class II	35-39.9	230.2
Class III	≥40	263.1

*average height male, age 20 or older[163]

Obesity-related Health Concerns

A wealth of research explores the relationship between weight status and disease, disability and death. Positive associations between obesity and increased risk for hypertension, high blood pressure, cholesterol, type 2 diabetes (T2DB), coronary heart disease,[164] stroke, disability, certain cancers, osteoarthritis, gall bladder disease and excess deaths have been documented.[165] The risk of developing a comorbidity increases as the degree of obesity increases.[166] The National Heart, Lung, and Blood Institute describe disease risk for T2DB, hypertension and cardiovascular diseases (CVD) relative to the normal weight population by weight status and waist circumference. Relative to normal weight individuals, individuals who are:

- Overweight have increased or high disease risk;
- Class I obese have high or very high risk;
- Class II obese have very high to extremely high risk; and
- Class III obese have extremely high risk.[167]

For each weight status, the higher disease risk indicated is for individuals with a waist circumference predictive of substantial abdominal fat (>40 inches for men and >35 inches for women). The most serious health problems are associated with extreme obesity.[168]

Class III obesity is associated with a 5 to 20 year shorter life expectancy. It is also associated with increased risk of more than thirty illnesses and medical conditions.[169] Commonly, Class III or extreme obesity is called morbid obesity or clinically severe obesity due to the increased risk of morbidity and mortality compared to that experienced by adults in other weight classifications.[170] In some cases, individuals with Class II obesity and chronic disease(s) or medical condition(s) (comorbidities) such as heart disease, sleep apnea or T2DB are

[163] Centers for Disease Control and Prevention. Body measurements. 2009. Available at: http://www.cdc.gov/nchs/fastats/bodymeas.htm. Accessed February 23, 2011.

[164] Obesity Education Initiative. 1998. Clinical guidelines to the identification, evaluation, and treatment of overweight and obesity in adults. Available at: http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.pdf. Accessed February 23, 2011.

[165] American Society for Metabolic & Bariatric Surgery. Obesity in America. Available at: http://www.asbs.org/Newsite07/media/asmbs_fs_obesity.pdf. Accessed February 23, 2011.

[166] Hensrud DD, Klein S. 2006. Extreme obesity: a new medical crisis in the United States. *Mayo Clinic Proc*. October 2006; 81(10, suppl):S5-S10.

[167] Obesity Education Initiative. 1998. Clinical guidelines to the identification, evaluation, and treatment of overweight and obesity in adults. Available at: http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.pdf. Accessed February 23, 2011.

[168] Sturm R. 2007. Increases in morbid obesity in the USA: 2000-2005. *Public Health* 121(7): 492-496.

[169] Hensrud DD, Klein S. 2006. Extreme obesity: a new medical crisis in the United States. *Mayo Clinic Proc*. October 2006; 81(10, suppl):S5-S10.

[170] *Ibid.*

also considered morbidly obese.

Obesity Trends and Prevalence

An analysis of data from the National Health Assessment and Nutrition Evaluation Survey (NHANES) conducted by the National Center for Health Statistics (NCHS) concludes, "The entire adult population is heavier, and the heaviest have become much heavier since 1980." [171] Similarly, Sturm's analysis of the Behavioral Risk Factor Surveillance Survey (BRFSS) shows overall obesity prevalence increasing by 24 percent between 2000 and 2005, class III obesity prevalence (BMI ≥40) increasing twice as fast (52 percent) and the prevalence of BMI ≥50 (about 200 pounds overweight) increasing three times as fast.[172]

According to NHANES data from 2007-2008 more than one-third of the adult population was obese. 19.6 percent of the population qualified as Class I obese, 8.6 percent as Class II obese and 5.7 percent as Class III obese. The rate of Class III obesity was higher among women (4.2 percent) than men (7.2 percent) and especially high for non-Hispanic black women (14.2 percent).[173]

In Connecticut, the rate of obesity is significantly lower than the national rate.[174] Based on BRFSS for 2009, Connecticut's obesity rate for adults was the second lowest in the nation at 21 percent, compared to a national average of 26.9 percent. The BRFSS obesity estimates are lower than NHANES estimates (above) due to BRFSS' reliance on self-report data for weight and height rather than direct measurement during a physical examination which is the method used for NHANES. For 2007-2008 an additional 7.6 percent adults are identified as obese using NHANES data when compared to BRFSS findings. Since BRFSS estimates are generally biased downward due to underestimating and under-reporting of higher weights, it may be reasonable to assume that the rate of obesity in Connecticut is closer to 30 percent than 21 percent reported under BRFSS. Roughly, 8-12 percent of the adult population would be considered morbidly obese (Class III obese or Class II obese with a comorbid condition).

Treatments for Weight Loss

The *NHLBI Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults* states three goals for weight loss and weight management:

1) prevent further weight gain,
2) reduce body weight, and
3) maintain lower body weight over the long term.[175]

The goals and related treatment guidelines are supported by the medical literature which documents the positive effect of weight loss on reducing the presence and/or development of many chronic diseases and their risk factors.[176] The recommended strategies for weight loss include dietary therapy, physical activity, behavior therapy, combining therapy (physical activity and dietary therapy), lifestyle therapy (dietary therapy, physical activity and behavior therapy combined), and in some cases pharmacotherapy or surgery. As noted in the clinical guidelines, weight is usually regained unless a weight maintenance program consisting of dietary therapy, physical activity and behavior therapy is continued indefinitely.[177]

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[171] Ogden CL, Carroll MD, McDowell M, *et al.* 2007. Obesity among adults in the United States—No statistically significant change since 2003-2004. Available at: www.cdc.gov/nchs/data/databriefs/db01.pdf. Accessed February 23, 2011.

[172] Sturm R. 2007. Increases in morbid obesity in the USA: 2000-2005. *Public Health* 121(7): 492-496.

[173] Flegal KM, Carroll MD, Ogden CL, *et al.* Prevalence and trends in obesity among US adults, 1998-2008. *JAMA*.2010; 303(3): 235-241.

[174] Trust for America's Health. 2010. New report: Connecticut ranks second least obese state in the nation. Available at: http://healthyamericans.org/reports/obesity2010/release.php?stateid=CT. Accessed February 23, 2011.

[175] Obesity Education Initiative. 1998. Clinical guidelines to the identification, evaluation, and treatment of overweight and obesity in adults. Available at: http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.pdf. Accessed February 23, 2011.

[176] *Ibid.*

[177] *Ibid.*

The Bariatric Practice Guidelines set by the American Society of Bariatric Physicians (ASBP), a professional organization focused on medical treatment and management of overweight and obese patients, suggests similar modes of treatment. The term "bariatric" refers to the field of medicine pertaining to weight loss,[178] the study, prevention or treatment of overweight[179] or "relating to or specializing in the treatment of obesity."[180] The 2004 ASBP guidelines outline dietary modification, exercise prescription, behavior modification and when appropriate, medication as medical (non-surgical) methods for weight loss and body fat reduction.[181] A recent statement by the ASBP in response to lowering BMI standards used to qualify patients for weight loss (bariatric) surgery, states:

> Bariatric surgery has been and should remain a second line therapy after comprehensive medically-managed weight loss. Bariatric surgery does not end one's challenges with weight; rather, it creates new and different nutritional, medical and psychiatric challenges that must be carefully taken into consideration. In conclusion, the ASBP does not support the lowering of BMI standards to qualify for bariatric surgery.[182]

There are seven types of bariatric surgeries that are generally accepted for use in the United State as of 2008.[183] The most common procedures are gastric bypass, laparoscopic adjustable gastric band (LAGB also known as ***Lap-Band*** ®), bioliopancreatic diversion with duodenal switch (BPD/DS) and sleeve gastrectomy or gastric sleeve.[184] Procedures are restrictive, malabsorptive or both. Restrictive procedures limit food intake by reducing the size of the stomach, either through removal, banding or stapling off a section of the stomach to create a smaller gastric pouch. Procedures induce the malabsorption of calories and nutrients by changing the pathway of the food as it travels from the stomach through the small intestine.

Gastric bypass is the most common type of bariatric surgery in the United States and is considered the gold-standard for bariatric surgery.[185] Although the proportion of surgeries by type is changing with the advent of LAGB, according to a 2008 report 80 percent of bariatric surgeries were identified by the ASBS as gastric bypass.[186] Results from the CPHHP poll of Connecticut bariatric surgery centers with COE designations suggests that gastric bypass is the procedure used in about 56 percent of weight loss surgeries in the state. In recent years, the advent of laparoscopic surgery has shifted the procedure away from riskier open surgeries, significantly reducing complications and decreasing procedure costs.[187] Gastric bypass promotes weight loss by combining restriction and malabsorption.

The ***Roux-en-Y gastric bypass*** (RYGB), typically completed as a hospital-based inpatient procedure, is a

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[178] MedicineNet.com. Definition of bariatric. Available at: http://www.medterms.com/script/main/art.asp?articlekey=26127. Accessed February 23, 2011.

[179] TheFreeDictionary.com. Bariatric. Available at: http://medical-dictionary.thefreedictionary.com/Bariatric. Accessed February 23, 2011.

[180] Merriam-Webster. Bariatric. Available at: http://www.merriam-webster.com/dictionary/bariatric. Accessed February 23, 2011.

[181] American Society of Bariatric Physicians. About ASBP. Available at: http://www.asbp.org/siterun_data/about_asbp/. Accessed February, 23 2011.

[182] American Society of Bariatric Physicians. Bariatric physicians question FDA recommendations to lower BMI requirements for lap-band surgery. Available at: http://www.asbp.org/siterun_data/about_asbp/position_statements/doc8199431321294271132.html. Accessed February, 23 2011.

[183] Mechanick JI, Kushner RF, Sugerman HJ, *et al.* 2008. AACE, TOS and ASMBS' Medical Guidelines for Clinical Practice for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric patient. *Endocor Pract.* 2008;12(Suppl 1).

[184] Buchwald H. 2005. Consensus conference statement: Bariatric surgery for morbid obesity: health implications for patients, health professionals, and third-party payers. *J Am Coll Surg.* 200: 593-604.

[185] Mechanick JI, Kushner RF, Sugerman HJ, *et al.* 2008. AACE, TOS and ASMBS' Medical Guidelines for Clinical Practice for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric patient. *Endocor Pract.* 2008;12(Suppl 1).

[186] *Ibid.*

[187] Zhao Y, Encinosa W. Bariatric surgery utilization and outcomes in 198 and 2004. Statistical Brief #23. January 2007. Agency for Healthcare Research and Quality. Rockville, MD. http://www.hcup-us-ahrq.gov/reprts/statbriefs/sb23.pdf.

very invasive surgical procedure where the upper part of the stomach is partitioned from the lower stomach by stapling or separation (but not removal) to form a small (10-30 mL) pouch. The jejunum, which is the first two-fifths of the small intestine beyond the duodenum, is divided into upper and lower parts, and a Y-shaped anastomosis [surgical connection] is formed by "attaching the free end of the lower part of the jejunum to a new outlet on the upper stomach pouch and attaching the free end of what was the upper jejunum to a new opening on the small intestine."[188] In other words, the newly created small stomach pouch is connected to the bowel by a piece of small intestine, bypassing most of the stomach.

Laparoscopic Adjustable Gastric Banding is the second most common bariatric surgery in the United States. Recent estimates suggest that LAGB accounts for 37 percent[189] or more bariatric surgeries and that approximately half of these surgeries are completed at outpatient surgery centers, rather than as hospital-based inpatient procedures. The CPHHP poll of COE designated bariatric surgery centers suggests that about 41 percent of bariatric surgeries in Connecticut are for LAGB. The procedure involves the laparoscopic placement of an adjustable silicone ® band around the stomach and tightening the band to create two chambers. With the band, the top of the stomach where food and liquid enter is smaller thus filling quicker and triggering satiety earlier than would occur without the band. The band is lined with an inflatable balloon which can be inflated or deflated through an access port to manage the tightness of the band and extent of weight loss.[190]

Gastric Sleeve or Sleeve Gastrectomy is a newer laparoscopic procedure involving the vertical removal of 85 percent of the stomach so that the remaining stomach takes the shape of a sleeve or tube. The new smaller stomach or "sleeve" is then closed with staples. At times, this procedure has been used as a staged procedure to promote initial weight loss and reduce related surgical risk prior to completion of a gastric bypass or other bypass procedure such as the biliopancreatic diversion with or without a duodenal switch.[191]

Biliopancreatic Diversion with or without Duodenal Switch: According to the poll of COE designated bariatric surgery centers in Connecticut, it appears that BPD with or without a duodenal switch is not offered.

According to the national Healthcare Cost and Utilization Project (HCUP) data from 2004, 98.3 percent of bariatric surgeries were received by 18-64 year olds and 82 percent of patients receiving surgery were women. Only 1.5 percent of surgeries were for adolescents and the elderly combined.[192]

Bariatric Surgery and Health Improvement

Bariatric surgery in general is documented as an effective strategy for remission of numerous comorbid conditions, decreased mortality, and greater percentages of excess weight loss. (Excess weight refers to the pounds that a person weighs that exceed normal weight). Numerous studies reviewing the effectiveness of bariatric surgery document higher rates of improvement to health when compared to population counterparts who do not receive bariatric surgery. Table 4.2 presents the preoperative incidence and postoperation remission rate for conditions such as T2DB and hypertension as summarized in the AACE/

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[188] Merriam-Webster. Roux-en-Y gastric bypass. Available at: http://www.merriam-webstercollegiate.com/medical/roux-en-y%20gastric%20bypass. Accessed February 23, 2011.

[189] American Society for Metabolic & Bariatric Surgery. 2005. Brief history and summary of bariatric surgery, gastric bypass. Available at: http://www.asbs.org/html/patients/bypass.html. Accessed February 23, 2011.

[190] American Society for Metabolic & Bariatric Surgery. 2005. Brief history and summary of bariatric surgery, gastric banding. Available at: http://www.asbs.org/html/patients/banding.html. Accessed February 23, 2011.

[191] Mann D. Gastric sleeve surgery. Consumer Guide to Bariatric Surgery. Available at: http://www.yourbariatricsurgeryguide.com/gastric-sleeve/. Accessed February 23, 2011.

[192] Mechanick JI, Kushner RF, Sugerman HJ, *et al.* 2008. AACE, TOS and ASMBS' Medical Guidelines for Clinical Practice for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric patient. *Endocor Pract.* 2008;12(Suppl 1).

TOS/ASMBS Guidelines (2008).[193] Notably, of the 34 percent of patients who went into surgery with T2DM, 85 percent experienced a remission. Similarly, 66 percent of bariatric surgery patients with hypertension experienced a remission. The same review also notes evidence of reduced mortality with several studies directly attributing the reduction in mortality to myocardial infarction, diabetes and cancer-related deaths. [194] In addition, mechanical improvements may be observed following weight loss. These improvements can include less weight bearing on joints, enhanced lung compliance, and decreased fatty tissue around the neck, which relieves obstruction to breathing.[195]

Table 4.2. Effects of bariatric surgery on obesity-related comorbidities (%)

Comorbidity	Preoperative incidence	Remission >2 years postoperative
T2DM, IFG, or IGT	34	85
Hypertension	26	66
Hypertriglyceridemia and low HDL cholesterol	40	85
Sleep apnea	22 (in men) 1 (in women)	40
Obesity-hypoventilation syndrome	12	76

Source: This data was presented in the AACE/TOS/ASMBS Bariatric Surgery Guidelines, *Endocr Pract.* 2008; 14 (Suppl 1). The incidence and remission rates were identified through a review of the literature.
HDL=high-density lipoprotein; IFG=impaired fasting glucose; IGT=impaired glucose tolerance

However, it is worth noting that research examining weight loss over time has documented that the durability of weight loss over time is not constant. One review article notes that 20 percent of the surgery population in the study regained the weight. Notably, there is variation in the durability of weight loss over time by type of weight loss procedure.

Bariatric Surgery: Complications

According to Livingston's analysis of multiple national data sets, the complication rate for bariatric surgery was 7.6 percent in 2006 which is similar to the 4.3 percent rate estimated from The Longitudinal Assessment of Bariatric Surgery.[196] Complications related to bariatric surgery may occur during surgery or after surgery. Complications that may arise during surgery include pulmonary thromboembolism,[197] anastomotic leak (leak at the surgical unions between parts such as the stomach and intestine), wound infections, bleeding, incidental surgical removal of the spleen, incisional and internal hernias, and clogging or blocking of the small bowel.[198] Postoperative complications include nausea and vomiting, dumping syndrome and nutrient deficiencies.[199] Dumping syndrome is a "condition characterized by weakness, dizziness, flushing and warmth, nausea, and palpitation immediately or shortly after eating and produced by abnormally rapid emptying of the stomach especially in individuals who have had part of the stomach removed." After malabsorptive procedures, nutrient deficiencies are common and adequacy of intake generally involves ongoing use of supplements and monitoring to confirm appropriate nutrient intake.

193 *Ibid.*

194 *Ibid.*

195 *Ibid.*

196 Livingston EH. The incidence of bariatric surgery has plateau in the U.S. The American Journal of Surgery (2010) 200, 378-385.

197 Pulmonary Thromboembolism as defined by Medterms.com "obstruction of the pulmonary artery or a branch of it leading to the lungs by a blood clot, usually from the leg, or foreign material causing sudden closure of the vessel. About 10-15% of pulmonary embolism patients die"

198 AHRQ-National Guideline Clearing House. 2009. Guideline Summary NGC-7470. World Gastroenterology Organisation Global Guideline: obesity. Available at: http://www.guideline.gov/content.aspx?id=15230. Accessed February 23, 2011.

199 Ibid.

Surgery patients may also experience dehydration, bowel obstruction, strictures, adhesions, erosions and ulcers, internal and incisional hernias and gallstones (cholelithiasis). [200] In addition, complications specific to LAGB (a restrictive procedure) include band slippage or erosion and the need for reversal or revision.[201]

The increased rate of mortality related to bariatric surgery is described in terms of deaths that occur in-hospital (perioperatively), 30 days after the surgery and 90 days after the surgery. The most common causes of death are pulmonary embolism and anastomotic leaks. Increases in bariatric surgery experience and the advent of laparoscopic bariatric surgery methods have generated a substantial decrease in the mortality risks associated with the procedure. In an analysis conducted by the Surgical Review Corporation, mortality rates for 55,567 patients were 0.14 percent for in-hospital mortality, 0.29 percent for 30 day mortality and 0.35 percent for 90 day mortality. Other studies suggest similar mortality rates, ranging from 0.1 to 0.2 percent for nationwide mortality and 0.19 percent for in-hospital mortality for all bariatric discharges in 2004.[202]

However, a study exploring the risk related to gastric bypass surgery using mortality risk scores based on BMI, male sex, hypertension, risk of pulmonary embolus and patient age suggests that "bariatric surgery is not uniformly a low-risk procedure." The authors found that mortality increased significantly by mortality risk score with mortality rates at 0.31 percent if low-risk, 1.9 percent if intermediate risk and 7.56 percent if high-risk.[203] Given elevated risk within subgroups of the population with clinically severe obesity, the authors concluded, "judicious patient selection and diligent perioperative care are imperative."[204]

Bariatric Surgery Guidelines

The primary guidelines used to determine eligibility for bariatric surgery include the National Institutes of Health (NIH) Consensus Development Conference Statement in 1991, and two sets of clinical guidelines, one issued by the NHLBI in 1998[205] and the other published jointly by the American Association of Clinical Endocrinologists (AACE), The Obesity Society (TOS), and the American Society for Metabolic and Bariatric Surgery (ASMBS) in 2008.

The Medical Guidelines for Clinical Practice for the Perioperative Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Patient, published collaboratively by AACE, TOS, and ASMBS, are based on a critical review of the scientific literature. The guidelines present selection criteria for bariatric surgery in terms of four factors: adult weight, weight loss history, commitment and exclusions.[206] The following excerpt from the *Medical Guidelines* summarizes the criteria for each factor.

- ***Weight*** (adult):
  - BMI≥40 kg/m^2 with no comorbidities
  - BMI ≥35 kg/m2 with obesity-associated comorbidities

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[200] Ibid.

[201] American Society for Metabolic & Bariatric Surgery. 2005. Brief history and summary of bariatric surgery, gastric banding. Available at: http://www.asbs.org/html/patients/banding.html. Accessed February 23, 2011.

[202] Mechanick JI, Kushner RF, Sugerman HJ, *et al.* 2008. AACE, TOS and ASMBS' Medical Guidelines for Clinical Practice for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric patient. *Endocor Pract.* 2008;12(Suppl 1).

[203] Nguyen NT, DeMaria EJ, Ikramuddin S, *et al.* The SAGES Manual: A Practical Guide to Bariatric Surgery. Chapter 31: The Betsy Lehman Center Guidelines for Weight Loss Surgery by Mathew M. Hutter. Springer Science and Business Media, New York. Pp.253-256.

[204] *Ibid.*

[205] Obesity Education Initiative. 1998. Clinical guidelines to the identification, evaluation, and treatment of overweight and obesity in adults. Available at: http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.pdf. Accessed February 23, 2011.

[206] Mechanick JI, Kushner RF, Sugerman HJ, *et al.* 2008. AACE, TOS and ASMBS' Medical Guidelines for Clinical Practice for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric patient. *Endocor Pract.* 2008;12(Suppl 1).

- ***Weight loss history***:
  - failure of previous nonsurgical attempts at weight reduction, including nonprofessional programs (for example, Weight Watchers, Inc)
- ***Commitment***:
  - expectation that patient will adhere to postoperative care
  - follow-up visits with physician(s) and team members
  - recommended medical management, including the use of dietary supplements
  - instructions regarding any recommended procedures or tests
- ***Exclusion***:
  - Reversible endocrine or other disorders that can cause obesity
  - current drug or alcohol abuse
  - uncontrolled, severe psychiatric illness
  - lack of comprehension of risks, benefits, expected outcomes, alternatives, and lifestyle changes required with bariatric surgery[207]

Overall, the Medical Guidelines for patient selection are very similar to those presented in the Consensus Conference Statement and the NHLBI Clinical Guidelines. It is important to note that the Medical Guidelines specify the criteria for patient selection based on adult weight, thus there is no criteria for selecting children or adolescents for participation in bariatric surgery. The lack of a recommendation for children to have this surgery is consistent with the NIH Consensus Conference Statement which concluded that "Children and adolescents have not been sufficiently studied to allow a recommendation for surgery for them even in the face of obesity associated with BMI over 40."[208] Despite this consensus, there is a growing trend of adolescents receiving bariatric surgery.

A recent ruling by the Food and Drug Administration (FDA) also diverges from the clinical guidelines for bariatric surgery, expanding coverage below the recommended adult weight thresholds for Allergan's Lap-Band® System, the first LAGB device approved for use in the U.S. As reported by Allergan, the FDA approved use of the Lap-Band® system for "adults with obesity who have failed more conservative weight reduction alternatives, such as diet and exercise and pharmacotherapy, and have a Body Mass Index (BMI) of 30-40 and at least one obesity related comorbid condition.[209]

Bariatric Surgery: Privileging and Practice Guidelines

The authority to grant clinical privileges for bariatric surgery at a hospital or in a given health system is within the purview of the individual hospital or health system governing board. However, both the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) [210] and the Betsy Lehman Center for Patient Safety and Medical Error Reduction have issued guidelines to address safety concerns that arose in the early 2000s.[211] As a result, voluntary guidelines and recommendations exist for the credentialing of surgeons and accreditation of hospitals.

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[207] *Ibid.*

[208] *NIH Consensus Statement Online* 1991 Mar 25-27 [cited February 9, 2011],9(1);1-20.

[209] Allergan. FDA approves expanded use of lap-band adjustable gastric banding system for obese adults. Available at: http://agn.client.shareholder.com/releasedetail.cfm?ReleaseID=550670. Accessed February 23, 2011.

[210] Nguyen NT, DeMaria EJ, Ikramuddin S, *et al.* The SAGES Manual: A Practical Guide to Bariatric Surgery. Chapter 31: The Betsy Lehman Center Guidelines for Weight Loss Surgery by Mathew M. Hutter. Springer Science and Business Media, New York. Pp.253-256.

[211] *Ibid.*

Hospitals and bariatric weight loss centers can pursue voluntary accreditation program from the American College of Surgeons (ACS) or a Center of Excellence (COE) designation from the ASMBS.[212] Administered through the Surgical Review Corporation, a bariatric surgery facility may apply to become a ASMBS Center of Excellence (COE). Connecticut bariatric programs with an ASMBS COE designation as of February 2011 include St. Vincent's Medical Center, Hartford Hospital, Saint Francis Hospital and Medical Center, Middlesex Hospital, The Hospital of Central Connecticut, Hospital of Saint Raphael, and Norwalk Hospital. To become a COE certain criteria related to quality of care must be met. The ACS accreditation requires programs to have the necessary physical resources, human resources, clinical standards, surgeon credentialing standards, data-reporting standards, and quality improvement practice. Danbury Hospital, Greenwich Hospital, Hartford Hospital, and Yale New Haven Hospital have ACS accreditation. As of 2006, CMS requires that for coverage of bariatric surgery, the surgery must be carried out in a facility with an ASMBS COE designation or an ACS accreditation. However, bariatric programs are not required to be ACS accredited or COE designated to operate in the state.

Bariatric Surgery and Health Insurance

During the course of the review, a number of parameters common to policies covering gastric bypass were identified. Policies reviewed specified coverage in terms of the "surgical treatment of obesity" or bariatric surgery, rather than a specific procedure such as gastric bypass.

Eligibility: Existing state mandates and some government employee health plans throughout the country extend coverage for bariatric surgery based on a diagnosis of morbid obesity or clinically severe obesity. Recognized guidelines for bariatric surgery are often referenced or Body Mass Index (BMI) thresholds are set and at times, the presences of co-occurring chronic conditions are required. Some policies are more restrictive than recognized guidelines. Some policies set age thresholds for the covered population, explicitly excluding the child population or requiring additional steps to approve adolescents as eligible.

Benefit design: Mandated and voluntary coverage of bariatric surgery often involves a maximum benefit amount, a maximum episode, co-insurance, deductibles and other cost control measures.

Approval: There are varying criteria used for qualification which may involve age, BMI thresholds, presence of comorbid conditions, documentation of weight loss history for a specified duration of time, participation in a weight loss or weight maintenance program, commitment to the procedure, a psychiatric consultation, or the need for bariatric surgery to resolve an existing chronic condition for which bariatric surgery.

Exclusion: Policies often include treatment of obesity as an excludable condition thus allowing for denial of gastric bypass or other bariatric surgeries for the purpose of weight loss.

III. Methods

Under the direction of CPHHP, medical librarians at the Lyman Maynard Stowe Library at the University of Connecticut Health Center (UCHC) gathered published articles and other information related to medical, social, economic, and financial aspects of the required benefit. Medical librarians conducted literature searches using PubMed, Scopus, National Institutes of Health websites, and Google. The primary search terms used include bariatric surgery, metabolic surgery, Roux-en-Y, gastric bypass, gastroplasty, laparoscopy,

[212] *Ibid.*

obesity, morbid obesity and weight loss. Supplemental terms included weight loss, economics, utilization, instrumentation, treatment outcome, and hospital costs/trends. Searches were limited to English studies published in the last ten years. An emphasis was placed on identifying systematic reviews, meta-analyses, practice guidelines, and randomized controlled trials.

CPHHP staff conducted independent literature searches using PubMed, Cochrane Database, and Westlaw. Where available, articles published in peer-reviewed journals are cited to support the analysis. Sources of information may also be cited in the absence of peer-reviewed journal articles. Staff also gathered additional information through telephone and e-mail inquiries to appropriate state, federal, municipal and non-profit entities and from internet sources such as the State of Connecticut website, Centers for Medicare and Medicaid (CMS) website, other states' websites, professional organizations' websites and non-profit and community-based organization websites. In addition, CPHHP also conducted a poll of Connecticut bariatric surgery centers with the Center of Excellence designation to assess the type of procedures available, annual patients/surgeries and the distribution of patients by procedure.

CPHHP received responses from Connecticut-domiciled insurers/MCOs to a survey requesting related policy documents and data for the proportion of members with policy exclusions, coverage, claims, and utilization review related to bariatric surgery and gastric bypass. Four out of seven Connecticut-domiciled insurers and managed care organizations (MCOs) responded.

CPHHP also contracted with IC to provide actuarial and economic analysis of the proposed health benefit mandate. A description of the methods used for the actuarial analysis and the full report are available under Appendix III. IC analyzed claims data from 2006-2009 using a proprietary national database of commercial health plan insurance claims to inform the cost estimate.

The cost estimates calculated by IC are based on the potential cost increase in bariatric surgery claims, rather than gastric bypass alone. The estimates are also dependent on the assumption that the level of overage and eligibility parameters required by the proposed mandate are consistent with the average level of coverage available under existing private health plans that do provide coverage. For example, if a proposed mandate sets a coinsurance or maximum benefit level that exceeds the current standard of care among plans with coverage, the expected cost would be greater than that presented in this report. Similarly, if the state requirements for determining eligibility extend eligibility to a larger population than covered among plans with coverage, the expected cost would also be greater than that presented in this report.

IV. Social Impact

1. The extent to which gastric bypass surgery is utilized by a significant portion of the population.

According to the Agency for Healthcare Quality and Research, in 2002 0.6 percent of the population with morbid obesity underwent surgery for weight loss.[213] National estimates suggest that 3.8 bariatric surgeries per 1,000 people (112,999 procedures) were completed in the United States in 2006. [214] These estimates calculated by Edward Livingston (2010) are based on data from the National Hospital Discharge Survey (NHDS), National Inpatient Survey (NIS), and the National Survey of Ambulatory Surgery (NSAS). The integration of NSAS data allows the estimates generated to capture both inpatient and outpatient surgeries.

Codes used to identify bariatric surgeries often cover a range of procedures. Excluding procedure codes

[213] Agency for Healthcare Research and Quality. 2005. AHRQ study finds weight-loss surgeries quadrupled in five years. Available at: http://www.ahrq.gov/news/press/pr2005/wtlosspr.htm. Accessed February 23, 2011.

[214] U.S. Census Bureau. Annual estimates of the population for the United States, Regions, and States and for Puerto Rico: April 1, 2000 to July 1, 2006. Available at: http://www.census.gov/popest/states/NST-ann-est2006.html. Accessed February 23, 2011.

specific to lap band and gastric procedures not elsewhere classifiable, there were 2.4 surgeries per 1,000 persons (70,688) that were potentially gastric bypass surgeries.[215, 216] (About 37 percent of bariatric surgeries were lap band procedures).[217] An alternative estimate for gastric bypass surgeries may be that they are closer to just over half of bariatric surgeries.[218]

The ASMBS estimates 220,000 (7.1 per 1,000 people) as the number of bariatric surgeries in 2008.[219] The CPHHP poll of bariatric surgery centers with a "Center of Excellence" or ACS accreditation suggests a ballpark estimate of 2,500-3,500 bariatric procedures completed during 2010. The CPHHP carrier survey of bariatric surgery utilization for fully insured group members permits a rough estimate of 1.8 to 2.2 per 1,000 group members as making bariatric surgery claims in 2010. [220]

2. The extent to which gastric bypass surgery is 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.

No information was found that would indicate the Department of Public Health or municipal health departments provide services for gastric bypass surgery or other bariatric surgeries. Under government health programs Medicare and Medicaid, gastric bypass may be covered under certain circumstances.

Medicare

Medicare typically does not cover services for obesity. However, Medicare coverage of gastric bypass surgery is possible in limited situations. Medicare will cover gastric bypass surgery if it is deemed medically necessary, or if it is necessary to correct an illness that was either caused or aggravated by a person's obesity. In a 2006 decision, Centers for Medicare and Medicaid Services (CMS) determined that to be considered for coverage, Medicare beneficiaries were required to have a BMI of 35 or higher, and to have exhibited a serious health condition in addition to morbid obesity, such as hypertension, coronary artery disease, or osteoarthritis. In that decision, CMS covered four types of bariatric surgery procedures: open gastric bypass and laparoscopic Roux-en-Y gastric bypass, laparoscopic adjustable gastric banding, and open and laparoscopic biliopancreatic diversion with duodenal switch. No other bariatric surgery procedure is currently covered.

CMS clarified its policy for coverage of bariatric surgery in 2009. CMS specified that T2DB is one of the comorbidities CMS would consider in determining whether bariatric surgery would be covered for a Medicare beneficiary who is morbidly obese, as long as the surgery is furnished at a CMS-approved facility. CMS-approved facilities must be designated as a Center of Excellence by ASMBS/SRC or accredited by the American College of Surgeons . An individual with a body-mass index (BMI) of at least 35 is considered morbidly obese. CMS announced that bariatric surgery will not be covered by Medicare when it is used to treat T2DB in a beneficiary with a BMI below 35.[221]

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[215] Livingston EH. 2010. The incidence of bariatric surgery has plateaued in the U.S. *The American Journal of Surgery* 200: 378-385.

[216] U.S. Census Bureau. Annual estimates of the population for the United States, Regions, and States and for Puerto Rico: April 1, 2000 to July 1, 2006. Available at: http://www.census.gov/popest/states/NST-ann-est2006.html. Accessed February 23, 2011.

[217] Livingston EH. 2010. The incidence of bariatric surgery has plateaued in the U.S. *The American Journal of Surgery* 200: 378-385.

[218] Unpublished results. CPHHP poll of bariatric surgery centers with COE designation. February 2011.

[219] Weight-control Information Network. Longitudinal assessment of bariatric surgery. Available at: http://win.niddk.nih.gov/publications/labs.htm#howmany. Accessed February 23, 2011.

[220] Based on: 1,128 members with claims out of 511,531 fully insured group members

[221] Centers for Medicare and Medicaid Services. 2009. Decision memo for surgery for diabetes. Available at: http://www.cms.gov/mcd/viewdecisionmemo.asp?from2=viewdecisionmemo.asp&id=219&. Accessed January 26, 2011.

Medicaid

The Connecticut Department of Social Services MMIS Provider Manual allows:

> ...surgical services necessary to treat morbid obesity when another medical illness is caused by, or is aggravated by, the obesity. Such illnesses shall include illnesses of the endocrine system or the cardio-pulmonary system, or physical trauma associated with the orthopedic system.[222]

Services to treat obesity, other than those described, are not covered. Generally, hospital stays and hospital outpatient visits are not covered for the treatment of obesity. The Department of Social Services policy states:

> The Department will not pay for a hospital stay, medical services or for procedures in the treatment of obesity, including gastric stapling. Although obesity is not itself an illness it may be caused by illnesses such as hypothyroidism, Cushing's disease and hypothalamic lesions. In addition, obesity can aggravate a number of cardiac and respiratory diseases as well as diabetes and hypertension. Services in connection with the treatment of obesity could be covered services when such services are an integral and necessary part of course of treatment for one of these illnesses.[223]

3. The extent to which insurance coverage is already available for gastric bypass surgery.

The CPHHP reviewed the literature and related public hearing testimony and surveyed Connecticut carriers regarding the level of coverage or policy exclusions for gastric bypass and bariatric surgery. Four out of six carriers submitted responses. The quality of the responses varied widely with some carriers not submitting data or policy documents where requested. The resulting response to this question is limited to a summary of coverage or exclusions described in the policy documents, what was received for data requests, and the literature review.

Both the literature and public hearing testimony suggest that prior to 2004 carriers covered bariatric surgery. Results from several published national and state level studies indicated that 100 percent of responding carriers covered bariatric surgery or surgical treatment for weight loss or morbid obesity. For the coverage policies in Pennsylvania, a survey found that all plans had a BMI cutoff and 88 percent required a comorbid condition to be present. The requirement for a comorbid condition to be present for patients with a BMI ≥40 removes part of the population from the eligibility pool who would be covered if the ASMBS or NIH guidelines were followed. Even so, concerns with large increases in surgery demand and the potential adverse effect on costs and premiums lead to the withdrawal of such coverage by CIGNA Healthcare in 2004 and Aetna, Inc in 2005.[224]

A public hearing testimony submitted in 2006 and endorsed by the Connecticut State Medical Society, describes the level of coverage in Connecticut.

> Beginning in January 2005, all of our state's insurance providers revoked coverage for these

[222] Department of Social Services. 2009. Provider Manual: physician. Available at: https://www.ctdssmap.com/CTPortal/Information/Get%20Download%20File/tabid/44/Default.aspx?Filename=ch7_iC_physician_V2.0.pdf&URI=Manuals/ch7_iC_physician_V2.0.pdf. Accessed February 23, 2011.

[223] Department of Social Services. 2008. Provider Manual: hospital. Available at: https://www.ctdssmap.com/CTPortal/Information/Get%20Download%20File/tabid/44/Default.aspx?Filename=ch7_iC_hospital_V1.0.pdf&URI=Manuals/ch7_iC_hospital_V1.0.pdf. Accessed February 23, 2011.

[224] Finkelstein EA, Brown DS, Avidor Y, *et al.* 2005. The role of price, sociodemographic factors, and health in the demand for bariatric surgery. *The American Journal of Managed Care* 11: 630-637.

> procedures from their general policies. …Insurers, however, continue to recognize the medical validity of these procedures. Despite revoking these procedures from the general policies, riders have been made available to large employer groups. This unfortunately leaves about 50% of our population without access to coverage.[225]

Similar to the testimony, 2011 correspondence with the Connecticut Insurance Department suggests the extent of coverage as follows: "most all carriers in Connecticut exclude gastric bypass and for that matter any surgery related to weight loss (i.e. bariatric surgery). From time to time gastric bypass will be included as a rider chosen by an employer, but most carriers do not even offer it as a rider."[226]

The information submitted to CPHHP by carriers provides insight on certain commonalities and variation across insurance carriers in terms of coverage for fully insured group policies and individual plans.

- Gastric bypass and adjustable gastric bands were listed as medically appropriate procedures.
- Positions varied across carrier regarding gastric sleeve and biliopancreatic diversion with or without duodenal switch.
- The individual plans offered by two carriers either exclude coverage or report no coverage for bariatric surgery.
- One carrier reported bariatric surgery coverage for 100 percent of its members.
- In 2010 the carrier approved 95 percent of gastric bypass and 92.7 percent of all requests for bariatric surgery.
- There is evidence that surgery requests submitted under claims with explicit exclusions for bariatric surgery or gastric bypass may still be approved by a carrier. One such carrier approved 53.8 percent of bariatric surgery and 62.5 percent of gastric bypass requests.

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.

Gastric bypass is considered an acceptable method for weight loss for individuals meeting the selection criteria described in the background. The extent to which gastric bypass surgery is considered a "necessary" health care treatment depends on the stakeholder. In either case, gastric bypass is regarded as an effective surgical method for reducing weight and obesity-related morbidity and mortality rates.

A variety of factors influence whether a person would undergo gastric bypass surgery. Access is limited to persons meeting the specified guidelines for adult weight, weight loss history, and commitment. The potential patient also must not meet exclusion criteria or have medical contraindications. [227] For those who are eligible and wanting to pursue surgery, willingness and ability to pay is a key determinant for receiving surgery. Surgery would be unlikely to be provided in the absence of an individual's willingness to pay for the procedure. In some cases, patients may be able to arrange payment plans through the institution or practice offering the surgery or secure a loan. Payment options where a patient can spread payments for the cost of the procedure over an extended period of time could potentially lessen the potential for financial hardship and increase the likelihood that the person elects to undergo the procedure.

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[225] Public Health Committee. File No. 338. Bill No. SB579. PH Date 3/13/2006. Report on bills favorably reported by committee. Title of Bill: An act concerning health insurance coverage for medical services and treatment for morbid obesity.

[226] Communication with Paul Lombardo, (reporting on response from Pat Levesque the manager of the Managed Care Program) Connecticut Insurance Department. January 24, 2011.

[227] Mechanick JI, Kushner RF, Sugerman HJ, *et al.* 2008. AACE, TOS and ASMBS' Medical Guidelines for Clinical Practice for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric patient. *Endocor Pract.* 2008;12(Suppl 1).nutritional, metabolic, and nonsurgical support of the bariatric patient. (2008)

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 the ASMBS, the average cost of bariatric surgery in 2009 was $14,000-26,000.[228] The northeast region in the U.S. is generally regarded as being towards the higher end of the cost range. Assuming a gastric bypass surgery cost of $25,000 paying for gastric bypass surgery would consume half the annual income of a family earning $50,000 and one-fourth the income of a family earning $100,000. Even if a health plan covered 80 percent of the cost of gastric bypass surgery, a covered family with an annual income of $50,000 needs to pay 10 percent of their income. Assuming a patient wishes to obtain gastric bypass surgery, the amount that must be covered by the patient may be perceived as a financial hardship even with health insurance coverage.

Some financial burdent by be offset under federal tax filings since the cost of surgery to treat weight related illness is a deductible medical cost. The amount of the surgery expense that exceeds 7.5 percent of the Adjusted Gross Income (AGI) can be deducted. To deduct the weight loss surgery expense, the treatment must be for a specific disease diagnosed by a physician (such as obesity, hypertension, or heart disease).[229]

One recent survey explored the willingness to pay (using contingent valuation methods) for gastric bypass procedures among a privately insured population likely to qualify for bariatric surgery. Participants were asked to rank how likely they would be to undergo gastric bypass or lap-band surgery in the next 5 years under different out-of-pocket cost arrangements. 25.8 percent of participants reported an 80 percent or higher likelihood that they would undergo gastric bypass in the next five years whereas reported likelihoods fell to 10.9 percent at out-of-pocket costs of $25,000. Based on the survey the estimated bariatric surgery demand curve shows: 1) decreasing out of pocket costs from $25,000 to $10,000 results in a small increase in the number of surgeries demanded; and 2) demand is more responsive to changes in out-of-pocket costs when costs are lower than $10,000.[230]

Another study found that extension of insurance coverage for bariatric surgery did not increase utilization. As suggested by the authors, the lack of an observed increase in utilization may have been influenced by the $5,000 cost-sharing requirement, the economic downturn, not meeting the criteria for surgery, or other factors not related to insurance.[231]

6. The level of public demand and the level of demand from providers for gastric bypass surgery.

Please refer to the response under Section IV, Social Impact #7 (IV-7), below.

7. The level of public demand and the level of demand from providers for insurance coverage for gastric bypass surgery.

Public hearing testimony indicates some public and provider demand for gastric bypass for weight loss and health insurance coverage for the procedure. At a public hearing on March 13, 2006 regarding SB-579: An Act Concerning Health Insurance Coverage for Medical Services and Treatment for Morbid Obesity, anecdotal testimonies were given by over a dozen individuals who received gastric bypass. These individuals generally noted the success of gastric bypass in helping them lose weight, gain independence, and reduce

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[228] http://www.asmbs.org/Newsite07/media/ASMBS_Metabolic_Bariatric_Surgery_Overview_FINAL_09.pdf

[229] Internal Revenue Service. 2010. Publication 502: medical and dental expenses. Available at: http://www.irs.gov/pub/irs-pdf/p502.pdf. Accessed February 23, 2011.

[230] Finkelstein EA, Brown DS, Avidor Y, *et al.* 2005. The role of price, sociodemographic factors, and health in the demand for bariatric surgery. The American Journal of Managed Care 11: 630-637.

[231] Kim K, White V, Buffington CK. 2010. Utilization rate of bariatric surgery in an employee-based healthcare system following surgery coverage. Obes Surg. 20: 1575-1578.

comorbidities. Most of the individuals also noted the importance of having a good health insurance policy that covered weight loss surgery.

The Commissioner of the Department of Public Health and the Executive Director of the Permanent Commission on the Status of Women reported on the decreases in mortality and morbidity for patients undergoing bariatric surgery and the high medical costs attributable to obesity in Connecticut.[232] In addition, a bariatric surgeon, a surgical director, a representative of the Connecticut Advanced Practice Nurse Society, and a testimony endorsed by the Connecticut State Medical Society supported the use of gastric bypass surgery and related insurance coverage. Similar testimonies were submitted for an additional bill SB-552: An act concerning health insurance coverage for medical services and treatment for morbid obesity and prosthetic devices. Nearly all of the testimonies submitted during the 2006 legislative session public hearings on SB 579 and SB 552 mentioned the importance of insurance coverage for gastric bypass surgeries. [233]

Although public hearing testimony generally reflects support for insurance coverage for gastric bypass surgery, the level of demand for coverage on the part of the general public and broader provider population may differ. Surveys of individuals identified as potentially qualified for weight loss surgery suggest that even at zero cost, only about one out of four individuals indicated an 80 percent or greater chance that they would undergo the surgery in the next five years.[234] Furthermore, in some states where gastric bypass was added or under consideration as a state employee health benefit, public opposition was voiced with regard to expending public dollars for gastric bypass.[235]

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

As of May 2010, the National Association of Insurance Commissioners identified Maryland, New Hampshire, Indiana, and Virginia as states with mandates either requiring inclusion of coverage or offers of coverage for the surgical treatment of morbid obesity.[236] In addition, CPHHP identified a statute from Georgia where insurers are explicitly granted the authority to offer coverage for morbid obesity."[237] Excerpts from each statute are provided below.

Maryland: Individual or group contracts issued or delivered in the State by insurers and nonprofit health service plans, health maintenance organizations and managed care organizations...

> ...shall provide coverage for the surgical treatment of morbid obesity that is (1) recognized by the National Institutes of Health as effective for the long-term reversal of morbid obesity; and (2) consistent with guidelines approved by the National Institutes of Health…An entity subject to this section shall provide the benefits required under this section to the same extent as for other medically necessary surgical procedures under the enrollee' or insured's contract or policy with the entity.[238]

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[232] Connecticut General Assembly. Report on Bills Favorably Reported By Committee Public Health Committee. SB-579. March 13, 2006. An act concerning health insurance coverage for medical services and treatment for morbid obesity.

[233] *Ibid.*

[234] Finkelstein EA, Brown DS, Avidor Y, *et al.* 2005. The role of price, sociodemographic factors, and health in the demand for bariatric surgery. *The American Journal of Managed Care* 11: 630-637.

[235] Employee Retirement System of Texas. 2010. Developing a cost-neutral or cost-positive plan for providing bariatric surgery coverage for eligible employees in the group benefits program. A study and recommendation by the Employees Retirement System of Texas.

[236] NAIC Compendium of State Laws on Insurance Topics. National Association of Insurance Commissioners. May 2010.

[237] Georgia Code Ann. § 33-24-69.7

[238] Maryland Code of Insurance § 15-839.

New Hampshire: Individual and group health policies...

> ...shall provide…coverage for the diseases and ailments caused by obesity and morbid obesity and treatment for such, including bariatric surgery, when the prescribing physician has issued a written order stating that treatment is medically necessary and in accordance with the patient qualifications and treatment standards set forth by the American Society for Metabolic and Bariatric Surgery or the American College of Surgeons. Such treatment standards may include, but not be limited to, pre-operative psychological screening and counseling, behavior modification, weight loss, exercise regimens, nutritional counseling, and post-operative follow-up, overview, and counseling of dietary, exercise, and lifestyle changes. The covered insured shall be at least 18 years of age. The benefits included in this section shall be subject to the terms and conditions of the policy and shall be no less extensive than coverage provided for similar conditions or illnesses. [239]

Virginia: Individual or group policies offered by insurers or corporations and health maintenance organizations...

> ...shall offer and make available coverage under any such policy, contract or plan for the treatment of morbid obesity through gastric bypass surgery or such other methods as may be recognized by the National Institutes of Health as effective for the long-term reversal of morbid obesity…The reimbursement for the treatment of morbid obesity shall be determined according to the same formula by which charges are developed for other medical and surgical procedures. Such coverage shall have durational limits, dollar limits, deductibles, copayments and coinsurance factors that are no less favorable than for physical illness generally. Standards and criteria, including those related to diet, used by insurers to approve or restrict access to surgery for morbid obesity shall be based upon current clinical guidelines recognized by the National Institutes of Health.[240]

Indiana:

> An insurer that issues an accident and sickness insurance policy shall offer coverage for nonexperimental, surgical treatment by a health care provider of morbid obesity: (1) that has persisted for at least five (5) years; and (2) for which nonsurgical treatment that is supervised by a physician has been unsuccessful for at least six (6) consecutive months.(b) An insurer that issues an accident and sickness insurance policy may not provide coverage for a surgical treatment of morbid obesity for an insured who is less than twenty-one (21) years of age unless two (2) physicians licensed under IC 25-22.5 determine that the surgery is necessary to: (1) save the life of the insured; or (2) restore the insured's ability to maintain a major life activity (as defined in IC 4-23-29-6); and each physician documents in the insured's medical record the reason for the physician's determination.[241]

Georgia: This Code, known as the 'Morbid Obesity Anti-Discrimination Act' presents the General Assembly findings and declares support for insurance coverage for and treatment of morbid obesity. The statute also states that...

> Every health benefit policy that is delivered, issued, executed, or renewed in this state or

[239] New Hampshire Revised Statute § 415:6-o and 415:18-t. Coverage for obesity and morbid obesity.

[240] Virginia Code Ann. § 38.2-3418.13.

[241] Indiana Code § 27-8-14.1 Chapter 14.1. Coverage for Services Related to Morbid Obesity.

approved for issuance or renewal in this state by the Commissioner on or after July 1, 1999, which provides major medical benefits may offer coverage for the treatment of morbid obesity.[242]

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

Thirty states require a fiscal note or an additional review process for any new required health insurance benefit prior to enactment.[243] Searches and inquiries focused on states that have or had an established process for studying mandated health insurance benefits, with a relatively large number of mandated health benefits, or located in the Northeast. States searched included Arkansas, California, Colorado, Indiana, Louisiana, Maine, Maryland, Massachusetts, Minnesota, New Jersey, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Texas, Virginia, Washington, and Wisconsin. CPHHP identified several mandated benefit reviews from Maryland regarding surgical treatment of morbid obesity. The other state with a report related to insurance coverage for surgical treatment of morbid obesity was Texas. The type of coverage evaluated in the Texas report is applicable only to group health benefit plans for State employees, not for fully insured group or individual policies. Findings from the reports identified are summarized in this section. In addition, a fact sheet published by the Connecticut Department of Health which highlights some of the social impacts of obesity in the state is also summarized.

Maryland Health Care Commission

Study of Mandated Health Insurance Services: A Comparative Evaluation (January 2008)

> As part of a larger evaluation, the MHCC surveyed the extent to which the self-funded market voluntarily covers surgical treatment of morbid obesity. MHCC found voluntary compliance for half of the self-funded market. The report further suggests that the 75 percent of the cost of surgery for morbid obesity would be covered without the mandate. After adjusting for the level of coverage in the self-funded market, the reported marginal cost was 0.2 percent of premiums.[244]
>
> Bariatric Surgery-Actuarial Analysis-Small Group Market: For the small group market, MHCC estimates an increase in bariatric surgery utilization of 28.3 percent to 124.5 percent. The MHCC also noted that potentially 6 to 9 percent of Maryland adults were morbidly obese, the broad negative health implications of obesity, the apparent effectiveness of weight loss surgery based on the medical literature, and a large public demand for weight loss surgery. The report also noted that the sample of the largest self-funded employers and self-funded organized labor groups surveyed generally provided coverage.[245]

Employees Retirement System of Texas (ERS)

The report provides an overview of obesity prevalence, the impact of obesity on health and health care costs, the risks of bariatric surgery and existing coverage for bariatric surgery under state and federal programs,

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[242] Georgia Code-Insurance-Title 33, Section 33-24-59.7.

[243] National Conference of State Legislatures. 2009. Health insurance coverage mandates: Are they too costly? Presentation at the Louisiana Department of Insurance 2009 Annual Health Care Conference. Available at: http://www.ncsl.org/portals/1/documents/health/MandatesCauchi09.pdf. Accessed May 7, 2010.

[244] Maryland Health Care Commission. 2008. Study of mandated health insurance services: a comparative evaluation. Available at: http://mhcc.maryland.gov/health_insurance/mandated_1207.pdf. Accessed February 23, 2011.

[245] Maryland Health Care Commission. 2008. Bariatric surgery actuarial analysis for the small group market. Available at: http://mhcc.maryland.gov/smallgroup/bariatricsurgery.pdf. Accessed February 23, 2011.

mandates or government employee health plans. The crux of the report projects the potential impact of an articulated set of benefits related to bariatric surgery. ERS projects that 1 to 5 percent of the morbidly obese population (which was estimated at 6-8 percent of the workforce) would become surgery patients per year with 97 percent undergoing laparoscopic procedures and the remaining 3 percent undergoing open surgery at an average cost of $13,000 (the maximum benefit stated in the proposed policy) for a total annual cost of $1.4 to $6 million per year (including costs related to 1 month pre-surgery and 2-months post-surgery). Based on available claims data and a methodology used by Cremieux, et al, ERS estimates that the 24 months as the average minimum time before surgery costs are offset by post-surgery savings.[246]

Connecticut Department of Public Health

Although not a mandated benefit review, the State Department of Public Health has published fact sheets on obesity in Connecticut. Information on prevalence, comorbidity and the economic impact of obesity is summarized using data up through 2003-2004. Facts presented show a higher prevalence of comorbid conditions such as hypertension, arthritis and diabetes were experienced by Connecticut adults who were obese compared to adults with a healthy weight. The positive correlation between body mass index and arthritis, diabetes, and hypertension for Connecticut adults is also presented.[247]

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

Bariatric surgery may be considered when typical intervention (i.e. drug therapy, low-calorie diets, dietary counseling, behavioral modification therapy, exercise) does not lead to adequate weight loss or resolution of obesity-related comorbidities. There are seven commonly accepted bariatric surgeries. A detailed description of two procedures (laparoscopic adjustable gastric banding (LAGB) and sleeve gastrectomy are provided in the background. These procedures represent the other bariatric procedures reported by accredited bariatric programs as available. Notably, some health plans may consider sleeve gastrectomy as unproven and thus not covered.

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 purpose of bariatric surgery, including gastric bypass, is to promote dramatic weight loss when other strategies have failed as a means to resolve medical issues related to clinically severe obesity. As described in the background, severe obesity substantially increases the risk for physical conditions and comorbid chronic diseases. Gastric bypass has been associated with dramatic weight loss and resolution of a number of severe medical conditions. To the extent that use of gastric bypass follows the guidelines established for bariatric procedures, the proposed mandate addresses the medical need of reducing the risk of complications related to obesity. The intent of gastric bypass is not for use simply to promote weight loss and change appearance.

Insurance is used to provide a financial safety net for times when an unexpected event with high cost occurs. Instead of potentially experiencing the uncertainty of potential financial losses related to incidents such as sickness, injury or accident, people often elect to pay a certain premium for protection if such an event were to occur. Through premiums, the cost of incidents that do occur is spread across all premium payers, rather than an individual bearing the cost. Gastric bypass surgery is a very high cost procedure with the medical potential for reducing morbidity and mortality related to clinically severe obesity. It has been estimated that

[246] Employee Retirement System of Texas. 2010. Review, discussion and consideration of the health insurance plans under the Texas Employees Group Benefits Program. Available at: http://www.ers.state.tx.us/calendar/board/documents/20100525_19f_bariatricsurgery_agenda.pdf. Accessed February 23, 2011.

[247] Connecticut Department of Public Health. The obesity challenge in Connecticut. Available at: http://www.ct.gov/dph/lib/dph/Obesity_FactSheet.pdf. Accessed February 23, 2011.

the cost of covering gastric bypass surgery could be recouped in as little as two years given certain coverage parameters.

Whether requiring coverage for gastric bypass is consistent with the concept of insurance could be debated. To some extent, this debate is reflected in the changing parameters for bariatric surgery coverage under insurance policies over time as described under Section IV: Social Impact #3. Since the insurer/MCO policy language submitted to CPHHP does not specify how the benefit would be administered, it is assumed that the proposal is consistent with the concept of managed care and the use of benefit design strategies such as co-insurance, deductibles, and preauthorization would be permitted to manage the cost of the benefit.

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.

It is possible that a comparable mandated benefit could be proposed for other types of bariatric surgeries or for alternative treatments for extreme obesity such as physical exercise programs, diet-related programs, or counseling. Future mandates may extend benefits to overweight or less-obese (Class I and Class II) individuals. It is also possible that mandated benefits may extend the use of gastric bypass for the treatment of conditions other than obesity, such as diabetes.

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

The Ingenix Consulting actuarial report anticipates that "an incremental cost increase of 0.5% is not likely to be highly noticeable during a period when health plans increase in premium cost [is] approximately 8% to 10% per year." The average change in cost due to the predicted increase in bariatric surgery claims following a coverage mandate will be less than 0.2 percent of the average monthly premium according to Ingenix Consulting. This cost is likely to continue to increase for several years due to a period of increased utilization as a result of pent up demand. However, given the size of the increase, it is not expected that other benefits will be noticeably impacted as a result of the mandate. Notably, in the longer run, some research suggests that reduction in comorbid conditions following surgery may result in a level of reduced medical costs that offsets the cost of the surgery, associated complications and postoperative medical interventions such as routine nutrition supplements within two to nine years.

In a case where the premium increases are noticeable, individuals and groups may respond by purchasing a lower level of coverage with increased member cost-sharing, which is referred to as a "benefit buy-down." Increased member sharing may result in benefits becoming less accessible for certain populations due to higher copays. There is some concern that high cost-sharing may lead to individuals foregoing necessary medical services or high-benefit preventive services.

For addition description of the effect of mandates on the availability and cost of health insurance refer to Section II.6 of the Ingenix Consulting report located in Appendix III.

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.

The Ingenix Consulting actuarial report suggests that on average self-funded plans in the U.S. cover bariatric surgery. Surveys of self-funded employers in other states generally report some level of coverage for bariatric surgery, especially among labor pools and the largest of employers. In one state, about half of self-funded plans covered bariatric surgery. The responses from the survey of Connecticut-domiciled insurers/MCOs did not indicate the level of coverage available for the self-funded plans they administer.

As described in the preceding response (Section IV: Social Impact #13), the cost increase expected from

a bariatric surgery mandate is not likely to be highly noticeable within the broader context of medical inflation. Employer decision to shift to self-funded from fully insured are influenced by a variety of factors. A major component of that decision relates to the profit charges and the premium tax which are costs that must be paid for fully-insured groups and individual health policies. Self-funded groups are exempt from these premium taxes, (1.75 percent of premium) and pay less in profit charges. As described by Ingenix Consulting,

> The largest self-funded groups are able to exert considerable leverage on the level of administrative fee that the insurer charges them to administer their self-funded business. It is likely that these large group economies of scale play a much more important role in the growth and size of the self-funded sector than does opposition to mandates.

Self-funded groups are also exempt from the purview of state mandated health benefits. Even so, as described in the CPHHP report on existing mandates, the majority of self-funded employers voluntarily cover the health benefits required of fully-insured group plans. Within the context of benefits offered to keep a competitive edge, switching to self-funded may not translate into the employer offering less of the mandated benefits or substantially decreasing premium costs as a result of being exempt from state health benefit mandates.

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

As reported in an interview with the State of Connecticut Comptroller's Office, the state employee medical plans cover surgical treatment for the treatment of morbid obesity, which includes gastric bypass. Coverage is subject to documentation of medical necessity and utilization review.[248] As one of the available policies states,"The surgical treatment or hospitalization for the treatment of morbid obesity, except when determined to be medically necessary" are "not covered services…except when approved…as part of case management."

Policy language also suggests that except when approved as part of case management, care, treatment, procedures, services or supplies that are primarily for dietary control including, but not limited to, any exercise or weight reduction programs, whether formal or informal, and whether or not recommended by a physician or provider."

The proposed mandate language submitted for review does not specify parameters for benefit design or participant eligibility related to gastric bypass thus it is assumed that the state employee health plans are already consistent with the proposal. Of note, as a self-funded group, the health plans administered for State of Connecticut employees are exempt from state health benefit mandates under the federal Employee Retirement Income Security Act (ERISA). The switch from fully-insured group health plans to self-funded health plans became effective July 1, 2010.

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

As described in the medical literature for bariatric surgery, gastric bypass as a specific type of bariatric surgery has been documented as safe and effective. Numerous guidelines and systematic reviews refer to gastric bypass as the gold standard for bariatric surgery. Gastric bypass is commonly noted for the high rates of percent excess weight loss and substantial reductions in comorbid conditions observed following surgery.

[248] Personal communication. Scott Anderson and Helen Sullivan, Comptroller's Office. February 15, 2010.

The following are findings summarized in a 2008 systematic review of the literature published in the AACE/TOS/ASMBS Bariatric Surgery Guidelines:[249]

- Excess weight loss of 48-85 percent at 1-2 years and 25-68 percent after 7-10 years
- Prevalence of metabolic syndrome decreases
- Insulin sensitivity improved by 5 months post op
- Remission of T2DB by 83-92%.

In most cases, when compared to other types of bariatric surgery, the improvements observed for gastric bypass are significantly greater. However, a higher risk of complications is also commonly associated with gastric bypass with mortality rates. Findings from a U.S. Academic Medical Center cohort study which includes 29 medical centers, found a compliation rate of 16 percent, an anastomotic leak rate of 1.6 percent, a 30-day readmission rate of 6.6 percent and a 30-day mortality rate of 0.4 percent.[250] Similarly, a 15-year study of surgeries in a French hospital reports a mortality rate of 0.5 percent for bariatric surgery. [251]

V. Financial Impact

1. The extent to which the mandated health benefit may increase or decrease the cost of gastric bypass surgery over the next five years

The Ingenix Consulting actuarial report suggests that in the initial year of the mandate, the total premium increase for the mandate would be less than 0.2 percent of the premium or 0.61 PMPM. For each subsequent year, the expected increase in cost assumes a 15 percent utilization increase and a 5 percent trend increase. By 2015, the premium cost attributable to the mandate is projected at $1.27 for the premium cost (which equals the paid medical cost plus retention).

The unit cost of bariatric surgery and gastric bypass has been decreasing in recent years.[252] To a large extent, this decrease is attributed to the shift towards laparoscopic from open surgery for gastric bypass and the shift toward LAGB from gastric bypass. LAGB is often conducted in an outpatient setting and when conducted on an inpatient basis the stay is often less than 24 hours compared to an approximate two day stay for gastric bypass. The shift to laparoscopic surgery from open surgery has lead to a reduction of complications and thus shorter hospitalizations resulting in lower costs. Other research suggests that surgeries conducted in Centers of Excellence or high volume surgery centers compared to low volume surgery centers are associated with lower rates of complications and lower costs.[253] Proficiency at the provision of bariatric surgery, as evidenced by the number of surgery completed, has been shown to be a predictor of complications. If Connecticut has an inadequate supply of bariatric surgeons for the increase in demand, surgeons with less experience may begin conducting procedures which may in turn lead to higher complication rates and higher unit costs.

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

[249] Mechanick JI, Kushner RF, Sugerman HJ, *et al.* 2008. AACE, TOS and ASMBS' Medical Guidelines for Clinical Practice for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric patient. *Endocor Pract.* 2008;12(Suppl 1).

[250] Nguyen NT, Silver M, Robinson M *et al.* 2006. Results of a national audit of bariatric surgery performed at academic centers: a 2004 University Health System Consortium Benchmarking Project. Arch Surg. 2006 May; 14(5): 445-9; discussion 449-50.

[251] Chevallier JM. 2010. From bariatric to metabolic surgery: 15 years experience in a French university hospital. Bull Acad Natl Med. 194(1): 25-36; discussion 36-8.

[252] Zhao Y, Encinosa W. Bariatric surgery utilization and outcomes in 1998 and 2004. Statistical Brief #23. January 2007. Agency for Healthcare Research and Quality. Rockville, MD. http://www.hcup-usahrq.gov/reprts/statbriefs/sb23.pdf.

[253] Encinosa WE, Bernard DM, Du D, Steiner CA. Recent improvements in bariatric surgery outcomes. *Medical Care.* 2009; 47:531-535

years.

The research on changes in utilization following the introduction of insurance coverage for bariatric surgery suggests minimal changes in utilization. One study looks at the extension of coverage by the Florida Hospital Healthcare System (FHHS) to employees of the eight hospitals and insured family members.[254] Despite the introduction of insurance coverage, the rate of utilization among employees potentially eligible for surgery did not increase. Prior to the coverage policy, 1.7 percent of the bariatric eligible received surgery compared to 1.4 percent of the bariatric eligible population in the year after coverage was implemented.[255]

A subsequent report by the Maryland Healthcare Commission (MHCC) documents a declining annual growth rate for inpatient bariatric surgeries in Maryland from 2001 to 2006. 2001 marked the introduction of coverage for bariatric surgery as a mandated benefit in the state and the extension of coverage under Medicare and Medicaid. The annual rate of change (which includes the self-funded groups not subject to the mandate) was greatest from 2001-2002 (92 percent) followed by a steady decrease.[256] The percent change for subsequent years was 57.0, 36.1, 16.8, and 1.0 for 2002-2003, 2003-2004, 2004-2005 and 2005-2006 respectively. There are several potential factors involved in the observed decrease in the annual growth rate. The summary provided in the MHCC report, describes it as follows, "First, as a medical intervention becomes more broadly available, the rate of growth slows even as the number of individuals receiving the intervention continues to increase. Second, treatment of the condition has begun to migrate to the outpatient setting."[257] This is especially the case with the LAGB procedure, for which the FDA approved the Lap-Band device in 2001.

3. The extent to which gastric bypass surgery may serve as an alternative for more expensive or less expensive treatment, service or equipment, supplies or drugs, as applicable.

National guidelines recognize bariatric surgery as a potential strategy for a select population (described in the background) when medical (non-surgical) interventions such as diet, dietary counseling, behavioral modification therapy, exercise, and weight loss programs have not led to successful weight loss and maintenance.[258] The success of bariatric surgery is generally evaluated in terms of related weight loss and surgery-related complications or necessary follow-up care. Gastric bypass is considered the gold standard for bariatric surgery and is the most common type of bariatric surgery in the United States and internationally.[259] In comparison to other restrictive weight loss procedures, gastric bypass results in greater success in terms of immediate and longer-term weight loss.[260] Although more successful at generating weight loss, the risk of complications and the types of follow-up care related to surgery tend to be greater than restrictive surgical

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[254] To be eligible for coverage, employees needed to have two years of consecutive coverage under the FHHS system, a previous medically supervised diet, and a copay of $5,000. The basis for qualification for surgery included meeting all the parameters outlined by the National Institutes of Health and those specified by the Florida Hospital COE program. The age range to qualify for surgery was 18-65 with the standard BMI requirement.

[255] Kim K, White V, Buffington CK. Utilization rate of bariatric surgery in an employee-based healthcare system following surgery coverage. *Obes Surg* (2010) 20: 1575-1578.

[256] Maryland Health Care Commission. 2007. Update on the utilization review of the surgical treatment of morbid obesity. December 2007. Maryland Health Care Commission. 2008. Available at: http://mhcc.maryland.gov/legislative/morbidobesity0108.pdf. Accessed February 23, 2011.

[257] Maryland Health Care Commission. 2007. Update on the utilization review of the surgical treatment of morbid obesity. December 2007. Maryland Health Care Commission. 2008. page 8. Available at: http://mhcc.maryland.gov/legislative/morbidobesity0108.pdf. Accessed February 23, 2011.

[258] Bray GA. 2010. Overview of therapy for obesity in adults. UpToDate Online 18.3. Last literature review version 18.3: September 2010. This topic last updated: January 22, 2010.

[259] Tice JA, Kartiner L, Walsh J, *et al.* 2008. Gastric banding or bypass? A systematic review of comparing the two most popular bariatric procedures. *The American Journal of Medicine* 121(10).

[260] Pories WJ. 2008. Bariatric surgery: risks and rewards. *The Journal of Clinical Endocrinology & Metabolism* 93(11): S89-S86.

alternatives such as the laparoscopic adjustable gastric band (LAGB or lap-band).[261]

A 2009 evidence based review by Farrell and colleagues compares the relative risk and benefits of gastric bypass, LAGB and BPD. For reference, the results of their analysis are in Table 4.3. Each procedure is ranked as 1, 2, or 3 where 1 indicates the mandate with the relative position for the specified risk or benefit.[262]

Table 4.3. Summary of Relative risks and benefits of laparoscopic bariatric surgical procedures[263]

	Gastric bypass	Adjustable band	BPD
Benefits			
Most effective durable weight loss*	2	3	1
Least chance of inadequate weight loss*	2	3	1
Best comorbidity resolution*	2	3	1
Durable weight loss despite poor patient compliance	2	3	1
Risks			
Least perioperative risk*	2	1	3
Best procedure for avoiding reoperation due to:			
Technical complications—early	2	1	3
Technical complications—late*	2	3	1
Metabolic complications—late	2	1	3
Other			
Most reversible	3	1	3
Fewest outpatient visits needed	1	3	2
Fewest unintended metabolic consequences of poor follow-up	2	1	3

According to the review, BPD is associated with the highest level of benefit followed by gastric bypass and then LAGB with regard to durable weight loss, the best comorbidity resolution, the least chance of inadequate weight loss, and durable weight loss despite poor compliance with lifestyle changes following surgery. However, BPD also poses the highest perioperative risk and receives the lowest rank (3) in terms of avoiding early technical complications and late metabolic complications. On the other hand, gastric bypass receives the next highest ranking in terms of benefits and at lower risk than BPD.

The analysis of outcomes from bariatric surgeries conducted over a 15 year period at a hospital in France illustrates the increased risk associated with more effective bariatric procedures. Chevallier (2010) found that excess weight loss at two years for LAGB, gastric sleeve, gastric bypass and BPD respectively is 49%, 56%, 63.3% and 73.3% and the mortality rates are 0.1%, 0.15%, 0.5% and 0.8%.[264]

4. The methods that will be implemented to manage the utilization and costs of gastric bypass

[261] *Ibid.*

[262] Farrell TM, Haggerty SP, Overby DW, *et al.* 2009. Clinical application of laparoscopic bariatric surgery: an evidence-based review. *Surg Endosc* 23: 942.

[263] *Ibid.*

[264] Chevallier JM. 2010. From bariatric to metabolic surgery: 15 years experience in a French university hospital. *Bull Acad Natl Med.* 194(1): 25-36; discussion 36-8.

surgery.

This review evaluates the impact of "an expansion of coverage for gastric bypass surgery." No additional language for the proposed health benefit was received. Therefore, it is assumed that health plan carriers may continue to use benefit design and patient selection criteria to manage the utilization and costs related to gastric bypass surgery as they would in the absence of a related mandate. The primary difference would be that if gastric bypass had been an excluded procedure or obesity an excluded diagnosis, gastric bypass procedures would no longer be deniable based on these criteria.

Patient selection criteria generally reflect the components defined in the ASMBS and other national guidelines related to bariatric surgery. In some cases, BMI and comorbidity guidelines are more stringent than those specified in guidelines from professional medical organizations. For example, as summarized by Employee Retirement Services of Texas, Blue Cross Blue Shield of Texas Medical Policy Guidelines require medical documentation of a five-year history of morbid obesity, participation in a non-surgical comprehensive weight loss program for twelve consecutive months prior to applying for predetermination of coverage, participation in a medically supervised lifestyle management program for twelve months following surgery and a BMI of ≥40 with at least one comorbidity that is uncontrolled via "maximum medical management, and which is generally expected to be reversed or improved by bariatric treatment."[265]

Benefit design components may also require predetermination and preauthorization prior to surgery, restriction on where and which providers may provide surgery (e.g. Centers of Excellence, "in-network" providers), a maximum lifetime benefit of one bariatric surgery, a maximum surgery benefit (e.g. $13,000 paid cost), a separate deductible for bariatric surgery ($5,000), and co-insurance (e.g. 20 percent of the costs related to surgery). For example, under the bariatric surgery coverage proposed for the HealthSelect plan in Texas, coverage allows for one bariatric surgery per lifetime for a maximum covered amount of $13,000. The patient must pay a separate $5,000 deductible for the surgery plus 20 percent of the total charges related to the surgery. [266]

Additional examples of benefit plan design are described in the response to Social Impact, response #2. As described, Medicare provides coverage for bariatric surgery as it relates to an uncontrolled comorbidity that is expected to resolve with the treatment of obesity. Furthermore, the Medicare plan design also limits coverage to surgeries performed at an authorized Center of Excellence (COE). To become a COE, a certain threshold of bariatric procedures must be completed. The underlying rationale is that institutions and surgeons with higher levels of experience in bariatric surgery have lower rates of complications during or after surgery. A recent study analyzing error rates before and after the COE requirement, reflect an association between the COE requirement and a reduced rate of complication.[267] Potentially, the use of COEs may reduce the charges associated with bariatric surgery.

5. The extent to which insurance coverage for gastric bypass surgery may be reasonably expected to increase or decrease the insurance premiums and administrative expenses for policyholders.

Insurance premiums are comprised of carrier paid medical claims and retention. Retention includes administrative expenses and profit/reserves. Ingenix Consulting projects an average increase in premiums of $0.61 PMPM for employers with fully insured group plans of which $0.50 PMPM is for paid medical costs and $0.11 PMPM for retention. The projected increase for individual health plans is $0.44 PMPM

[265] Employee Retirement System of Texas. 2010. Developing a cost-neutral or cost-positive plan for providing bariatric surgery coverage for eligible employees in the group benefits program. A study and recommendation by the Employees Retirement System of Texas.

[266] *Ibid.*

[267] Nguyen NT, Paya M, Stevens M, *et al.* 2004. The relationship between hospital volume and outcome in bariatric surgery at academic medical centers. *Ann Surg.* 2004 October; 240(4): 586-594.

of which $0.34 PMPM is for paid medical costs and $0.10 PMPM is for retention. The estimated increase projected for covering bariatric surgery represents less than 0.2 percent of the total monthly premium paid.

There is some evidence that improvement or resolution of comorbidities in bariatric surgery patients lead to a decrease in related pharmaceutical and medical care. Over time, these cost-savings may reduce the burden of the surgery cost provided that the cumulative savings are not outpaced by the need for routine nutritional therapy, follow up care or treatment of surgery complications.

6. The extent to which gastric bypass surgery 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.

On average, gastric bypass is generally reported to be a more expensive procedure than LAGB. Although the procedure costs more, gastric bypass is also considered more effective. Campbell and colleagues (2010) compared the cost-effectiveness of LAGB and gastric bypass with consideration of likelihood of changes in BMI, the probability of improvements and cost-savings related to improving comorbid conditions, treatment-related adverse events, probability of surgery reversal, survival and health-related quality of life. The probabilities used in the model were based on published research. Cost-effectiveness was measured in terms of the incremental cost-effectiveness ratio (ICER) of a given procedure compared to not having the procedure. The ICER is expressed as the long-term cost per quality-adjusted life years (QALY) gained as a result of the bariatric surgery. Campbell and colleagues (2010) found neither approach to be cost-saving but both approaches to be cost-effective with costs of less than $15,000 per QALY. The cost-effectiveness of these bariatric procedures compare favorably with other cost-effectiveness studies for the use of major surgeries for the treating chronic conditions.[268]

7. The impact of insurance coverage for gastric bypass surgery 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.

The total cost of health care is understood to be the funds flowing into the medical system, which are the medical costs of insurance premiums and cost sharing. According to Ingenix Consulting, the potential increase in health care spending for requiring bariatric surgery coverage in 2011 would be $8,500,745, of which $8,019,571 is for insurer/MCO paid medical costs and $481,174 represents cost-sharing paid out-of-pocket by bariatric surgery patients. Cost sharing represents 5.7 percent of the predicted increase in the total cost of health care for requiring bariatric surgery coverage.

The potential benefit to insurers may be an offset in paid medical claims over the lifetime of a bariatric patient. Published estimates on bariatric surgery related cost savings vary substantially due to differing approaches. Estimates comparing the use of specific medications before and after surgery or care related to a specific comorbid condition commonly show that costs related to the comorbid condition have often been reduced or eliminated to an extent greater than the initial cost of surgery. [269, 270] The range of available projections predicting return on investment for bariatric surgery range from 24 months to nine years

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[268] Campbell J, McGarry LJ, Shikora SA, *et al.* Cost-effectiveness of laparoscopic gastric banding and bypass for morbid obesity. *Am J Manag Care.* 2010; 16(7): e171-e187.

[269] Sampalis JS, Liberman M, Auguer S, *et al.* The impact of weight reduction surgery on health-care costs in morbidly obese patients. *Obes Surg.* 2004: 14: 939-47.

[270] Gallagher SF, Banasiak M, Gonzalvo, *et al.* The impact of bariatric surgery on the Veterans Administration healthcare system: a cost analysis. *Obes Surg.* 2003; 13:245-8.

depending on the type of procedure and model assumptions.[271, 272, 273] On the other hand, estimates that consider the broader possibility of long term health outcomes, fluctuations in BMI following surgery, and the cost impact of complications and follow-up care such as treatment of nutrient deficiencies have found bariatric surgery to be cost-effective but not cost saving.

The potential for cost-saving is higher for the employer than the insurer. Several researchers have documented improvements in worker productivity following bariatric surgery.[274, 275] One study found that obese workers had 87.8 percent the productivity of workers in general prior to surgery. Prior to surgery the median and mean work days lost for the prior year due to illness or injury was 33 days compared to a 3 days in the general population. Following surgery, workers missed 0-1 days.[276] The research suggesting cost-savings from improvements to worker productivity often face methodological limitations such as lack of a control group or reliance on self-reported data.

8. 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.

The average change in employer cost will be less than 0.2 percent the cost of the monthly premium. As described under Section IV: Social Impact #13, the impact of this increase in cost within the general trend of premiums rising by 8-10 percent is "unlikely to be highly noticeable" and thus unlikely to be the driving factor in "benefit buy downs" or decisions to drop coverage entirely.[277]

Generally speaking, small employers are more sensitive to the cost of health insurance. As described in the Ingenix Consulting actuarial report,

> 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.
>
> …A 15% increase in premium cost, all else equal, is expected to cause more small groups than large ones to drop health insurance coverage. 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.

Conversely, large groups could switch to a self-funded approach enabling them to avoid mandates if they wish and avoid premium tax. Given the small cost increase projected, this is not expected to occur. (Further discussion is available under Section IV: Social Impact #14).

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[271] Cremieux PY, Buchwald H, Shikora SA, *et al.* A study on the economic impact of bariatric surgery. *Am J Manag Care*. 2008; 14: 589-96.

[272] Finkelstein EA, Brown DS. A cost-benefit simulation of coverage for bariatric surgery among full-time employees. *Am J Manag Care*. 2005; 11: 641-6.

[273] Employee Retirement System of Texas. 2010. Developing a cost-neutral or cost-positive plan for providing bariatric surgery coverage for eligible employees in the group benefits program. A study and recommendation by the Employees Retirement System of Texas.

[274] Hawkins SC, Osborne A, Finlay IG, *et al.* Paid work increases and state benefit claims decrease after bariatric surgery. *Obesity Surgery* 17, 434-437.

[275] Ewing BT, Thompson MA, Wachtel MS, Frezza EE. A cost-benefit analysis of bariatric surgery on the South Plains region of Texas. *Obes Surg.* Published online: 18 September 2010.

[276] *Ibid.*

[277] Appendix III: Ingenix Consulting Report.

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 to the health care delivery system, as defined for this report, is comprised of paid medical costs, cost-sharing, administration fees and profit/reserves. Ingenix Consulting projected an increase to the overall cost to the health care delivery system of $10,320,213 for the proposed bariatric surgery mandate. Of the overall cost, $8,019,571 is for paid medical costs, $481,174 for cost sharing, and $1,819,468 for retention. Cost sharing paid out-of-pocket by bariatric surgery patients account for 4.7 percent of the overall cost increase.

Cost-shifting between private and public payers of health care coverage generally occurs when formerly privately insured persons, after enrolling in a public program or becoming un- or underinsured, require and are provided health care services. Cost-shifting also occurs when a formerly publicly funded service becomes the responsibility of private payers, which can result following enactment of a health insurance mandate. This scenario does not apply since the state does not fund gastric bypass or bariatric surgery for members of private health plans.

Most persons formerly covered under private payers lose such coverage due to a change in employer, change in employment status, or when private payers discontinue offering health care coverage as an employee benefit or require employee contributions to premiums that are not affordable. For this scenario, if a person is eligible and enrolls into Medicare or Medicaid, gastric bypass or bariatric surgery may be covered with public dollars.

Given the low predicted increase of 0.61 PMPM in monthly premiums associated with this mandate, it is unlikely that the mandate, taken individually, would have an impact on cost-shifting between private and public payers.

Although cost-shifting related to health care does not appear likely to occur, it is possible that the public payers in general and the broader economy may benefit due to a decrease in lost work days. Ewing, *et al.* (2010) conclude that for the South Plains region of Texas the decrease in lost work days could generate benefits to society far greater than the costs of paying for surgery. The authors' conclusion was based on a modeling approach exploring labor income lost, jobs lost or not sustained, indirect business taxes lost and output lost to the costs related to bariatric surgery.[278] Though limited by the lack of an adequate control group, a second study conducted in the United Kingdom also suggests that the mean weekly hours worked and engagement in paid work increase and state benefit claims decrease substantially following bariatric surgery.[279]

[278] Ewing BT, Thompson MA, Wachtel MS, Frezza EE. A cost-benefit analysis of bariatric surgery on the South Plains region of Texas. *Obes Surg.* Published online: 18 September 2010.

[279] Hawkins SC, Osborne A, Finlay IG, *et al.* Paid work increases and state benefit claims decrease after bariatric surgery. *Obesity Surgery* 17, 434-437.

Appendix I

Letter from the Insurance and Real Estate Committee dated July 22, 2010

State of Connecticut
GENERAL ASSEMBLY

Senator Joseph J. Crisco
CO-CHAIRMAN

Senator Joan V. Hartley, *Vice Chair*
Senator Sam S.F. Caligiuri, *Ranking Member*

Representative Steve Fontana
CO-CHAIRMAN

Representative Robert W. Megna, *Vice Chair*
Representative Tony D'Amelio, *Ranking Member*

INSURANCE AND REAL ESTATE COMMITTEE

July 22, 2010

Thomas R. Sullivan, Commissioner
State of Connecticut Insurance Department
P O Box 816
Hartford, CT 06141-0816

Dear Commissioner Sullivan,

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 that you seek the review of these proposed health benefits:

- an increase in coverage for prescription eye drops (as described in SB 92, File 24, from the 2010 General Assembly session)
- an increase in coverage for magnetic resonance imaging (MRI) (as described in SB 259, File 89, from the 2010 General Assembly session)
- an increase in coverage for Parkinson's disease and multiple sclerosis(MS) in clinical trials (as described in SB 260, File 247, of the 2010 General Assembly session)
- an expansion of coverage for neuropathic disorders associated with diabetes
- an expansion of coverage for gastric bypass surgery

Thank you for your attention to our request. We look forward to hearing from you and/or your designees this coming winter.

Best Regards,

Senator Joseph J. Crisco, Jr.
Co-Chair, Insurance & Real Estate Committee

Representative Steve Fontana
Co-Chair, Insurance & Real Estate Committee

2010 JUL 23 A 7:51

INSURANCE DEPARTMENT
STATE OF CONNECTICUT

Room 2800 L.O.B., 300 Capitol Avenue, Hartford, CT 06106-1591 ❖ Phone (860) 240-0510 ❖ FAX (860) 240-0027

Appendix II

Connecticut General Assembly

Bills

General Assembly

Raised Bill No. 92

February Session, 2010

LCO No. **607**

____SB00092APP__041310___

Referred to Committee on Insurance and Real Estate

Introduced by:
(INS)

AN ACT CONCERNING PRESCRIPTION EYE DROPS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 38a-492m of the 2010 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

Each individual health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 delivered, issued for delivery, amended, renewed or continued in this state, **[**on or after January 1, 2010,**]** that provides coverage for prescription eye drops, shall **[**not deny**]** provide coverage for: **[**a**]**

(1) A renewal of prescription eye drops when **[**(1)**]** (A) the renewal is requested by the insured less than thirty days from the later of **[**(A)**]** (i) the date the original prescription was distributed to the insured, or **[**(B)**]** (ii) the date the last renewal of such prescription was distributed to the insured, and **[**(2)**]** (B) the prescribing physician indicates on the original prescription that additional quantities are needed and the renewal requested by the insured does not exceed the number of additional quantities needed; and

(2) One additional bottle of prescription eye drops when (A) such bottle is requested by the insured or the prescribing physician at the time the original prescription is filled, and (B) the prescribing physician indicates on the original prescription that such additional bottle is needed by the insured for use in a day care center or school. Such additional bottle shall be limited to one every three months.

Sec. 2. Section 38a-518*l* of the 2010 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

Each group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 delivered, issued for delivery, amended, renewed or continued in this state, **[**on or after January 1, 2010,**]** that provides coverage for prescription eye drops, shall **[**not deny**]** provide coverage for: **[**a**]**

(1) A renewal of prescription eye drops when **[**(1)**]** (A) the renewal is requested by the insured less than thirty days from the later of **[**(A)**]** (i) the date the original prescription was distributed to the insured, or **[**(B)**]** (ii) the date the last renewal of such prescription was distributed to the insured, and **[**(2)**]** (B) the prescribing physician indicates on the original prescription that additional quantities are needed and the renewal requested by the insured does not exceed the number of additional quantities needed; and

(2) One additional bottle of prescription eye drops when (A) such bottle is requested by the insured or the prescribing physician at the time the original prescription is filled, and (B) the prescribing physician indicates on the original prescription that such additional bottle is needed by the insured for use in a day care center or school. Such additional bottle shall be limited to one every three months.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*January 1, 2011*	38a-492m

Sec. 2	*January 1, 2011*	38a-518*l*

INS *Joint Favorable*

APP *Joint Favorable*

General Assembly **Substitute Bill No. 259**

February Session, 2010 *____SB00259APP__042610___*

AN ACT CONCERNING INSURANCE COVERAGE FOR MAMMOGRAMS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 38a-503 of the 2010 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

(a) (1) Each individual health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), **[**(6),**]** (10), (11) and (12) of section 38a-469 delivered, issued for delivery, renewed, amended or continued in this state **[**on or after October 1, 2001,**]** shall provide benefits for mammographic examinations to any woman covered under the policy which are at least equal to the following minimum requirements: **[**(1)**]** (A) A baseline mammogram for any woman who is thirty-five to thirty-nine years of age, inclusive; and **[**(2)**]** (B) a mammogram every year for any woman who is forty years of age or older.

(2) Such policy shall provide additional benefits for comprehensive ultrasound screening and magnetic resonance imaging, of an entire breast or breasts if a mammogram demonstrates heterogeneous or dense breast tissue based on the Breast Imaging Reporting and Data System established by the American College of Radiology or if a woman is believed to be at increased risk for breast cancer due to

family history or prior personal history of breast cancer, positive genetic testing or other indications as determined by a woman's physician or advanced practice registered nurse.

(b) Benefits under this section shall be subject to any policy provisions that apply to other services covered by such policy.

(c) On and after October 1, 2009, each mammography report provided to a patient shall include information about breast density, based on the Breast Imaging Reporting and Data System established by the American College of Radiology. Where applicable, such report shall include the following notice: "If your mammogram demonstrates that you have dense breast tissue, which could hide small abnormalities, you might benefit from supplementary screening tests, which can include a breast ultrasound screening or a breast MRI examination, or both, depending on your individual risk factors. A report of your mammography results, which contains information about your breast density, has been sent to your physician's office and you should contact your physician if you have any questions or concerns about this report.".

Sec. 2. Section 38a-530 of the 2010 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

(a) (1) Each group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 delivered, issued for delivery, renewed, amended or continued in this state **[**on or after October 1, 2001,**]** shall provide benefits for mammographic examinations to any woman covered under the policy which are at least equal to the following minimum requirements: **[**(1)**]** (A) A baseline mammogram for any woman who is thirty-five to thirty-nine years of age, inclusive; and **[**(2)**]** (B) a mammogram every year for any woman who is forty years of age or older.

(2) Such policy shall provide additional benefits for comprehensive

ultrasound screening and magnetic resonance imaging, of an entire breast or breasts if a mammogram demonstrates heterogeneous or dense breast tissue based on the Breast Imaging Reporting and Data System established by the American College of Radiology or if a woman is believed to be at increased risk for breast cancer due to family history or prior personal history of breast cancer, positive genetic testing or other indications as determined by a woman's physician or advanced practice registered nurse.

(b) Benefits under this section shall be subject to any policy provisions that apply to other services covered by such policy.

(c) On and after October 1, 2009, each mammography report provided to a patient shall include information about breast density, based on the Breast Imaging Reporting and Data System established by the American College of Radiology. Where applicable, such report shall include the following notice: "If your mammogram demonstrates that you have dense breast tissue, which could hide small abnormalities, you might benefit from supplementary screening tests, which can include a breast ultrasound screening or a breast MRI examination, or both, depending on your individual risk factors. A report of your mammography results, which contains information about your breast density, has been sent to your physician's office and you should contact your physician if you have any questions or concerns about this report.".

This act shall take effect as follows and shall amend the following sections:		
Section 1	*January 1, 2011*	38a-503
Sec. 2	*January 1, 2011*	38a-530

INS *Joint Favorable Subst.*

APP *Joint Favorable*

General Assembly **Substitute Bill No. 260**

February Session, 2010 *____SB00260APP__041310___*

AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CERTAIN CLINICAL TRIAL PATIENTS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 38a-504a of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

Each individual health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 delivered, issued for delivery, **[**or**]** renewed, amended or continued in this state, **[**on or after January 1, 2002,**]** shall provide coverage for the routine patient care costs, as defined in section 38a-504d, as amended by this act, associated with **[**cancer**]** clinical trials, in accordance with sections 38a-504b to 38a-504g, inclusive, as amended by this act. As used in this section and sections 38a-504b to 38a-504g, inclusive, as amended by this act, **[**"cancer clinical**]** "clinical trial" means an organized, systematic, scientific study of therapies, tests or other clinical interventions for purposes of treatment or palliation or therapeutic intervention for the prevention of cancer, Parkinson's disease or multiple sclerosis in human beings. **[**, except that a clinical trial for the prevention of cancer is eligible for coverage only if it involves a therapeutic intervention and is a phase III clinical trial approved by one of the entities identified in section 38a-504b and is conducted at multiple institutions.**]**

Sec. 2. Section 38a-504b of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

(a) A clinical trial for the prevention of cancer, Parkinson's disease or multiple sclerosis shall be eligible for coverage of routine patient care costs only if it involves a therapeutic intervention, is a phase III clinical trial approved or qualified by one of the entities identified in subsection (b) of this section and is conducted at multiple institutions.

(b) In order to be eligible for coverage of routine patient care costs, as defined in section 38a-504d, as amended by this act, a **[**cancer**]** clinical trial shall be (1) conducted under the auspices of an independent peer-reviewed protocol that has been reviewed and approved by: **[**(1)**]** (A) One of the National Institutes of Health; **[**or (2)**]** (B) a National Cancer Institute affiliated cooperative group; **[**or (3)**]** (C) the federal Food and Drug Administration as part of an investigational new drug or device exemption; or **[**(4)**]** (D) the federal Department of Defense or Veterans Affairs; or (2) qualified to receive Medicare coverage of its routine patient care costs under the Medicare Clinical Trial Policy established under the September 19, 2000, Medicare National Coverage Determination, as amended from time to time. Nothing in sections 38a-504a to 38a-504g, inclusive, as amended by this act, shall be construed to require coverage for any single institution **[**cancer**]** clinical trial conducted solely under the approval of the institutional review board of an institution, or any trial that is no longer approved by an entity identified in **[**subdivision (1), (2), (3) or (4) of this section**]** subparagraph (A), (B), (C) or (D) of subdivision (1) of this subsection.

Sec. 3. Section 38a-504c of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

In order to be eligible for coverage of routine patient care costs, as defined in section 38a-504d, as amended by this act, the insurer, health care center or plan administrator may require that the person or entity seeking coverage for the **[**cancer**]** clinical trial provide: (1) Evidence

satisfactory to the insurer, health care center or plan administrator that the insured person receiving coverage meets all of the patient selection criteria for the **[**cancer**]** clinical trial, including credible evidence in the form of clinical or preclinical data showing that the **[**cancer**]** clinical trial is likely to have a benefit for the insured person that is commensurate with the risks of participation in the **[**cancer**]** clinical trial to treat the person's condition; **[**and**]** (2) evidence that the appropriate informed consent has been received from the insured person; **[**and**]** (3) copies of any medical records, protocols, test results or other clinical information used by the physician or institution seeking to enroll the insured person in the **[**cancer**]** clinical trial; **[**and**]** (4) a summary of the anticipated routine patient care costs in excess of the costs for standard treatment; **[**and**]** (5) information from the physician or institution seeking to enroll the insured person in the clinical trial regarding those items, including any routine patient care costs, that are eligible for reimbursement by an entity other than the insurer or health care center, including the entity sponsoring the clinical trial; and (6) any additional information that may be reasonably required for the review of a request for coverage of the **[**cancer**]** clinical trial. The health plan or insurer shall request any additional information about a **[**cancer**]** clinical trial **[**within**]** not later than five business days **[**of**]** after receiving a request for coverage from an insured person or a physician seeking to enroll an insured person in a **[**cancer**]** clinical trial. Nothing in sections 38a-504a to 38a-504g, inclusive, as amended by this act, shall be construed to require the insurer or health care center to provide coverage for routine patient care costs that are eligible for reimbursement by an entity other than the insurer, including the entity sponsoring the **[**cancer**]** clinical trial.

Sec. 4. Section 38a-504d of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

(a) For purposes of sections 38a-504a to 38a-504g, inclusive, as amended by this act, "routine patient care costs" means: (1) **[**Coverage for medically**]** Medically necessary health care services that are incurred as a result of the treatment being provided to the insured

person for purposes of the **[**cancer**]** clinical trial that would otherwise be covered if such services were not rendered pursuant to a **[**cancer**]** clinical trial. Such services shall include those rendered by a physician, diagnostic or laboratory tests, hospitalization or other services provided to the **[**patient**]** insured person during the course of treatment in the **[**cancer**]** clinical trial for a condition, or one of its complications, that is consistent with the usual and customary standard of care and would be covered if the insured person were not enrolled in a **[**cancer**]** clinical trial. Such hospitalization shall include treatment at an out-of-network facility if such treatment is not available in-network and not eligible for reimbursement by the sponsors of such clinical trial, **[**;**]** and (2) **[**coverage for routine patient care**]** costs incurred for drugs provided to the insured person, in accordance with section **[**38a-518b**]** 38a-492b, as amended by this act, provided such drugs have been approved for sale by the federal Food and Drug Administration.

(b) Routine patient care costs shall be subject to the terms, conditions, restrictions, exclusions and limitations of the contract or certificate of insurance between the subscriber and the insurer or health plan, including limitations on out-of-network care, except that treatment at an out-of-network hospital as provided in subdivision (1) of subsection (a) of this section shall be made available by the out-of-network hospital and the insurer or health care center at no greater cost to the insured person than if such treatment was available in-network. The insurer or health care center may require that any routine tests or services required under the **[**cancer**]** clinical trial protocol be performed by providers or institutions under contract with the insurer or health care center.

(c) Notwithstanding the provisions of subsection (a) of this section, routine patient care costs shall not include: (1) The cost of an investigational new drug or device that has not been approved for market for any indication by the federal Food and Drug Administration; (2) the cost of a non-health-care service that an insured person may be required to receive as a result of the treatment being

provided for the purposes of the **[**cancer**]** clinical trial; (3) facility, ancillary, professional services and drug costs that are paid for by grants or funding for the **[**cancer**]** clinical trial; (4) costs of services that (A) are inconsistent with widely accepted and established regional or national standards of care for a particular diagnosis, or (B) are performed specifically to meet the requirements of the **[**cancer**]** clinical trial; (5) costs that would not be covered under the insured person's policy for noninvestigational treatments, including, but not limited to, items excluded from coverage under the insured person's contract with the insurer or health plan; and (6) transportation, lodging, food or any other expenses associated with travel to or from a facility providing the **[**cancer**]** clinical trial, for the insured person or any family member or companion.

Sec. 5. Section 38a-504e of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

(a) Providers, hospitals and institutions that provide routine patient care services as set forth in subsection (a) of section 38a-504d, as amended by this act, as part of a **[**cancer**]** clinical trial that meets the requirements of sections 38a-504a to 38a-504g, inclusive, as amended by this act, and is approved for coverage by the insurer or health care center shall not bill the insurer or health care center or the insured person for any facility, ancillary or professional services or costs that are not routine patient care services as set forth in subsection (a) of section 38a-504d, as amended by this act, or for any product or service that is paid by the entity sponsoring or funding the **[**cancer**]** clinical trial.

(b) Providers, hospitals, institutions and insured persons may appeal a health plan's denials of payment for services only to the extent permitted by the contract between the insurer or health care center and the provider, hospital or institution.

(c) Providers, hospitals or institutions that have contracts with the insurer or health care center to render covered routine patient care

services to insured persons as part of a **[**cancer**]** clinical trial **[**may**]** shall not bill the insured person for the cost of any covered routine patient care service.

(d) Providers, hospitals or institutions that do not have a contract with the insurer or health care center to render covered routine patient care services to insured persons as part of a **[**cancer**]** clinical trial **[**may**]** shall not bill the insured person for the cost of any covered routine patient care service.

(e) Nothing in this section shall be construed to prohibit a provider, hospital or institution from collecting a deductible or copayment as set forth in the insured person's contract for any covered routine patient care service.

(f) Pursuant to subsection (b) of section 38a-504d, as amended by this act, insurers or health care centers shall be required to pay providers, hospitals and institutions that do not have a contract with the insurer or health care center to render covered routine patient care services to insured persons the lesser of (1) the lowest contracted per diem, fee schedule rate or case rate that the insurer or health care center pays to any participating provider in the state of Connecticut for similar in-network services, or (2) the billed charges. Providers, hospitals or institutions **[**may**]** shall not collect any amount more than the total amount paid by the insurer or health care center and the insured person in the form of a deductible or copayment set forth in the insured person's contract. Such amount shall be deemed by the provider, hospital or institution to be payment in full.

Sec. 6. Section 38a-504f of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

(a) (1) For purposes of cancer clinical trials, the Insurance Department, in cooperation with the Connecticut Oncology Association, the American Cancer Society, the Connecticut Association of Health Plans and Anthem Blue Cross of Connecticut, shall develop a standardized form that all providers, hospitals and institutions shall

submit to the insurer or health care center when seeking to enroll an insured person in a cancer clinical trial. An insurer or health care center **[**may**]** shall not substitute any other approval request form for the form developed by the department, except that any insurer or health care center that has entered into an agreement to provide coverage for cancer clinical trials approved pursuant to section 38a-504g, as amended by this act, may use the form or process established by such agreement.

(2) For purposes of Parkinson's disease or multiple sclerosis clinical trials, the Insurance Department, in cooperation with at least one state nonprofit Parkinson's disease or multiple sclerosis research or advocacy organization, as applicable, at least one national nonprofit Parkinson's disease or multiple sclerosis research or advocacy organization, as applicable, the Connecticut Association of Health Plans and Anthem Blue Cross of Connecticut, shall develop a standardized form that all providers, hospitals and institutions shall submit to the insurer or health care center when seeking to enroll an insured person in a Parkinson's disease or multiple sclerosis clinical trial. An insurer or health care center shall not substitute any other approval request form for the form developed by the department, except that any insurer or health care center that has entered into an agreement to provide coverage for clinical trials approved pursuant to section 38a-504g, as amended by this act, may use the form or process established by such agreement.

(b) Any insurer or health care center that receives the department form from a provider, hospital or institution seeking coverage for the routine patient care costs of an insured person in a **[**cancer**]** clinical trial shall approve or deny coverage for such services **[**within**]** not later than five business days **[**of**]** after receiving such request and any other reasonable supporting materials requested by the insurer or health plan pursuant to section 38a-504c, as amended by this act, except that an insurer or health care center that utilizes independent experts to review such requests shall respond **[**within**]** not later than ten business days after receiving such request and supporting materials. Requests

for coverage of phase III clinical trials for the prevention of cancer, Parkinson's disease or multiple sclerosis pursuant to section [38a-504a] 38a-504b, as amended by this act, shall be approved or denied [within] not later than fourteen business days after receiving such request and supporting materials.

(c) The insured, or the provider with the insured's written consent, may appeal any denial of coverage for medical necessity to an external, independent review pursuant to section 38a-478n. Such external review shall be conducted by a properly qualified review agent whom the department has determined does not have a conflict of interest regarding the [cancer] clinical trial.

(d) The Insurance Commissioner shall adopt regulations, in accordance with chapter 54, to implement the provisions of this section.

Sec. 7. Section 38a-504g of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

(a) Any insurer or health care center with coverage policies for care in [cancer] clinical trials shall submit such policies to the Insurance Department for evaluation and approval. The department shall certify whether the insurer's or health care center's coverage policy for routine patient care costs associated with [cancer] clinical trials is substantially equivalent to the requirements of sections 38a-504a to 38a-504g, inclusive, as amended by this act. If the department finds that such coverage is substantially equivalent to the requirements of sections 38a-504a to 38a-504g, inclusive, as amended by this act, the insurer or health care center shall be exempt from the provisions of sections 38a-504a to 38a-504g, inclusive, as amended by this act.

(b) Any such insurer or health care center shall report annually, in writing, to the department that there have been no changes in the policy as certified by the department. If there has been any change in the policy, the insurer or health care center shall resubmit its policy for certification by the department.

(c) Any insurer or health care center coverage policy found by the department not to be substantially equivalent to the requirements of sections 38a-504a to 38a-504g, inclusive, as amended by this act, shall abide by the requirements of sections 38a-504a to 38a-504g, inclusive, as amended by this act, until the insurer or health care center has received such certification by the department.

Sec. 8. Section 38a-542a of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

Each group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 delivered, issued for delivery, **[**or**]** renewed, amended or continued in this state, **[**on or after January 1, 2002,**]** shall provide coverage for the routine patient care costs, as defined in section 38a-542d, as amended by this act, associated with **[**cancer**]** clinical trials, in accordance with sections 38a-542b to 38a-542g, inclusive, as amended by this act. As used in this section and sections 38a-542b to 38a-542g, inclusive, as amended by this act, **[**"cancer clinical**]** "clinical trial" means an organized, systematic, scientific study of therapies, tests or other clinical interventions for purposes of treatment or palliation or therapeutic intervention for the prevention of cancer, Parkinson's disease or multiple sclerosis in human beings. **[**, except that a clinical trial for the prevention of cancer is eligible for coverage only if it involves a therapeutic intervention and is a phase III clinical trial approved by one of the entities identified in section 38a-542b and is conducted at multiple institutions.**]**

Sec. 9. Section 38a-542b of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

(a) A clinical trial for the prevention of cancer, Parkinson's disease or multiple sclerosis shall be eligible for coverage of routine patient care costs only if it involves a therapeutic intervention, is a phase III clinical trial approved or qualified by one of the entities identified in subsection (b) of this section and is conducted at multiple institutions.

(b) In order to be eligible for coverage of routine patient care costs, as defined in section 38a-542d, as amended by this act, a **[**cancer**]** clinical trial shall be (1) conducted under the auspices of an independent peer-reviewed protocol that has been reviewed and approved by: **[**(1)**]** (A) One of the National Institutes of Health; **[**or (2)**]** (B) a National Cancer Institute affiliated cooperative group; **[**or (3)**]** (C) the federal Food and Drug Administration as part of an investigational new drug or device exemption; or **[**(4)**]** (D) the federal Department of Defense or Veterans Affairs; or (2) qualified to receive Medicare coverage of its routine patient care costs under the Medicare Clinical Trial Policy established under the September 19, 2000, Medicare National Coverage Determination, as amended from time to time. Nothing in sections 38a-542a to 38a-542g, inclusive, as amended by this act, shall be construed to require coverage for any single institution **[**cancer**]** clinical trial conducted solely under the approval of the institutional review board of an institution, or any trial that is no longer approved by an entity identified in **[**subdivision (1), (2), (3) or (4) of this section**]** subparagraph (A), (B), (C) or (D) of subdivision (1) of this subsection.

Sec. 10. Section 38a-542c of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

In order to be eligible for coverage of routine patient care costs, as defined in section 38a-542d, as amended by this act, the insurer, health care center or plan administrator may require that the person or entity seeking coverage for the **[**cancer**]** clinical trial provide: (1) Evidence satisfactory to the insurer, health care center or plan administrator that the insured person receiving coverage meets all of the patient selection criteria for the **[**cancer**]** clinical trial, including credible evidence in the form of clinical or pre-clinical data showing that the **[**cancer**]** clinical trial is likely to have a benefit for the insured person that is commensurate with the risks of participation in the **[**cancer**]** clinical trial to treat the person's condition; **[**and**]** (2) evidence that the appropriate informed consent has been received from the insured person; **[**and**]** (3) copies of any medical records, protocols, test results

or other clinical information used by the physician or institution seeking to enroll the insured person in the **[**cancer**]** clinical trial; **[**and**]** (4) a summary of the anticipated routine patient care costs in excess of the costs for standard treatment; **[**and**]** (5) information from the physician or institution seeking to enroll the insured person in the clinical trial regarding those items, including any routine patient care costs, that are eligible for reimbursement by an entity other than the insurer or health care center, including the entity sponsoring the clinical trial; and (6) any additional information that may be reasonably required for the review of a request for coverage of the **[**cancer**]** clinical trial. The health plan or insurer shall request any additional information about a **[**cancer**]** clinical trial **[**within**]** not later than five business days **[**of**]** after receiving a request for coverage from an insured person or a physician seeking to enroll an insured person in a **[**cancer**]** clinical trial. Nothing in sections 38a-542a to 38a-542g, inclusive, as amended by this act, shall be construed to require the insurer or health care center to provide coverage for routine patient care costs that are eligible for reimbursement by an entity other than the insurer, including the entity sponsoring the **[**cancer**]** clinical trial.

Sec. 11. Section 38a-542d of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

(a) For purposes of sections 38a-542a to 38a-542g, inclusive, as amended by this act, "routine patient care costs" means: (1) **[**Coverage for medically**]** Medically necessary health care services that are incurred as a result of the treatment being provided to the insured person for purposes of the **[**cancer**]** clinical trial that would otherwise be covered if such services were not rendered pursuant to a **[**cancer**]** clinical trial. Such services shall include those rendered by a physician, diagnostic or laboratory tests, hospitalization or other services provided to the **[**patient**]** insured person during the course of treatment in the **[**cancer**]** clinical trial for a condition, or one of its complications, that is consistent with the usual and customary standard of care and would be covered if the insured person were not enrolled in a **[**cancer**]** clinical trial. Such hospitalization shall include

treatment at an out-of-network facility if such treatment is not available in-network and not eligible for reimbursement by the sponsors of such clinical trial; and (2) **[**coverage for routine patient care**]** costs incurred for drugs provided to the insured person, in accordance with section 38a-518b, as amended by this act, provided such drugs have been approved for sale by the federal Food and Drug Administration.

(b) Routine patient care costs shall be subject to the terms, conditions, restrictions, exclusions and limitations of the contract or certificate of insurance between the subscriber and the insurer or health plan, including limitations on out-of-network care, except that treatment at an out-of-network hospital as provided in subdivision (1) of subsection (a) of this section shall be made available by the out-of-network hospital and the insurer or health care center at no greater cost to the insured person than if such treatment was available in-network. The insurer or health care center may require that any routine tests or services required under the **[**cancer**]** clinical trial protocol be performed by providers or institutions under contract with the insurer or health care center.

(c) Notwithstanding the provisions of subsection (a) of this section, routine patient care costs shall not include: (1) The cost of an investigational new drug or device that has not been approved for market for any indication by the federal Food and Drug Administration; (2) the cost of a non-health-care service that an insured person may be required to receive as a result of the treatment being provided for the purposes of the **[**cancer**]** clinical trial; (3) facility, ancillary, professional services and drug costs that are paid for by grants or funding for the **[**cancer**]** clinical trial; (4) costs of services that (A) are inconsistent with widely accepted and established regional or national standards of care for a particular diagnosis, or (B) are performed specifically to meet the requirements of the **[**cancer**]** clinical trial; (5) costs that would not be covered under the insured person's policy for noninvestigational treatments, including, but not limited to, items excluded from coverage under the insured person's contract

with the insurer or health plan; and (6) transportation, lodging, food or any other expenses associated with travel to or from a facility providing the **[**cancer**]** clinical trial, for the insured person or any family member or companion.

Sec. 12. Section 38a-542e of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

(a) Providers, hospitals and institutions that provide routine patient care services as set forth in subsection (a) of section 38a-542d, as amended by this act, as part of a **[**cancer**]** clinical trial that meets the requirements of sections 38a-542a to 38a-542g, inclusive, as amended by this act, and is approved for coverage by the insurer or health care center shall not bill the insurer or health care center or the insured person for any facility, ancillary or professional services or costs that are not routine patient care services as set forth in subsection (a) of section 38a-542d, as amended by this act, or for any product or service that is paid by the entity sponsoring or funding the **[**cancer**]** clinical trial.

(b) Providers, hospitals, institutions and insured persons may appeal a health plan's denials of payment for services only to the extent permitted by the contract between the insurer or health care center and the provider, hospital or institution.

(c) Providers, hospitals or institutions that have contracts with the insurer or health care center to render covered routine patient care services to insured persons as part of a **[**cancer**]** clinical trial **[**may**]** shall not bill the insured person for the cost of any covered routine patient care service.

(d) Providers, hospitals or institutions that do not have a contract with the insurer or health care center to render covered routine patient care services to insured persons as part of a **[**cancer**]** clinical trial **[**may**]** shall not bill the insured person for the cost of any covered routine patient care service.

(e) Nothing in this section shall be construed to prohibit a provider, hospital or institution from collecting a deductible or copayment as set forth in the insured person's contract for any covered routine patient care service.

(f) Pursuant to subsection (b) of section 38a-542d, as amended by this act, insurers or health care centers shall be required to pay providers, hospitals and institutions that do not have a contract with the insurer or health care center to render covered routine patient care services to insured persons the lesser of (1) the lowest contracted per diem, fee schedule rate or case rate that the insurer or health care center pays to any participating provider in the state of Connecticut for similar in-network services, or (2) the billed charges. Providers, hospitals or institutions **[**may**]** shall not collect any amount more than the total amount paid by the insurer or health care center and the insured person in the form of a deductible or copayment set forth in the insured person's contract. Such amount shall be deemed by the provider, hospital or institution to be payment in full.

Sec. 13. Section 38a-542f of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

(a) (1) For purposes of cancer clinical trials, the Insurance Department, in cooperation with the Connecticut Oncology Association, the American Cancer Society, the Connecticut Association of Health Plans and Anthem Blue Cross of Connecticut, shall develop a standardized form that all providers, hospitals and institutions shall submit to the insurer or health care center when seeking to enroll an insured person in a cancer clinical trial. An insurer or health care center **[**may**]** shall not substitute any other approval request form for the form developed by the department, except that any insurer or health care center that has entered into an agreement to provide coverage for cancer clinical trials approved pursuant to section 38a-542g, as amended by this act, may use the form or process established by such agreement.

(2) For purposes of Parkinson's disease or multiple sclerosis clinical trials, the Insurance Department, in cooperation with at least one state nonprofit Parkinson's disease or multiple sclerosis research or advocacy organization, as applicable, at least one national nonprofit Parkinson's disease or multiple sclerosis research or advocacy organization, as applicable, the Connecticut Association of Health Plans and Anthem Blue Cross of Connecticut, shall develop a standardized form that all providers, hospitals and institutions shall submit to the insurer or health care center when seeking to enroll an insured person in a Parkinson's disease or multiple sclerosis clinical trial. An insurer or health care center shall not substitute any other approval request form for the form developed by the department, except that any insurer or health care center that has entered into an agreement to provide coverage for clinical trials approved pursuant to section 38a-504g, as amended by this act, may use the form or process established by such agreement.

(b) Any insurer or health care center that receives the department form from a provider, hospital or institution seeking coverage for the routine patient care costs of an insured person in a **[**cancer**]** clinical trial shall approve or deny coverage for such services **[**within**]** not later than five business days **[**of**]** after receiving such request and any other reasonable supporting materials requested by the insurer or health plan pursuant to section 38a-542c, as amended by this act, except that an insurer or health care center that utilizes independent experts to review such requests shall respond **[**within**]** not later than ten business days after receiving such request and supporting materials. Requests for coverage of phase III clinical trials for the prevention of cancer, Parkinson's disease or multiple sclerosis pursuant to section **[**38a-542a**]** 38-542b, as amended by this act, shall be approved or denied **[**within**]** not later than fourteen business days after receiving such request and supporting materials.

(c) The insured, or the provider with the insured's written consent, may appeal any denial of coverage for medical necessity to an external, independent review pursuant to section 38a-478n. Such external

review shall be conducted by a properly qualified review agent whom the department has determined does not have a conflict of interest regarding the **[**cancer**]** clinical trial.

(d) The Insurance Commissioner shall adopt regulations, in accordance with chapter 54, to implement the provisions of this section.

Sec. 14. Section 38a-542g of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

(a) Any insurer or health care center with coverage policies for care in **[**cancer**]** clinical trials shall submit such policies to the Insurance Department for evaluation and approval. The department shall certify whether the insurer's or health care center's coverage policy for routine patient care costs associated with **[**cancer**]** clinical trials is substantially equivalent to the requirements of sections 38a-542a to 38a-542g, inclusive, as amended by this act. If the department finds that such coverage is substantially equivalent to the requirements of sections 38a-542a to 38a-542g, inclusive, as amended by this act, the insurer or health care center shall be exempt from the provisions of sections 38a-542a to 38a-542g, inclusive, as amended by this act.

(b) Any such insurer or health care center shall report annually, in writing, to the department that there have been no changes in the policy as certified by the department. If there has been any change in the policy, the insurer or health care center shall resubmit its policy for certification by the department.

(c) Any insurer or health care center coverage policy found by the department not to be substantially equivalent to the requirements of sections 38a-542a to 38a-542g, inclusive, as amended by this act, shall abide by the requirements of sections 38a-542a to 38a-542g, inclusive, as amended by this act, until the insurer or health care center has received such certification by the department.

Sec. 15. Section 38a-492b of the general statutes is repealed and the

following is substituted in lieu thereof (*Effective January 1, 2011*):

(a) Each individual health insurance policy delivered, issued for delivery, **[**or**]** renewed, amended or continued in this state, **[**on or after October 1, 1994, which**]** that provides coverage for prescribed drugs approved by the federal Food and Drug Administration for treatment of certain types of cancer or for Parkinson's disease or multiple sclerosis shall not exclude coverage of any such drug on the basis that such drug has been prescribed for the treatment of a type of cancer or for Parkinson's disease or multiple sclerosis for which the drug has not been approved by the federal Food and Drug Administration, provided the drug is recognized for treatment of the specific type of cancer for which the drug has been prescribed or for Parkinson's disease or multiple sclerosis in one of the following established reference compendia: (1) The U.S. Pharmacopoeia Drug Information Guide for the Health Care Professional (USP DI); (2) The American Medical Association's Drug Evaluations (AMA DE); or (3) The American Society of Hospital Pharmacists' American Hospital Formulary Service Drug Information (AHFS-DI).

(b) Nothing in subsection (a) of this section shall be construed to require coverage for any experimental or investigational drugs or any drug which the federal Food and Drug Administration has determined to be contraindicated for treatment of the specific type of cancer for which the drug has been prescribed or for Parkinson's disease or multiple sclerosis.

(c) **[**Nothing**]** Except as specified, nothing in this section shall be construed to create, impair, limit or modify authority to provide reimbursement for drugs used in the treatment of any other disease or condition.

Sec. 16. Section 38a-518b of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

(a) Each group health insurance policy delivered, issued for delivery, **[**or**]** renewed, amended or continued in this state, **[**on or after

October 1, 1994, which**]** that provides coverage for prescribed drugs approved by the federal Food and Drug Administration for treatment of certain types of cancer or for Parkinson's disease or multiple sclerosis shall not exclude coverage of any such drug on the basis that such drug has been prescribed for the treatment of a type of cancer or for Parkinson's disease or multiple sclerosis for which the drug has not been approved by the federal Food and Drug Administration, provided the drug is recognized for treatment of the specific type of cancer for which the drug has been prescribed or for Parkinson's disease or multiple sclerosis in one of the following established reference compendia: (1) The U.S. Pharmacopoeia Drug Information Guide for the Health Care Professional (USP DI); (2) The American Medical Association's Drug Evaluations (AMA DE); or (3) The American Society of Hospital Pharmacists' American Hospital Formulary Service Drug Information (AHFS-DI).

(b) Nothing in subsection (a) of this section shall be construed to require coverage for any experimental or investigational drugs or any drug which the federal Food and Drug Administration has determined to be contraindicated for treatment of the specific type of cancer for which the drug has been prescribed or for Parkinson's disease or multiple sclerosis.

(c) **[**Nothing**]** Except as specified, nothing in this section shall be construed to create, impair, limit or modify authority to provide reimbursement for drugs used in the treatment of any other disease or condition.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*January 1, 2011*	38a-504a
Sec. 2	*January 1, 2011*	38a-504b
Sec. 3	*January 1, 2011*	38a-504c
Sec. 4	*January 1, 2011*	38a-504d
Sec. 5	*January 1, 2011*	38a-504e
Sec. 6	*January 1, 2011*	38a-504f

Sec. 7	*January 1, 2011*	38a-504g
Sec. 8	*January 1, 2011*	38a-542a
Sec. 9	*January 1, 2011*	38a-542b
Sec. 10	*January 1, 2011*	38a-542c
Sec. 11	*January 1, 2011*	38a-542d
Sec. 12	*January 1, 2011*	38a-542e
Sec. 13	*January 1, 2011*	38a-542f
Sec. 14	*January 1, 2011*	38a-542g
Sec. 15	*January 1, 2011*	38a-492b
Sec. 16	*January 1, 2011*	38a-518b

INS *Joint Favorable Subst.*

APP *Joint Favorable*

General Assembly

Substitute Bill No. 579

February Session, 2006

____SB00579PH___032006___

AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR MEDICAL SERVICES AND TREATMENT FOR MORBID OBESITY.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective from passage*) (a) As used in this section:

(1) "Morbid obesity" means (A) a weight that is at least one hundred pounds over or twice the ideal weight for frame, age, height and gender as specified in the 1983 Metropolitan Life Insurance tables, (B) a BMI equal to or greater than thirty-five kilograms per meter squared with comorbidity or coexisting medical conditions related to morbid obesity such as hypertension, cardiopulmonary conditions, sleep apnea or diabetes, or (C) a BMI of forty kilograms per meter squared without such comorbidity; and

(2) "BMI" means body mass index that equals weight in kilograms divided by height in meters squared.

(b) On or before October 1, 2007, the Insurance Commissioner shall adopt regulations, in accordance with chapter 54 of the general statutes, establishing guidelines for health insurance coverage for medical services and treatment for morbid obesity. Such regulations shall:

(1) Require that each individual and 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, amended, renewed or continued in this state on or after October 1, 2007, provide coverage for the medically necessary expenses of the diagnosis and treatment of morbid obesity, including, but not limited to, bariatric surgery, physician office visits, health and behavior assessments, nutrition education, patient self-management education and training and therapeutic exercises.

(2) Limit coverage of bariatric surgery to providers of surgical services that are: (A) Certified by the American College of Surgeons as a level 1a Bariatric Surgery Center; or (B) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence.

(c) The regulations adopted pursuant to subsection (b) of this section do not apply to any health insurer that obtains approval from the Insurance Department on or before October 1, 2007, to provide coverage for the medically necessary expenses of the diagnosis and treatment of morbid obesity, including, but not limited to, bariatric surgery, physician office visits, health and behavior assessments, nutrition education, patient self-management education and training and therapeutic exercises.

Sec. 2. (NEW) (*Effective October 1, 2007*) Each health insurer, as defined in section 38a-478n of the 2006 supplement to the general statutes, hospital service corporation, as defined in section 38a-199 of the general statutes, or medical service corporation licensed to conduct health insurance business in this state shall offer to any individual, partnership, corporation or unincorporated association providing group hospital or medical insurance coverage for its employees a group hospital or medical service plan or contract providing coverage for the medically necessary expenses of the diagnosis and treatment of morbid obesity.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*from passage*	New section
Sec. 2	*October 1, 2007*	New section

PH *Joint Favorable Subst.*

Appendix III

Ingenix Consulting

Actuarial Report

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INGENIX CONSULTING—

ACTUARIAL REPORT For The STATE OF CT On FOUR PROPOSED 2011 HEALTH INSURANCE BENEFIT MANDATES COVERED By PUBLIC ACT NUMBER 09-179

February 25, 2011

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I. INTRODUCTION:

This report serves to record the findings of Ingenix Consulting (IC) pursuant to our engagement to provide actuarial services to the State of CT in conjunction with Substitute House Bill No. 5021, Public Acts 09-179. This report is intended to communicate the results of our work and serve as a tool for discussion purposes.

IC 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 IC and with the workgroup that includes the CT Department of Insurance and the CT Center for Public Health and Health Policy. Daniel Bailey managed the actuarial work for the project and worked on the mandates. Dr. Thomas Knabel, MD, and his clinical staff were responsible for clinical guidance and support. Mary Canillas, FSA, MAAA carried out the data research that involved our extensive commercial health claims databases.

IC will also provide a separate report on the economic aspects of these four proposed mandates. This work will be carried out under the direction of Tanvir Khan with the assistance of Krista King.

IC was retained by the state to assess four proposed health insurance benefit mandates for 2011. In this document, the findings and conclusions related to the actuarial evaluation are presented for each of the four mandates. Each mandate has been reviewed with respect to cost, socio-economic impact, and effect on the finance and delivery system.

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.

IC reviewed the following four mandates:

1. **Prescription Eye Drops—Additional Supply:** New mandate. Requires two things: First, insurers must pay for one additional bottle of eye drops for use at child's day care center or school once every three months. Second, for people of all ages, this mandate requires prescription eye drops to be refilled prior to the end of the month, if the patient runs out, as long as an additional refill remains. Typically, in a retail pharmacy, prescriptions are filled for a 30 or 31 day period; technically, this time period is not required to coincide with the calendar month.

2. **MRI for Breast Cancer Screening under Certain Conditions:** Requires coverage of MRI (magnetic resonance imaging) as a supplement to mammogram and ultrasound for breast cancer screening for women meeting specified conditions including family history of breast cancer and presence of dense breast tissue.

3. **Clinical Trials for Parkinson's Disease and Multiple Sclerosis—Coverage of Cost of Routine Care for People Enrolled in Such Trials:** Similar to the current mandate applying to clinical trials for cancer only. Extends the mandate to include Parkinson's and MS. Also requires coverage of off-label prescribing for these two conditions similar to the current mandate for off-label prescribing of cancer drugs.

4. **Extension of Coverage for Gastric Bypass Surgery:** New mandate requires coverage of gastric bypass surgery. The prior bills pertaining to the treatment for morbid obesity considered coverage for all kinds of bariatric surgery, of which gastric bypass is one type. The mandate does not specify preconditions for treatment, such as authorized only for morbidly obese individuals (BMI of 40+) and obese individuals with a BMI of 35+ and co-morbidities of obesity such as diabetes, hypertension, heart disease, and sleep apnea. Without the specification of preconditions, a more hypothetical approach had to be employed in assessing the potential cost and effects of this mandate.

Note: All four mandates apply to group and individual coverage. All four mandates apply to comprehensive health insurance plans such as Health Maintenance Organizations (HMO) and Preferred Provider Organizations (PPO).

I.2 Cost of Mandates—Two Components of Health Insurance Premium:

With respect to the cost of the benefit mandates and their effect on health insurance premiums, two separate pieces were examined—medical costs and non-medical expenses, with an emphasis on the former since it represents the far greater portion of overall 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. This is to be distinguished from "Allowed" cost, which is described later in this report. Allowed Cost includes member cost-sharing, which is not part of health insurance premiums.

For group plans, non-medical cost is 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 is approximately twenty-one cents of associated cost that also goes into health insurance premiums—this non-medical expense covers the operational costs associated with payment of claims, collection of premium, medical management, profit, and more. For individual coverage, non-benefit expense is a larger portion of health care cost—it is 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.

These two components, medical cost and non-medical expense, are the two building blocks of health insurance premiums. There is yet another separate category of cost that is not part of health insurance premium, and that is the cost-sharing that is 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 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 medical cost is referred to as Allowed Cost. Most of the focus in this report is on Paid medical cost, since it is ultimately the primary underlying driver of health insurance premiums.

The annual medical cost in 2011 dollars is indicated based on current and projected utilization and medical cost levels. Medical costs were also projected forward for the next four years. Expected changes in the finance and delivery system were considered, as was the effect of trend on unit cost and utilization. IC's internal commercial health claims data for 2006 – 2009 was examined, with emphasis on 2008 and 2009. 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. Survey information provided by CT carriers as requested by the state was also considered.

First, a summary of the expected 2011 medical cost is presented without detail or long-range projections. Later in this report, the medical cost of each mandate will be elaborated on. The socio-economic consequences of the mandates and their ramifications on the finance and delivery system will be examined, including their effect on health insurance cost and availability. The cost of group coverage has been emphasized more than the cost of individual plans because fully insured group coverage constitutes about 90% of the commercial health insurance market. Fully insured coverage does not include self-funded group coverage. In CT, the number of people covered by self-funded coverage is roughly as large as the number covered by fully insured group coverage. 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.

In estimating the 2011 medical cost of the mandates, it was assumed that the mandates would become effective on January 1, 2011 and remain in effect throughout the entire calendar year. In the five year projection provided in the appendix to this report, future cost increases are explained. This is a complicating factor especially in the case of the MRI and Bariatric Surgery mandates because it is expected that the frequency of these services will increase in time as public awareness increases.

I.3 EXECUTIVE SUMMARY OF 2010 MEDICAL COST ASSESSMENT:

Note: In the estimates below, 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 2011 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. About one-third or more of those insured are children, and on average, their annual medical costs are roughly half that of adults.

The PMPM medical costs presented in this section are for <u>group</u> coverage. Individual data and costs will be presented later in Section II.4.

The numbering of the mandates below does not reflect their relative importance.

1. Mandate one involves prescription eye drops for two separate circumstances. The first concerns an extra bottle for children for their school and day care. The second involves an extra refill for children and adults who run out before the end of the month. The medical cost is estimated to be an additional **$0.07 PMPM** in 2011 for group coverage. The actual cost could be from $0.00 to $0.20 PMPM depending on the level of increase in utilization that results from the mandate. In the adult and child population, the mandate is assumed to cause

a utilization increase of 10% for early refill. This is expected to increase over the next several years.

For adults and children combined, the allowed cost of the average eye drop prescription is $63, of which the member paid $31 and the insurer paid $32. For children only, the average prescription cost $36, of which the insurer paid $14 and the member or member's family paid $22.

This mandate would involve administrative cost resulting from its implementation. Insurers, pharmacy benefit managers, and pharmacies would have to adjust their systems to accommodate such a mandate. Rules would need to be established in their transaction-based systems so that every claim is handled correctly. These systems changes would involve a one-time set-up cost. After set-up, the administrative cost for this mandate would be reduced to a steady-state level.

This mandate could encourage additional utilization of bottles of eye drops relative to today's utilization level. The convenience of having an extra bottle may cause some bottles to be filled early for adults and children, and this may lead to a higher level of wastage due to left-over medication. The same wastage could occur with the extra bottle for school or day care. This mandate essentially gives the member the right to determine the medical necessity of early or extra refills. As such, it is open to potential abuse; however, the cost of abuse would be limited by the overall demand for prescription eye drops, which add less than $1.00 PMPM to the cost of health insurance today. Once implemented, it would be difficult as well as impractical to determine whether abuse exists and to what extent. While the increased utilization for this mandate in 2011 is assumed to be 10%, in actuality it could be higher or lower. Thus, there is variability around the estimated 2011 cost.

5. Mandate two requires insurers to pay for magnetic resonance imaging (MRI) for breast cancer screening as a supplement to mammograms and ultrasound. This mandate applies only to women who meet certain conditions that increase either their likelihood of developing breast cancer or the possibility that it may not be detected by mammograms and ultrasound. An example of one of these conditions is family history of breast cancer or presence of the BRCA 1 or BRCA 2 gene; another is the presence of dense breast tissue. Most women will not meet these extended criteria. The rules for applying the criteria are not clearly black and white and rely on physician judgment. It is estimated that about 40% of women have dense breast tissue. It is higher for women who are 40 - 50 than those 60+, that is, the presence of dense breast tissue decreases with age for women in the 40 to 65 age group.

According to the Ingenix data, in the two year period from 2006 to 2008, the PMPM cost for MRIs for breast cancer screening doubled in CT. If the rate doubles again on account of the mandate, the incremental cost of this mandate in 2011 would be about **$0.92 PMPM**.

As we saw in the phase two report, the utilization of MRI for all reasons has increased significantly over the past ten years, and the 2008 medical cost in CT for all complex imaging MRI, CAT, and PET scans) for all reasons was $11.25 PMPM based on data submitted by the six carriers domiciled in the state.

This suggests that this mandate could reach a significantly higher cost level over a period of several years. The utilization level of MRI for breast cancer screening in CT is already two to three times the level of the rest of the nation. The data show that CT is an early adopter of

this improved standard of care. In the rest of the nation, the utilization rate for this service and the PMPM cost roughly doubled from 2006 to 2009. The same was found to be true in the data for CT only. The existing breast cancer screening mandate in CT requires notification to the patient of breast density according to the BI-RADS standards.

In order to estimate the potential cost of this mandate, 2008 and 2009 experience was projected forward at varying levels of utilization. The 2009 allowed cost in CT was $0.83 PMPM, and the 2011 paid cost using 5% trend is projected to be $0.92 PMPM. The projected 2011 paid cost has been developed from the 2009 allowed cost because, under PPACA (federal health care reform), members will no longer have any cost sharing associated with preventive services. The assumed doubling of the $0.92 PMPM projected 2011 cost without the mandate yields the incremental $0.92 PMPM of cost for the mandate. In actuality, the PMPM could be substantially less or more—there is a great deal of variability around this estimate.

No diagnostic or screening tool can be 100% effective, and there will be false positives and negatives for every test. Passage of the mandate may cause physicians to practice defensive medicine and order more MRIs for breast cancer screening than they would in the absence of the mandate. As awareness of the clinical advantage of MRI for breast cancer screening increases, it is expected that more requests for MRIs will come from patients, some of whom might not meet the criteria.

Under federal health reform, preventive services, such as this one, cannot charge a copay or coinsurance. Since the member would have no cost-sharing for MRIs under this mandate, there is no monetary disincentive to deter marginally necessary services. This lack of member cost-sharing can be expected to induce some requests for MRIs that would not otherwise occur.

At issue is the cost-effectiveness of MRIs for breast cancer screening because of the cost of MRI in comparison with the cost of mammograms and ultrasounds. Studies are still forthcoming on this topic.

3. Mandate three is an expansion of two current mandates that require health insurers to cover the cost of 1) routine care for people with cancer who are involved in clinical trials for cancer, and 2) off-label prescribing of cancer drugs. The expansion here involves extending the mandate to include Parkinson's disease (PD) and Multiple Sclerosis (MS) in addition to cancer, which is already covered. In phase two of this project, the estimated 2010 costs for these two mandates for cancer only for group coverage was $0.00 PMPM and $2.56 PMPM respectively. There are far fewer people with these two diseases than with cancer, and there are far fewer clinical trials for them. For these two diseases, there are also fewer new pharmaceuticals developed to combat them than there are new chemotherapeutic agents and oral medications to fight cancer. With cancer, many drugs and chemotherapeutic agents that are approved for one type of cancer have eventually proven effective for other types and stages of cancer. For Parkinson's disease, there is only type of the disease, so no off-label prescribing could be expected for drugs approved for one type of Parkinson's but not another. For MS, there are four types of the disease, and many MS drugs are approved for one type but not another; in actual practice, they may be prescribed for all types of MS. There could be some off-label prescribing of PD drugs for MS, but it would be *de minimis* because 1) the frequency would be low, and 2) the cost of PD drugs is far less per script than MS drugs. The mandate was interpreted to apply specifically to drugs for MS or PD, not for other illnesses or

medical conditions. (Given the low prevalence of either disease, this broader definition of off-label prescribing would not generate additional cost unless the medications used off-label were extremely expensive ones, which is not currently the case.) Cancer is different than MS or PD in that it is actually a combination of substantially different disease types that affect different body parts. For this reason, unlike cancer, there is expected a *de minimis* amount of off-label prescribing for MS and Parkinson's. The expected medical cost is $0.00 PMPM, and the expected cost for off-label prescribing is *de minimis*—in total, the expected medical cost for this mandate is ***de minimis***. Even if this proposed mandate becomes law, it would not prevent insurers from keeping their precertification (prior authorization) process in place by which members are not able to initially fill a new prescription without a medical necessity approval from the insurer. This process serves to make sure that members are given access to certain high cost drugs that are necessary for their condition or disease without opening access to all possible requests, some of which may be unwarranted.

4. Mandate four involves an expansion of coverage for gastric bypass surgery. The mandate description is ambiguous with respect to the parameters and conditions of coverage such as medical necessity. For this reason, a more hypothetical approach was employed in assessing the cost and effects of this proposed mandate. It should be noted that most insurers already cover bariatric surgery, including gastric bypass surgery, for those who are morbidly obese (BMI > 40) or have a BMI greater than 35 with additional co-morbidities of obesity such as diabetes, hypertension, and sleep apnea. A systematic and comprehensive pre-authorization exists for each prospective patient prior to the surgery. In order to estimate the cost of this mandate, a range of possible costs was developed based on level of coverage and potential increase in utilization. A cost of **$0.50 PMPM** was calculated for year one, 2011, based on assumptions concerning utilization level and other criteria around who is covered, types of bariatric surgery covered, and conditions for coverage. Without such specificity around this mandate, the medical costs could substantially greater or less than estimated here, and insurers would also have a large amount of associated administrative cost in setting up and covering the ambiguously defined services required under the mandate. Thus, there is a great deal of potential variability around this cost estimate. Additionally, after substantial weight loss, formerly morbidly obese people, particularly those that have lost a large portion of excess body weight, are often left with excess skin that must be corrected with dermatological surgery. It is not clear whether this cosmetic surgery would be paid by insurers also.

The cost of this mandate is expected to rise each year over the next several years as increasing public awareness leads to higher utilization of these services. However, it should be noted that there will also be offsetting savings associated with these surgeries, especially with respect to the elimination or improvement of diabetes. Some studies show that bariatric surgery pays for itself by reducing subsequent medical costs; there is roughly a three year payback period. In that sense, the cost of bariatric surgery can be perceived as an initial investment or expenditure that will ultimately improve the quality of life and potential productivity of the patient, as well as reduce future medical costs associated with obesity. As the mandate is currently described, there is no requirement that the patient must be morbidly obese or otherwise meet specified medical criteria as a precondition for surgery. Without such preconditions, the costs of this mandate could be far greater. There are FDA standards that apply to some devices used for bariatric surgery that act as pre-conditions for use.

In late 2010, the FDA (Food and Drug Administration) advisory committee voted to recommend that the FDA itself grant a request from Allergan to market its Lap-Band device to people with a body mass index (BMI) of between 30 and 35. IC estimates that the pool of

potential candidates for bariatric surgery would be increased substantially by this revision of eligibility criteria. In the IC national 2008 and 2009 data, there are more than twice as many people in the BMI range of 30 to 40 as in the range of 40+. Moreover, the number in each of those two categories is increasing annually as the national problem of obesity continues.

Currently, the Lap-Band device, which is implanted around the stomach to restrict the amount of food consumed, is approved only for people who have either a BMI of 40 or above or a combination of BMI of 35 or above and at least one serious weight-related health problem. Allergan requested changing that to a BMI of 35 without health problems or 30 with. The committee voted that there was sufficient evidence that the device was safe and effective for patients with lower BMI scores and any risks were outweighed by the benefits. A 5-foot-9 inch person would have to weigh 203 instead of 271 to be eligible for the device under the new criteria. This significantly increases the potential utilization of this service. The cost of a Lap-Band surgery is somewhere in the range of $15,000. According to the National Center for Health Statistics, over 20% of men in the US have a BMI between 30 and 35, which is about double the proportion of U.S. men with a BMI above 35.

In a world in which the population and rate of obesity is static, after an initial period of several years or more, the savings from bariatric surgeries would offset their cost, thus creating a steady-state pay-as-you-go situation. The overall population itself is growing, however, and the rate of obesity is increasing so quickly that public health officials and the medical community have sounded an alarm.

Unlike a quadruple bypass operation that corrects a cardio-vascular problem and extends life, bariatric surgery has a cosmetic aspect in addition to a medical one—beyond the obvious health benefits, people with a BMI of 30+ are generally regarded as more attractive after losing a large percentage of their excess body weight. This cosmetic element may act as an additional incentive for surgery.

Bariatric surgery has been proven to provide the patient with significant long-term loss of weight. It also improves or eliminates diabetes, improves risk factors for cardiovascular disease, and reduces mortality, despite having side-effects, potential adverse consequences, and a mortality rate on account of the surgery itself, which has declined considerably over the past 20 years as more such surgeries are performed. The mortality rate as a result of the operation is now less than 1%. Gastric bypass has been so successful in diabetes improvement that clinical trials are now underway to test its effectiveness on those with BMI of 26 to 35.

Like other developing social problems, the problem of obesity has arrived at the door of insurers before a general social remedy has been found. The increasing rate of obesity also contributes to the complexity of estimating a long-range cost estimate for this ambiguously described mandate.

I.3A SUMMARY OF EXPECTED MEDICAL COSTS OF MANDATES IN 2010

1.	Eye Drops	$0.07	PMPM	less than 0.1%
2.	MRI	$0.92	"	0.3%
3.	Clinical Trials	$0.00	"	0.0%
4.	Gastric Bypass	$0.50	"	0.16%
TOTAL		**$1.49**	**"**	**0.5%**

A more appropriate range of medical cost for the six would be $0.75 to $2.20 PMPM. In terms of three scenarios, low, medium, and high, $0.75 PMPM is the low estimate, and $2.20 PMPM is the high estimate. The cost estimate for the medium scenario is $1.50 PMPM.

In calculating the percentage of overall medical cost, we used a denominator of **$315** PMPM for all calculations. This represents the medical cost for the average group plan in 2011.

Due to the nature of the MRI and Gastric Bypass Mandates, it is expected that costs in future years beyond 2011 could increase at a rate that is greater than overall medical trend as a result of increasing demand for these services.

I.4 THE DATA

Ingenix Consulting data was extracted for the purposes of this study. IC's internal commercial health claims data for 2006 – 2009 was examined, with emphasis on 2008 and 2009. 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. IC used national and CT-specific health claims data that was split between fully insured and self-funded coverage. Survey information was provided by CT carriers at the request of the state. It pertained primarily to whether the mandated services are currently covered.

II. ELABORATION ON THE FOUR MANDATES:

II.1 COMMENTARY ON ADMINISTRATIVE COST (ADMIN):

Any change in health benefits resulting from the mandates will need to be addressed by the 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.

The year one non-medical expense for these four mandates is expected to be about **$0.32** PMPM in addition to the $1.49 of medical cost for group plans. As a range, this total non-medical cost is about $0.20 to $0.50 PMPM, depending on the level of medical cost.

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 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 on hand to weather greater claims than anticipated and thereby assure their financial security. 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.

On average, the portion of the health insurance premium dollar that is assumed to apply to administrative cost, excluding profit, is approximately as follows:

Non-Benefit Expense as Percentage of Total Premium:

Individual	17% to 24%
Small Group	13% to 18%
Large Group	10% to 15%

This is reasonably consistent with the retention percentages provided by the CT DOI based on 2010 CT HMO filings.

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 (medical CPI) than administrative cost (CPI), 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 them.

II.1A SUMMARY OF EXPECTED TOTAL COSTS OF MANDATES IN 2010

For 2010 medical cost we used a projected range of $0.75 to $2.20 PMPM, and a point estimate of $1.49 PMPM for a medium-cost scenario. For non-medical cost, we assumed a range of $0.20 to $0.60 PMPM for the four mandates, with a point estimate of $0.32. This yields a total cost estimate of **$1.81 PMPM**, which would need to be added to health insurance premiums to cover these four mandates, all else equal.

$1.49 PMPM Medical Cost
$0.32 PMPM Non-Medical Cost—Includes Administrative Cost and Risk/Profit Charge
$1.81 PMPM TOTAL

For future calculations later in this report, we have used **0.5%** of premium as the incremental cost of these mandates, which is a best estimate, although there is a substantial amount of variability around this overall projection. The average cost of premium per member for group coverage in 2011 is assumed to be $378 PMPM ($378 = $315 / .8333).

II.2 EXPLANATION OF THE MEDICAL ASPECTS OF THE MANDATES:

1. **PRESCRIPTION EYE DROPS:** Eye drops for children are most commonly prescribed for minor ailments, such as pink-eye, also known as bacterial conjunctivitis, which is usually remedied with a single script of antibiotic. Additional conditions affecting children include seasonal allergies, dry eyes, and occasional viral infections. Most eye drops are antibiotics or steroids or both. Uses are anti-inflammatory, anti-allergy, antibiotic, antiviral, and other. Adults are more often affected by more serious eye conditions, such as glaucoma, than children are. The incidence of other serious eye conditions such as macular degeneration and diabetic neuropathy tend to increase with age; these conditions are more an issue with the more elderly Medicare population than with commercial insurance. The cost for a one-month supply of most prescription medications ranges from roughly two dollars to two hundred dollars.

   Most eye drops are prescribed for short-term acute conditions. About 90%+ of children using eye drops in a two year period used one fill only. For the adult population, about 80%+ used just one fill. The data indicates that there are relatively few eye drops users who use them for long-term conditions, especially in the non-adult population. Those who use eye drops long-term for chronic eye conditions like glaucoma tend to be older; these users are also more likely to suffer the loss of manual dexterity that comes with age. Running out of a script before month-end due to spillage is more a problem in the Medicare population than in the commercially insured population. The question arises whether doctors can prescribe an increased quantity for some patients that better accommodates their personal need for a larger monthly supply. Also, is there a limitation that arises from the way the pharmaceutical companies package prescription eye drops? They may wish to balance sufficiency of supply with potential wastage.

   Early refill is less a problem with children's eye drops than adults. Many children's eye drops require application 3 times daily; thus, before and after school is sufficient, and during school is unnecessary. This would eliminate the need for the extra bottle for some children.

2. **MRI for BREAST CANCER SCREENING:** MRI is not recommended for every woman as a routine breast cancer screening tool. It is estimated that about 40% of women have a sufficient percentage of dense breast tissue to warrant using the adjunct diagnostic tools of ultrasound and MRI. Over the past decade, breast cancer researchers and clinicians around the world have come to recognize that mammograms miss some cases of breast cancer (false negatives). The main reason for these false negatives is dense breast tissue, which also shows up white on a mammogram, as does the tumor itself. (Fatty breast tissue shows up as dark area on the mammogram.) Ultrasound helps the physician identify lumps or abnormalities that do not show up on mammograms of women with dense breast tissue. It picks up cancers that are undetectable by mammogram. The primary disadvantage of ultrasound is that it can miss micro-calcifications. MRIs go one step beyond the mammogram/ultrasound combination. They are used to detect disease as well as assess the extent of disease. MRIs, however, are accompanied by false positives. The decision to proceed from mammogram to ultrasound to MRI is made by the physician. This decision is made easier by the criteria, but an element of physician judgment is involved.

As described in the executive summary, CT requires notification to the patient of her breast density with her mammogram results. The density findings are in accordance with BI-RADS standards. CT is currently the only state that requires such notification as described below in section 2.c of Raised Bill 259 from February, 2010:

> On and after October 1, 2009, each mammography report provided to a patient shall include information about breast density, based on the Breast Imaging Reporting and Data System established by the American College of Radiology. Where applicable, such report shall include the following notice: "If your mammogram demonstrates that you have dense breast tissue, which could hide small abnormalities, you might benefit from supplementary screening tests, which can include a breast ultrasound screening or a breast MRI examination, or both, depending on your individual risk factors. A report of your mammography results, which contains information about your breast density, has been sent to your physician's office and you should contact your physician if you have any questions or concerns about this report."

3. **CLINICAL TRIALS and OFF-LABEL PRESCRIBING for PARKINSON's DISEASE and MULTIPLE SCLEROSIS:** Clinical trials consist of four phases—I through IV. There are two types of trials—those for treatment of disease and those for prevention. Only phase IV preventive trials are covered by this mandate.

Far more people have cancer than have Multiple Sclerosis (MS) or Parkinson's disease. The prevalence rate for each of the latter two in the commercially insured population is about 0.1%, whereas for cancer it is about 3.9%

Multiple Sclerosis (MS) is an inflammatory disease of the brain and spinal cord, which constitute the central nervous system (CNS). It specifically affects the myelin sheath that insulates and protects white-matter nerve cells, and it can potentially impair any bodily function that is controlled by the CNS. It is generally a slow progressive disease that may result in loss of muscle control, vision, balance, and sensation. For those with MS, the nerves of the brain and spinal cord are damaged by one's own immune system. For this reason it is categorized as an autoimmune disease.

According to the National Multiple Sclerosis Society, the condition affects approximately 400,000 Americans. Other estimates range from 150,000 to 500,000. With the exception of trauma, it is the most frequent cause of neurological disability beginning in early to middle adulthood. About 0.1% of the US population has MS, which is around one per thousand. A study by the CDC confirmed that MS prevalence is higher in northern US states than southern. There is no cure for MS. Medications might help ease MS attacks and possibly slow the disease. MS medications tend to be costly—in the range of $2,500 to $3,000 per script.

MS is two to three times as common in females as in males. Its occurrence is unusual before adolescence. A person has an increased risk of developing the disease from the teen years to age 50 with the risk gradually declining thereafter.

Parkinson's disease (PD) is a degenerative disease of the central nervous system. It is progressive in that it worsens with time, but it generally does so slowly. It adversely affects motor skills and cognition. Its onset typically affects those over age 60, so it is more common in the Medicare population than in the commercially insured. It can, however, occur in people much younger than 60. Medications help manage the symptoms, particularly during the early stages of the disease. Without treatment, people with PD lose the ability to walk in about 8 years and are bed-ridden by 10. Unlike cancer, it does not generally cause premature death. Some people with PD continue working for many years following diagnosis. It is often accompanied by tremor. In later stages, speech may be affected. Levodopa (also called L-dopa) is the best drug for controlling symptoms of Parkinson's disease. If used over a long period, however, it can cause problems. For this reason, physicians sometimes use other medicines to treat people in the early stages of the disease and delay the use of levodopa. Other medicines have more side effects and don't control symptoms as well as levodopa. Like MS, there is no cure for PD, but medications can help control the symptoms and make the disease easier to live with. PD medications tend to be far less costly than those for MS.

4. **GASTRIC BYPASS SURGERY:** Bariatric surgery is a term used for a range of surgeries that manage obesity. There are two general types—restrictive and malabsorptive. The former involves a mechanical constriction or reduction of the stomach that prevents the patient from eating normal or large portions without a feeling of fullness. The latter involves bypassing a portion of the small intestine in order to reduce the ability of the body to digest and absorb nutrients. Gastric bypass surgery involves both. Lap band surgery is restrictive only. Most of the bariatric surgeries performed today are for gastric bypass. The number of bariatric surgeries of all types has increased by well over ten-fold over the past twenty years. From 1990 to 2000, the utilization rate increased six-fold. Most can be performed laparoscopically today, and there is a reduced risk of death or adverse consequences compared with ten or twenty years ago.

There are numerous types of bariatric surgery. Gastric bypass is one type of bariatric surgery, but it is the most frequently performed type. The Roux-en-Y gastric bypass is the most frequently performed. In addition to reducing stomach capacity, it also allows food to bypass part of the small intestine. It involves re-routing the small intestine such that fewer calories can be digested and absorbed. Gastric bypass was initially performed as an open operation twenty years ago. Today, it is usually performed laparoscopically. It has become a safer operation over time. In general, there is more risk in operating on a morbidly obese person than on the average surgical candidate. Similarly, there is more risk in operating on a less healthy morbidly obese person than a healthy one. For some patients, laparoscopic methods will not work and an open surgical approach must be employed. It is difficult, however, for the prospective patient to determine the true risk of bariatric surgery. There are 30-day, 90-day, and one-year rates, and there may be ineffective tracking of patient mortality over the long-term as some entrepreneurial surgeons handle an exponentially increasing patient load. There are numerous complications and side effects that can result, and this may not be clear to the patient contemplating bariatric surgery. A 2003 study reports:

> One of the major and most common complications after Roux-en-Y gastric bypass is an anastomotic leak from the gastrojejunal anastomosis, which is often a source of mortality in these patients. Investigators from the Medical College of Virginia, a

center with extensive experience with these operations, reported on factors that predicted mortality and leak.[1] This study of over 3000 open and laparoscopic gastric bypass procedures reported a 1.5% mortality and 3% leak rate. Stratifying their patients by the various approaches used, they detected similar mortality rates for open primary bypass operations (1.5%) and for revision of previous gastric procedures (2.7%), although mortality was very low after a laparoscopic gastric bypass (0.2%). There was no difference in leak rates between primary open procedures (2.2%) and laparoscopic procedures (3.8%), but there was a higher rate of leak in patients undergoing revised procedures (6.8%). Other predictors of leak and mortality included older age, male sex, higher body mass index (BMI), and the presence of diabetes mellitus and/or sleep apnea.

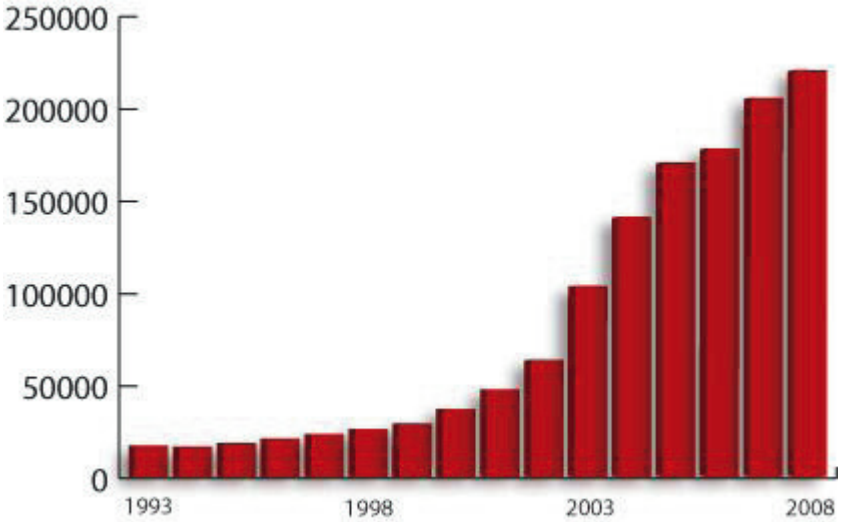
(Fernandez AZ, Demaria EJ, Tichansky DS, et al. Experience with over 3000 open and laparoscopic bariatric procedures: multivariate analysis of factors related to mortality and leak. Program and abstracts of the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) Annual Scientific Session and Postgraduate Course; March 12-15, 2003; Los Angeles, California.)

TYPES OF BARIATRIC SURGERY AND NATIONAL COST ESTIMATES:

Bariatric Surgery	Average Cost	Price Range
Gastric bypass	$25,000	$18,000 - $35,000
LAP-BAND®	$18,000	$12,000 - $25,000
REALIZE™ Band	$20,000	$16,000 - $25,000
Gastric sleeve	$15,000	$10,000 - $25,000
Roux-en-Y gastric bypass	$25,000	$20,000 - $35,000
Biliopancreatic diversion bypass (BDP)	$23,000	$20,000 - $25,000
Duodenal switch	$20,000	$18,000 - $30,000

Source: *ebariatricsurgery.com 2/2/2011*

Number of U.S. Bariatric Surgeries



Source: *American Society for Bariatric Surgery*

II.3 FURTHER EXPLANATION OF THE MEDICAL COST OF THE MANDATES:

The PMPM medical costs presented in this section are for group coverage. Individual data and costs will be presented later in Section II.4.

Note: 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 mandates 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 on a 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. Prescription Eye Drops: The current utilization of prescription eye drops by children is only a small portion of overall prescription drug utilization; they add about 0.1 scripts to the number of scripts used annually by the average member. A one month supply of prescription eye drops is relatively inexpensive. The allowed cost of the most expensive script for children in 2009 was $232, and the average script cost was $36. A study of the number of eye drop scripts per child was conducted, and 98% of those children with eye drop prescriptions had only one or two eye drop scripts in a 24 month period. Only 0.04% of children using prescription eye drops used 12 or more scripts during the 24 month period. This data suggests that the vast majority of children who use prescription eye drops do so for short-term acute conditions (such as pink-eye), not chronic long-term ones.

Since the mandate requires a second bottle for children at time of original fill, and since over 90% of eye drop scripts for children are filled only once, it is possible that the utilization rate for children could almost double under a highest possible use scenario, although this is highly unlikely. For children and adults combined, about 81% of people who used prescription eye drops in a two year period used only one script. About 2/3 of the incremental cost is expected to pay for the extra refill for children and adults, and the other 1/3 is for children who need an extra bottle at school or day care. In the adult and child population, the mandate is assumed to cause a utilization increase of 10% for early refill. In the child only population, the mandate is expected to cause a utilization increase of 10% for extra bottle for use at school or day care. The actual increase could be more or less than the projected increase. Also, the utilization level could increase over the next several years as more and more prescribing doctors and their patients become aware of the mandate.

In the IC 2009 data, the average script for children's eye drops cost $36; of this, the member paid $22, and the insurer paid $14. Although some rare eye diseases affect children, the data indicates that the vast majority of prescription eye drops are for mild short-term acute conditions involving bacterial infection or seasonal allergies (allergic conjunctivitis). The data shows that even for these conditions, often a more expensive brand drug is prescribed when a less expensive but effective generic alternative is available.

A range of potential costs has been created in the table of scenarios below based on assumed increases in utilization levels:

Utilization Increase	Incremental Cost
0%	$0.00 PMPM
5%	$0.04
10%	$0.07
20%	$0.14
50%	$0.35
100%	$0.70

2. MRI as Adjunct Procedure for Breast Cancer Screening: In the IC data for the national fully insured population, about 2.4% of women between 40 and 65 years of age had an MRI breast cancer screening in 2009. For CT only, it was 5.1%. Amongst self funded groups, the national average was 2.1% and CT was 5.7%. These 2009 MRI utilization statistics are roughly double what they were in 2006. The cost of mammography, ultrasound, and MRI differ considerably. Mammograms are less than $100 if non-digital, but they are around $200 if digital. Ultrasounds cost around $100. MRIs are closer to $2,000.

MRI FOR BREAST CANCER SCREENING, IC NATIONAL DATA, INSURED:

2006	NATIONAL	CT
ALLOWED PMPM	$0.12	$0.41
PAID PMPM	$0.10	$0.38
Utilization per 1,000 members	1.7	4.1
Estimated % Women Tested *	1.2%	2.7%

2009	NATIONAL	CT
ALLOWED PMPM	$0.24	$0.83
PAID PMPM	$0.19	$0.78
Utilization per 1,000 members	3.7	7.7
Estimated % Women Tested *	2.4%	5.1%

* For women 40 to 65. Calculated using Utilization per member per year divided by 15%, since women in the 40 to 65 age group represent about 15% of the overall insured population.

A secondary hypothetical approach was used to examine the highest cost scenarios that could occur as a result of this mandate. This involved assuming that all women in the 40 to 65 year age group underwent one MRI annually for breast cancer screening. This is an extreme hypothetical example that could not play out in actuality, but it helps depict the highest possible cost:

Women in the 40 to 65 age group represent about 15% of the insured population. If each one uses a $2,000 MRI annually, this would add $300 to the annual per member cost of health care, which $25 PMPM when spread to all insured members--

15% x $2,000 = $300 per member per year

$300 / 12 months = $25 PMPM.

The accuracy of this upper-bound estimate can be refined one step further by reducing this estimate for the percentage of women who will meet the medical necessity criteria for MRI. This is estimated to be 40%, which reduces the estimate to $10 PMPM--

40% x $25 PMPM = $10 PMPM.

It is not likely that every eligible woman will receive an MRI for breast cancer screening annually—that would assume a perfect compliance rate. If only half of the eligible women had one every two years, that would reduce the cost to $2.50 PMPM = $10 PMPM x 50% x 50%. Since there is already $0.92 PMPM spent on these services annually, the incremental cost would be $2.50 - $0.92 = $1.58 PMPM. This is about 60% greater than the best estimate of $0.92 PMPM.

3. Clinical Trials and Off-Label Prescribing for Parkinson's Disease and Multiple Sclerosis: There are fewer people with MS and Parkinson's disease than cancer. Consequently, there are fewer clinical trials conducted for these two diseases than for cancer. In the 2008 and 2009 national IC data, the percentage of people involved in clinical trials for either MS or Parkinson's is less than 0.5% of all people in clinical trials. Their cost is a similarly small fraction of the overall medical cost of those in clinical trials.

The table below illustrates that there are far more people with cancer than MS and PD. Also, like cancer, PD is more prevalent as age increases. There is a lower prevalence of both cancer and PD in commercial insurance populations than in the Medicare population.

	Cancer	MS	Parkinson's
National Prevalence Rate (All Ages)	3.9%	0.1% or less	0.1% to 0.3%

The other part of the mandate that could potentially add to the cost of health insurance is off-label prescribing. However, there are far fewer drugs for MS and Parkinson's than for cancer. Whereas cancer consists of many different types and stages, there is only one type of Parkinson's and four of MS, which are not as various as the many types and stages of cancer that affect different body parts.

Pharmacy and Medical Cost of Drugs Used for MS and PD, Nationally and CT Only, based on 2009 IC data for Group Coverage only:

SUMMARY for NATIONAL
2009

		Allowed	Paid	Cost-Share
MS	RX	$ 1.85	$ 1.80	$ 0.05
	MED	$ 0.14	$ 0.14	$ 0.01
	Total	**$1.99**	**$1.94**	**$0.06**
PD	RX	$ 0.16	$ 0.12	$ 0.03
	MED	$ 0.00	$ 0.00	$ 0.00
	Total	**$0.16**	**$0.12**	**$0.03**

CT ONLY
2009

		Allowed	Paid	Cost-Share
MS	RX	$ 3.04	$ 2.98	$ 0.06
	MED	$ 0.18	$ 0.18	$ 0.00
	Total	**$3.22**	**$3.16**	**$0.06**
PD	RX	$ 0.14	$ 0.12	$ 0.02
	MED	$ 0.00	$ 0.00	$ 0.00
	Total	**$0.14**	**$0.12**	**$0.02**

4. Gastric Bypass: The cost of bariatric surgery consists of several components:

- Anesthesia fees
- The hospital facility fee
- The surgeon's fee
- Pre-op lab and X-ray fees
- Follow-up appointments.

There is additional cost incurred prior to surgery. During this time there will be a number of appointments with medical providers as part of the pre-approval process.

IC national and CT data for 2008 and 2009 was examined for various types of bariatric surgeries. The IC 2009 national data below show that there is higher utilization of bariatric surgery in the ASO (self-funded) population than in fully insured plans.

Analysis of Commercial Bariatric Experience 2009
IC Research Data

	2009			
Fully Insured:	**PMPM**	**PMPM**		
	Paid	**Allowed**	**Paid**	**Allowed**
Total	**0.15**	**0.17**	**7,848,357**	**8,407,623**
ASO:	**PMPM**	**PMPM**		
	Paid	**Allowed**	**Paid**	**Allowed**
Total	**0.88**	**0.94**	**132,633,586**	**140,751,698**

The difference in total dollars Paid reflects, in part, the larger size of the self-funded population in the sample. The difference in PMPM costs, however, is interpreted to mean that many large self-funded employers' benefit plans cover bariatric surgery while some fully insured plans do not. Self-funded employers see the reduced health care expenditures and the productivity gains that result from bariatric surgery and may be more progressive in their handling of this cost as a subsidized employee benefit.

It is difficult to project the future cost of bariatric surgery because there are a number of forces that act over time to change utilization and the cost per patient. Apart from the change in unit cost of the surgery itself, there are several drivers that will affect the utilization of this surgery over time. First, there will be people who want the surgery who cannot get it currently. These are people who already show up in the prevalence rate for morbid obesity. It may take several years before their pent-up demand is satisfied. Thus, their year one cost may be higher as a result of accommodating their demand. Second, there will be those who become morbidly obese each year who thereby become candidates for bariatric surgery. This cohort will be represented by the annual incidence rate. If the rate of obesity were static in time, this would be substantially lower than the prevalence rate. However, the obesity rate is in fact increasing, and this will lead to increasing annual demand and cost for bariatric surgery unless the obesity rate levels off or begins to decline. Third, there will be those who have already had bariatric surgery that needs to be surgically revised.

In addition to the change in utilization, changes in medical technology, such as the invention of banding done laparoscopically, reduce the cost per surgery. This in turns increases the utilization of such surgeries.

Denominator Used in Medical Cost Percentage Calculations:

From the CT DOI, IC obtained arithmetic (not weighted) averages for filed 2010 insured HMO premiums (includes administrative cost and profit) for medical and RX combined:

Individual	$245.22
SG	$316.06
LG	$349.92

Note: This does not include any PPO or other non-HMO health insurance policies. The average retention (administrative cost + profit) associated with these filed HMO premiums is:

Individual	25%
SG	20%
LG	15%.

The HMO premiums are expected to be less than the non-HMO plans, but non-HMO rates are not filed in CT, so we assumed that on average they are 10% more costly than HMO.

In view of these numbers, it was decided to use $300 PMPM for the 2010 medical cost for group coverage in the denominator of our percentage calculations, which is within the range of the various filed and calculated 2010 medical cost amounts above. This was established in the prior phase of this project. For the average 2010 premium cost for group coverage, $360 PMPM was used.

For phase three and the 2011 medical (paid) cost, **$315 PMPM** was used for group coverage, which is 5% greater than the 2010 amount. This is the paid medical cost only. When non-benefit expenses are added, the assumed 2011 premium cost for group coverage is $378 PMPM, which includes all administrative cost and a risk/profit charge. ($378 PMPM = $315 / 0.8333).

II.4 DIFFERENTIAL EFFECT OF THE MANDATES ON INDIVIDUAL vs. GROUP INSURANCE COVERAGE:

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. Based on the carrier data, the average cost sharing for individual plans was determined to be 25%; (it is 13% for group plans). 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.

Individual insurance is not inexpensive, however, and the policy-holder must bear the entire premium cost alone. 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. The average cost of an individual health policy in CT is less than a group policy, and it typically provides less benefit, on average, than 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.

The medical cost of group plans in the CT data was significantly higher than individual plans both on an allowed and especially on a paid basis. There was also a significant difference between the Allowed Cost and Paid Cost for Group vs. Individual. For group plans, paid cost was about 87% of the allowed cost based on the CT data provided by all six carriers domiciled in CT. For individual plans, paid cost was 75% of allowed. (This restates the cost sharing statistics of 13% and 25% presented above.) Thus, as a percentage of allowed cost, the member cost-sharing in individual plans is about twice as much as it is in group plans.

During phase two of this project, $300 PMPM was used as the assumed average medical cost for group coverage in 2010 for the CT insured population. In 2010, $360 PMPM was used for the full group insurance premium, which includes all non-benefit expenses including a profit/risk charge where $360 = $300 / .8333. In this phase three report, **$315 PMPM** was used for the **2011** paid medical cost of group coverage. For 2011, the premium cost for group coverage used in this report is $378 PMPM. In 2010 and 2011, medical cost represents 83.33% of insurance premium for group coverage. Based on the carrier data submitted for phase two, member cost-sharing for group coverage represented 13% of “allowed” cost, which is mathematically equivalent to 15% of paid medical cost.

For individual insurance coverage, $210 PMPM was used as the paid medical cost in 2010 and $272 PMPM was used for the insurance premium. For **2011**, the paid medical cost of individual coverage used in this report is $220 PMPM, and the insurance premium is $286 PMPM.

During phase two of this project, the six insurance carriers domiciled in CT submitted claims and membership data. They reported that there were more than twelve times as many group members as individual in the 2007 carrier data submitted. There were about 1.2 million group

members but only about 92,000 individual members in the 2007 medical. Of these members, only 829,000 and 79,000 also had RX coverage.

The total 2011 projected paid medical cost for all four proposed mandates was $1.49 PMPM for group coverage, which is 0.5% of total medical cost. (The $1.49 is medical cost only and excludes administrative cost and profit.) **For individual health insurance, for the four mandates, the 2011 projected paid cost is $1.00 PMPM, which represents 0.5% of the total medical cost** (0.5% = $1.00 / $220)**.** It is also 67% of the group cost (67% = $1.00 / $1.49). As a percent of total medical cost, individual is expected to be the same as group for these four mandates.

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.

II.5 DIFFERENTIAL EFFECT ON LARGE GROUP vs. SMALL GROUP

The mandates are expected to have roughly the same effect on the allowed cost of small group plans as large. 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.

Like individual coverage, there is typically more adverse selection of benefits among small groups than large groups. Seen from another perspective, there are more uninsured people that work for small employers than large employers. These four proposed mandates do not invite adverse selection in the sense that formerly uninsured people with costly diseases will attempt to buy coverage as a result of the passage of these mandates.

The small group market is more sensitive to the cost of health insurance. A 15% 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, especially very large groups, may switch to a self-funded approach, which enables them to avoid complying with the mandates if they wish. This will be discussed further in the next section.

II.6 EFFECT OF MANDATES ON THE AVAILABILITY AND COST OF HEALTH INSURANCE:

Traditionally, the function of insurance, health insurance included, has been to provide financial security to those who are faced with economic uncertainty due to premature death, disease, accident, disability, loss of property, and the like. People who buy insurance believe there is greater utility in paying a certain monthly premium than potentially sustaining the uncertain loss that could occur. Because of group coverage and the fact that most insured people are insulated from most of the cost of health insurance, which is largely borne by the employer, health insurance is different than life insurance. It is increasingly perceived as fundamental to the health, commonwealth, and productivity of the nation. Those without access to health insurance, however, have difficulty maintaining the same level of health as the insured. Although the uninsured rate is lower in CT than the national average, it is estimated that there are still approximately 340,000 people in CT under the age of 65 currently without health insurance. This number has been increasing over the past ten years as the cost of coverage (premium) has increased at a rate about double that of inflation. A significant number of the uninsured are undocumented immigrants. A recently released national report estimates that there were about 110,000 undocumented immigrants in CT in 2007, which represented a leveling off of an increasing rate during the prior decade.

Although the data shows that the cost of the mandates is significant, it would be false to conclude that the mandates in isolation are the primary driver behind the growth in the cost of health insurance.

In this section of our report, the increase in total insurance premium cost caused by the mandates is discussed in the context of the expected consumer decision whether or not to renew health insurance coverage. Some actuarial evaluations of new and revised mandates now consider not only the effect of the mandate on health insurance premiums, but also the number or percentage of policy holders that will choose not to renew coverage due to the premium cost increase. This may be more an issue at the time a mandate is first introduced or revised, but less so once its cost has been embedded in the cost of coverage for several years. An incremental cost increase of 0.5% is not likely to be highly noticable during a period when health plans increase in premium cost approximately 8% - 10% per year. These mandates will continue to increase in cost each year for the next few years, but their effect on health insurance premium levels will not be highly conspicuous.

In the last section, the difference in lapse rate between small and large groups that results from the same-sized annual premium increase was mentioned. The likelihood of disenrollment due to cost increase is not easily calculated; it depends on the economic environment and other factors. Disenrollment tends to occur more often as a result of an abnormally large increase to a specific policy-holder. As the cost of health insurance premiums rises, fewer residents of CT can afford coverage.

If normal medical trend is about 8%, and if an annual premium increase can be reduced to around 4% with some moderate increase in copays, coinsurance, and or deductible (benefit "buy-downs"), such a small cost increase is less likely to cause disenrollment. Groups may choose to "buy-down" their benefit plan somewhat further rather than lapse coverage altogether. If lapsation occurs as a result of a mandate, it would tend to occur in the year the mandate is introduced because the price increase would be noticed then.

As employer groups reduce the level of coverage by shifting more cost to the insureds year after year (in the form of increased member cost-sharing), two things happen. One is that members pay a larger portion of the total plan cost, and the other is that members might forego some medically important services to avoid the personal expense of higher copays, deductibles, or coinsurance. Mandates generally increase the cost of insurance and, in conjunction with medical trend, individuals and groups will respond at time of renewal by purchasing a lower level of coverage with increased member cost-sharing. The end-game of all these buy-downs is a plan in which considerably more expense is shifted to the insured. Unless the plan makes high-value services available for reduced or no copays, under-insured people might forego some necessary services because the member cost-sharing acts as a barrier to access. Many carriers have shifted to plans that cover certain preventive services (or other high value services) at low or no cost to the member. This is intended to discourage underutilization of important care. The reforms to health care under the Patient Protection and Affordable Care Act of 2010 will also require insurers to offer plans that cover more preventive services with no member cost-sharing. (This report does not cover the effect of the PPACA on the CT health insurance system.)

On an ongoing basis, the group or individual insurance consumer tends not to notice the cost of mandates buried in the plan. Although actuaries have estimated lapse rates as a function of premium increases, there is not a great deal of hard data to work with. As a result, many of the expected lapse rate estimates tend to be "soft." The level of cost of health insurance plans is high enough today, however, that some groups simply cannot afford coverage. This is especially true for individuals who are not eligible for group coverage, since they personally bear the full premium cost.

The other group reaction to increasing premium cost that should be considered is that some groups, especially larger ones, will choose to move to a self-funded approach as a result of additional mandates that add to the cost of health insurance. This will be especially true if they perceive the mandates to be of low value. By switching to self-funding, groups can avoid mandates. Roughly half of the commercial health coverage in CT is already self-funded.

In phase two of this project, there was little evidence to support the assertions that groups are leaving the fully insured sector on account of mandates. Self-funded groups pay less in profit charges, and the largest self-funded groups are able to exert considerable leverage on the level of administrative fee that the insurer charges them to administer their self-funded business. It is likely that these large group economies of scale play a much more important role in the growth and size of the self-funded sector than does opposition to mandates. Self funded groups also do not pay state premium tax as do fully insured groups and individuals. This tax is considered part of administrative cost, and it is 1.75% of premium.

When all carriers in CT are subject to the mandates, the playing field is level and affects all insurers equally in the sense that all must provide at least a minimum standard of coverage.

If various CT insurers are examined, it is possible that there is currently some variation around who is pre-approved for gastric bypass surgery due to varying precertification standards and medical necessity criteria. By adopting a minimum, insurers are not prevented from offering a richer benefit than the mandated minimum.

It should be noted that above and beyond the availability of insurance, the substantial increases in health care cost over the past decade have left employers with less and less money to spend on other employee benefits and on wages and salaries.

The last point to cover in this section pertains to the cost of health insurance. When health insurance is priced, it is broken into cost categories depending on the "tier" that is purchased. A single person buys a single policy. A couple that wishes coverage will purchase a couple policy, also known as the employee plus dependent tier. A single parent with one or more children will purchase an employee plus children policy. And a couple with a child or children will purchase a family policy. Based on a paid medical cost of $315 PMPM and insurance premium of $378 PMPM in 2011 for group coverage, the following costs by tier are approximated: (Employee is EE)

	MONTHLY	ANNUAL (rounded)
Single EE	$450	$5,250
EE + Spouse	$975	$11,550
EE + Child(ren)	$900	$10,500
Family	$1,310	$15,750

(Note that the Single Employee cost is different than the PMPM because the average member is a mix of adults and children, and the average medical costs for children are roughly half that of adults.)

The 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 raised more forcefully when mandates are for services that are perceived to be non-essential. There is no easy answer to the question of which services to include in the essential benefits package of a health plan. By excluding items such as bariatric surgery or MRI for breast cancer screening, those individuals who need these services may end up with higher personal out-of-pocket expense. In the case of gastric bypass, this personal expense could be $5,000 to $30,000 or more.

Excluding some benefits from the package of essential benefits covered by the health plan is a complex problem. 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 insureds 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. 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%.

The carriers were surveyed to determine whether they already provide these mandated benefits in their insured and self-funded plans. Further information about these surveys is contained in section IV of this report.

II.7 EFFECT OF MANDATES ON PUBLIC HEALTH:

The public health gains resulting from the mandates will be discussed in this section. Depending on the nature of the mandate, their positive medical effect occurs over a continuum ranging from those that affect everyone to those that affect only a vulnerable minority. Mandates that serve to improve the health of individuals also increase their productivity. Due to the small number of individuals affected by the narrow focus of some mandates, their overall affect on the public health of the entire insured population will not be as sweeping as a mandate that affects all. For the few that are affected, however, these mandates provide strongly beneficial health interventions that will enable them to live higher quality, more productive lives.

Most studies of the cost of disease, illness, and injury include not only the direct cost of medical care but also the cost of lost productivity and other costs to society.

The eye drops mandate affects a very small number of people in the insured population. It is not a life or death medical need, but for the limited number of people with serious sight-threatening conditions like glaucoma, it is problematic to run-out early.

The MRI for breast cancer screening potentially affects women between 40 and 65. In particular, it affects the subset of women with dense breast tissue and those with an increased likelihood of breast cancer due to personal genetic make-up or family history. Women between 40 and 65 comprise about 15% of the fully insured population. Applied appropriately, this mandate can enhance early detection of cancer and reduce the number of deaths from breast cancer for CT women. A more exact and quantitative prognosis of the improvement is still emerging in the medical literature.

Approximately 0.2% of the fully insured population has MS or PD. Neither MS nor PD cuts life short as quickly as cancer can. This mandate may improve the quality of life for those affected, but not dramatically extend life expectancy. Even after passage of this mandate, it is likely that insurers would still use pre-authorization of certain high cost drugs for appropriateness, even for those with MS or PD.

Gastric bypass and bariatric surgery in general would make a significant improvement in quality of life, productivity, and reduced medical cost, particularly for those who are morbidly obese and have diabetes. Studies show that these surgeries can effectively help people reduce excess weight by 50% or more for those that are overweight by 100 pounds or more. Those that alter their lifestyle after surgery can maintain that weight loss. Results of one study by Cremieux et al. established that insurers recover the cost of bariatric surgery in two to four years depending on surgical approach and the savings are then ongoing.

II.8 EFFECT OF MANDATES ON THE DELIVERY OF HEALTH CARE INCLUDING THE UTILIZATION AND UNIT COST OF HEALTH CARE SERVICES, MEDICAL SUPPLIES, AND DEVICES (Includes provider and supplier reactions as well as individuals):

One of the consequences of any benefit mandate is reactionary change elsewhere in the system for the finance and delivery of health care. Sometimes the consequence is anticipated and intended; at other times, it is not. If the evolution of Medicare over the past forty plus years is observed, similar actions and reactions can be seen as the package of benefits, provider reimbursement methods, and eligibility standards changed over time.

Any mandate that adds to the list of things health insurers must cover generally adds to the cost of medical care and insurance. Although there is often initial hope that certain advances produce savings, most mandates as well as advances in medical technology are additive in cost. The market reacts to the mandate in many ways. The mandate may induce utilization, and providers may increase the rate at which the service is performed. It may increase the unit cost of medical goods and services as increased demand increases price. For complex surgeries, the price can also decrease over time.

One of the aspects of the mandates that was asked to be addressed is the effect on public-private cost-shifting. Generally, the public sector, due to its authority and purchasing power, is able to establish lower provider reimbursement rates for its programs, especially Medicare and Medicaid, than private sector insurers pay for the same services. Historically, Blue Cross Blue Shield plans had larger market share and were able to negotiate somewhat lower rates than their competitors in the private sector, but both paid more than public payers. Health care experts argue that private payers generally pay more for most medical services because public payers (Medicare and Medicaid) reimburse providers at cost or less than cost. The shortfall, it is argued, must be made up by charging commensurately more to those with private coverage.

In general, because the vast majority of private insurance is group coverage provided through employers that pay for the majority of the premium, most people are buffered from the true cost of health care. Employers are tax-subsidized to provide insurance to employees and their dependents. Some policy experts argue that this situation contributes to the high and increasing cost of health care. Part of this high cost stems from the unnecessarily high utilization of services that is, in part, caused by the fact that insured people with employer coverage are buying those services with the help of “other people’s money.” Without the employer subsidy for the cost of health insurance premiums, the member cost-sharing would have to be much greater; it is also likely that many services would have to be cut out of the insurance coverage to keep premiums affordable. The same experts argue that this induced demand in group coverage drives up the unit cost per service. This affects all medical care--not just the care covered by the mandates. If that is the case, some marginally necessary services may be deemed to be more essential than they would be if individuals had to pay the full cost of care entirely out of their own pockets.

Especially in the private health insurance market, healthcare is not a pure market-based system, so it is difficult to apply the usual laws of supply and demand to health care. Nonetheless, it seems likely that the employer subsidy in the group market helps to drive up the demand for and the overall cost of care. The presence of mandated benefits in conjunction with that employer subsidy also pushes cost in the same upward direction.

For the prescription eye drops mandate, there are likely to be consequences if it is passed. There is not a great deal of evidence to suggest that lack of an extra bottle of prescription eye drops for children for school affects many children or is otherwise a significant barrier to crucial care. Similarly, for those adults who run out of their eye drops before the end of the month, the out of pocket cost is not prohibitively expensive. If the mandate is passed, it will substantially alter the way prescription eye drop benefits are made available for all that use them rather than just addressing the limited few who might run out early in the month or the very small number of children that medically need an extra bottle for school. Fixing the problem using the insurance system seems a heavy-handed approach. For those who run out early, can doctors prescribe larger monthly supplies? Can doctors make free samples available for those who truly cannot afford the cost of a prescription? Does the problem stem from the way that pharmaceutical companies package the product in terms of the amount of monthly supply they provide? The objective is to assure adequacy of supply without causing wastage of eye drops. Requiring insurers to follow the mandate may raise utilization for many eye drop users that currently do not need the mandate in order to access their needed medical care. In order to protect the few, this mandate may cause a utilization increase for many prescription eye drop users.

For the mandate involving MRI for breast cancer screening for some women, there is likely to be continued controversy as to who is eligible and how often. In 2009, an advisory panel to the federal Health and Human Services department recommended a reduction in mammogram screening from once annually beginning at age 40 to once every two years beginning at 50. The panel cited lack of evidence demonstrating that annual screening reduces mortality due to breast cancer, and it warned that false positives lead to unnecessary, expensive follow-up treatments. This recommendation was criticized by physicians and the American Cancer Society; they continue to advocate for annual screening beginning at age 40. Similarly, the evidence-based value of MRI for breast cancer screening is still being tested, and the opinions of cancer experts can be expected to further evolve as the body of medical evidence grows. Cancer experts agree that early detection helps combat breast cancer. The specifics as to which types of screening, at what age, and how often will become more informed over time. It is clear that there are personal risk factors that predispose certain women to a greater than average risk. With additional research, more of these personal factors are likely to emerge. With the passage of this mandate, women's doctors may feel the need to practice defensive medicine and request the MRI for breast cancer screening more frequently.

For the mandate involving clinical trials and off-label prescribing for Parkinson's disease (PD) and Multiple Sclerosis (MS), it is possible that the mandate will have an insignificant effect on health benefits. Insurers already pay the routine care costs of people in clinical trials. Moreover, insurers generally pay for off-label prescribing, except possibly for those drugs that require preauthorization or step therapy. Insurers may still apply preauthorization and step therapy standards to expensive drugs in order to assure they are prescribed for reasons of sufficient medical necessity. One example of a drug requiring preauthorization is Provigil, which promotes alertness and is intended for people with narcolepsy. It is also of benefit to people who suffer drowsiness for a variety of different reasons, including MS or PD. The passage of this mandate would not preclude insurers from continuing to use preauthorization to assure appropriate utilization of certain drugs. Managed care techniques such as

preauthorization help to keep the price of health insurance affordable and assure that people obtain the right services in the right setting at the right time.

For the mandate on gastric bypass surgery, there will likely be more and more people undergoing such surgery. For those who are morbidly obese (BMI > = 40), there are subsequent savings, especially related to ongoing treatment of diabetes, that help offset the cost of the operation(s). More surgeons and hospitals are marketing their services around bariatric surgery, and this can be expected to drive the utilization rate higher. Depending on who is eligible for this surgery under this mandate, the range in future cost can vary considerably. Some preliminary cost-benefit studies of bariatric surgery have been conducted. As more are published, the standards regarding medical necessity will likely be modified to accommodate this new medical evidence. It is difficult to predict how this will play out on the health care system. If the pharmaceutical industry succeeds in developing a drug that can safely reduce curb appetite, bariatric surgery could become an outmoded mode of medical treatment.

III. LONG-TERM COST IMPLICATIONS OF THE FOUR PROPOSED MANDATES

Appendix Two presents a five-year pro forma of mandate costs for group coverage from 2011 to 2015. For each mandate, it contains four separate items: 1) paid medical cost, 2) non-medical expenses, 3) the total insurance premium cost (the combined cost of paid medical plus non-medical expenses including profit/risk), and 4) member cost-sharing. These are items are projected out over a five year horizon according to the assumptions listed at the bottom of the spreadsheet. Below is a summary of these costs:

	YEAR				
MANDATE	**2011**	**2012**	**2013**	**2014**	**2015**
1. Prescription Eye Drops	$0.07	$0.07	$0.08	$0.08	$0.09
2 MRI for BC Screen	$0.92	$1.06	$1.22	$1.40	$1.61
3 MS & PD, Clinical Trials	$0.00	$0.00	$0.00	$0.00	$0.00
4. Gastric Bypass	$0.50	$0.60	$0.73	$0.88	$1.06
TOTAL Medical (Paid) COST	**$1.49**	**$1.74**	**$2.02**	**$2.36**	**$2.76**
Non-Medical Expenses	$0.32	$0.35	$0.40	$0.47	$0.55
TOTAL AFFECT ON HEALTH INSURANCE PREMIUM	$1.81	$2.08	$2.43	$2.83	$3.31
EXPECTED MEMBER COST SHARING (not part of health insurance premium cost)	$0.11	$0.13	$0.15	$0.17	$0.20

The 2011 (year one) cost is based on the assumption that the mandate becomes effective on January 1, 2011. In order to project to future years, assumptions of increased utilization formed the basis of cost increases in addition to 5% annual trend increases. These assumptions are described in Appendix Two.

IV. HEALTH INSURANCE CARRIER SURVEYS

A survey was developed by the workgroup consisting of the CT Center for Public Health and Health Policy, the CT Insurance Department, and Ingenix Consulting. This survey was sent to each of the six health insurance carriers domiciled in CT. 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, most but not all the carriers had returned their survey responses. Some were not entirely complete, and in some cases, data pertaining to frequency of utilization raised questions.

Based on the returned surveys, we draw these general inferences about current insurer coverage in CT of the benefits in the proposed mandates in the fully insured market:

Prescription Eye Drops are included in all insured policies, but early refills or extra bottles are not typically covered as a standard benefit. In some special cases, some carriers may accommodate members' requests for early refills with their doctor's approval, but there is no guarantee of this.

MRI for breast cancer screening is generally covered according to the criteria recommended by the American Cancer Society.

The cost of routine care for members in clinical trials is covered by CT insurers. The cost of off-label prescribing is also generally covered except where the prescription does not meet the conditions required by the insurer's pharmacy pre-authorization rules.

Bariatric surgery, which includes gastric bypass surgery, is not a standard part of every insurer's plan of benefits in CT. Most plans explicitly exclude bariatric surgery. Some insurance plans may include it as a supplemental benefit, presumably at additional cost.

The plans revealed they already cover MRI for breast cancer screening and clinical trials and off-label prescribing for MS and PD for their ASO plans. There were no responses regarding bariatric surgery and gastric bypass for ASO.

V. CONCLUSION

For group coverage, the 2011 paid medical cost of the four mandates is projected to be $1.49 PMPM. For individual coverage, it is projected to be $1.00 PMPM. Either way, they will add about **0.5%** to the cost of medical care and the cost of health insurance. The vast majority will come from MRIs for breast cancer screening and bariatric surgery, in that order. With bariatric surgery, offsetting savings are expected as the future medical costs of formerly morbidly obese people declines along with the medical problems that coexist with obesity. The cost of the mandate for clinical trials and off-label prescribing for PD and MS is expected to be *de minimis*. There is considerable variance around this total cost estimate because there are numerous factors that could drive this cost higher or lower. For each mandate itself, the variance around the future cost of gastric bypass surgery is greatest, followed by MRI for breast cancer screening.

VI. LIMITATIONS IN USE:

This study was conducted by IC exclusively for the State of CT, specifically and solely as it applies to the evaluation of the four proposed benefit mandates covered by Public Acts Number 09-179. This report is not intended for any other application or purpose.

I, Daniel Bailey, am a Director of Actuarial Services with Ingenix Consulting. 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 Daniel.Bailey@IngenixConsulting.com, and my office phone is 860-221-0245.

Daniel Bailey, FSA, MAAA

VII. APPENDIX 1.A

Group Insurance Coverage Only
(Some totals may not add exactly due to rounding)

MANDATE 1--PRESCRIPTION EYE DROPS
COST CALCULATION

Summary of 2008-2009 Rx for Ophthalmologic NDC Codes
National vs CT Only

CHILDREN ONLY

		Member Months	Rx/1000	Allowed PMPM	Paid PMPM	Cost-Shr PMPM
2008						
	National	10,648,446	125.25	$0.37	$0.11	$0.26
	CT	55,694	166.77	$0.55	$0.22	$0.33
2009						
	National	9,961,370	116.33	$0.35	$0.11	$0.24
	CT	58,375	163.63	$0.60	$0.25	$0.35

ALL AGES

2008						
	National	45,319,451	139.35	$0.69	$0.30	$0.39
	CT	206,798	170.54	$0.89	$0.45	$0.44
2009						
	National	42,372,542	128.22	$0.66	$0.31	$0.35
	CT	212,179	158.75	$0.91	$0.48	$0.43

INCREMENTAL CT 2011 COST FOR

EXTRA BOTTLE(S), Adults and Children--Early Refill		
BEST ESTIMATE	$ 0.08	$ 0.04
EXTRA BOTTLE for Children for School		
BEST ESTIMATE	$ 0.06	$ 0.03
TOTAL	**$ 0.15**	**$ 0.07**

VII. APPENDIX 1.B
Group Coverage Only
(Some totals may not add exactly due to rounding)

MRI FOR BREAST CANCER SCREENING
2011 PROJECTIONS

	Util/1000	ALLWD	PD	Cost Shr
WithOUT mandate				
CT				
2006	4.10	$0.41	$0.38	
2008	7.52	$0.81	$0.74	
2009	7.71	$0.83	$0.78	
2011	8.10	$0.92	$0.86	$0.05
	2.5% Util trend	5% PMPM trend	5% PMPM trend	
NATIONAL				
2006	1.73	$0.12	$0.10	
2008	3.24	$0.22	$0.18	
2009	3.66	$0.24	$0.19	
2011	3.89	$0.26	$0.21	$0.05
	2.5% Util trend	5% PMPM trend	5% PMPM trend	
Ratio of CT/National				
2006	2.4	3.4	3.7	
2008	2.3	3.7	4.2	
2009	2.1	3.4	4.1	
2011	2.1	3.5	4.1	
	2.5% Util trend	5% PMPM trend	5% PMPM trend	

INCREMENTAL COST OF MANDATE	
ASSUMING DOUBLING OF PROJECTED 2011 COST	
Projected with Doubling	$1.83
Less Expected 2011 Cost without mandate	$0.92
INCREMENTAL (NET NEW) COST	**$0.92**

Due to the Affordable Care Act, there will be no cost sharing for preventive services in 2011. Thus, 2011 Paid cost will equal Allowed.

VII. APPENDIX 1.C
Group Coverage Only
(Some totals may not add exactly due to rounding)

Summary of Clinical Trials by Diagnosis Type
All Claims Containing Diagnosis Code V707, National IC Data

2009: Member Months = 200,669,548

Total Category	Paid	Allowed	Paid PMPM	Allow PMPM
Other	3,225,954	3,406,508	0.02	0.02
Circulatory	3,926,338	4,118,924	0.02	0.02
Parkinsons	29,957	31,109	0.00	0.00
MS	15,735	16,495	0.00	0.00
Cancer	16,663,937	17,174,221	0.08	0.09
Totals	**23,861,921**	**24,747,257**	**0.12**	**0.12**

Physician

Category	SvcCnt	Paid	Allowed	Util/1000	Paid PMPM	Allow PMPM
Other	4,469	312,428	347,122	0.267	0.00	0.00
Circulatory	971	126,547	141,534	0.058	0.00	0.00
Parkinsons	10	13,494	14,647	0.001	0.00	0.00
MS	11	1,720	1,910	0.001	0.00	0.00
Cancer	14,653	2,472,410	2,654,800	0.876	0.01	0.01
Totals	**20,114**	**2,926,598**	**3,160,012**	**1.203**	**0.01**	**0.02**

Outpatient Hospital

Category	Visits	Paid	Allowed	Visits/1000	Paid PMPM	Allow PMPM
Other	828	940,814	1,019,972	0.050	0.00	0.01
Circulatory	160	1,241,871	1,310,051	0.010	0.01	0.01
Parkinsons	1	16,463	16,463	0.000	0.00	0.00
MS	9	13,327	13,897	0.001	0.00	0.00
Cancer	4,421	11,601,894	11,885,625	0.264	0.06	0.06
Totals	**5,419**	**13,814,368**	**14,246,008**	**0.324**	**0.07**	**0.07**

Inpatient Hospital

Category	Admits	Paid	Allowed	Admits/1000	Paid PMPM	Allow PMPM
Other	135	1,972,712	2,039,414	0.008	0.01	0.01
Circulatory	103	2,557,920	2,667,338	0.006	0.01	0.01
Parkinsons	0	0	0	0.000	0.00	0.00
MS	1	688	688	0.000	0.00	0.00
Cancer	104	2,589,633	2,633,796	0.006	0.01	0.01
Totals	**343**	**7,120,954**	**7,341,237**	**0.021**	**0.04**	**0.04**

VII. APPENDIX 1.D.1 Group Coverage Only

BARIATRIC SURGERY CALCULATION, Method 1				
Using Prevalence (Frequency) Times Avg Cost (Severity)				
Annual Incidence	0.100%			
Take-Up	25%			
Annual Utiliz	0.025%	Equivalent to 1 in 4,000 people		
Avg Allowed Cost		$ 25,440		
Paid / Allwd Factor	94.34%			
Avg Paid Cost		$ 24,000		
PMPY			$ 6.00	
	12			
PMPM			**$ 0.50**	

Analysis of Commercial Bariatric Experience 2009				
IC National Research Data				
		2009		
Fully Insured (FI):	**PMPM**	**PMPM**	TOTAL $ *	
SvcCatg	**Paid**	**Allowed**	**Paid**	**Allowed**
IP Admit	0.08	0.08	$3,856,132	$4,131,540
OP Visit	0.05	0.06	$2,593,344	$2,829,492
Physician	0.03	0.03	$1,398,880	$1,446,591
Total	**0.15**	**0.17**	**$7,848,357**	**$8,407,623**
ASO Self-Funded):	**PMPM**	**PMPM**	TOTAL $ *	
SvcCatg	**Paid**	**Allowed**	**Paid**	**Allowed**
IP Admit	0.26	0.27	$38,500,143	$40,154,972
OP Visit	0.42	0.45	$62,977,876	$67,273,262
Physician	0.21	0.22	$31,155,567	$33,323,463
Total	**0.88**	**0.94**	**$132,633,586**	**$140,751,698**
DIFFERENCE = ASO - FI	**PMPM**	**PMPM**	TOTAL $ *	
SvcCatg	**Paid**	**Allowed**	**Paid**	**Allowed**
IP Admit	0.18	0.19	$34,644,012	$36,023,432
OP Visit	0.37	0.39	$60,384,531	$64,443,771
Physician	0.18	0.19	$29,756,687	$31,876,872
Total	**0.73**	**0.77**	**$124,785,230**	**$132,344,074**
*** TOTAL $ included only to show that ASO data has more members and is more credible than FI.**				

ESTIMATED COST BASED ON ASSUMPTIONS BELOW, Method 2				
		% of 2009	PMPM	PMPM
		Difference *	**Paid**	**Allowed**
2011		68%	**$0.50**	$0.53
2012		83%	**$0.60**	$0.64
2013		100%	**$0.73**	$0.77
2014		121%	**$0.88**	$0.93
2015		146%	**$1.06**	$1.12
* Yr over Yr Increase Based on 15% Utilization Increase in addition to 5% trend				

VII. APPENDIX 1.D.2
Group Insurance Coverage Only

PREVALENCE OF OBESITY

IC Data, Based on ICD-9 Diagnosis Codes

Obesity defined as BMI > = 30
Morbid Obesity defined as BMI > = 40

National			Connecticut ONLY	
2008:			**2008:**	
Diag Code	**Patients**		**Catg**	**Patients**
27800	273,221		27800	2,249
27801	119,774		27801	1,074
Total Patients	**392,995**		**Total Patients**	**3,323**
Total Members	20,763,287		Total Members	206,505
Overall Prevalence of Obesity	**1.89%**		**Prevalence**	**1.61%**
Morbidly Obese Only (BMI > = 40)	0.6%			0.5%
BMI 35 to 40 (40% of 278.00)	0.5%			0.4%
Assume 50% w/ Complications	0.3%			0.2%
TOTAL ELIGIBLE	0.8%			0.7%
2009:			**2009:**	
Catg	**Patients**		**Catg**	**Patients**
27800	292,477		27800	2,677
27801	128,461		27801	1,196
Total Patients	**420,938**		**Total Patients**	**3,873**
Total Members	20,399,317		Total Members	220,123
Overall Prevalence of Obesity	**2.06%**		**Prevalence**	**1.76%**
Morbidly Obese Only (BMI > = 40)	0.6%			0.5%
BMI 35 to 40 (40% of 278.00)	0.6%			0.5%
Assume 50% w/ Complications	0.3%			0.2%
TOTAL ELIGIBLE	0.9%			0.8%
Increment added if BMI minimum drops 5				
	0.7%			0.6%

278.00 Obesity Unspecified, BMI = 30 to 40
278.01 Morbid Obesity, BMI > = 40

VII. APPENDIX TWO:
Group Insurance Coverage Only
(Some totals may not add exactly due to rounding)

FIVE YEAR PRO FORMA OF PROJECTED PAID MEDICAL COST
for Group Coverage

	YEAR				
MANDATE	**2011**	**2012**	**2013**	**2014**	**2015**
1. Prescription Eye Drops	$0.07	$0.07	$0.08	$0.08	$0.09
2 MRI for BC Screen	$0.92	$1.06	$1.22	$1.40	$1.61
3 MS & PD, Clinical Trials	$0.00	$0.00	$0.00	$0.00	$0.00
4. Gastric Bypass	$0.50	$0.60	$0.73	$0.88	$1.06
TOTAL Medical (Paid) COST	**$1.49**	**$1.74**	**$2.02**	**$2.36**	**$2.76**

Annual Increase Assumptions:
1. Eye Drops increase annually at 5% Trend
2. MRI for Breast Cancer Screening increases at 5% Trend plus 10% annual utilization increase
3. Cost of Clinical Trials and Off-Label Prescribing for MA and PD remains *de minimis* in the event that there is not a medical breakthrough that radically alters the cost structure of either disease.
4. Gastric Bypass--year one cost assumed to be a portion of the current difference between the cost of Self-funded and Insured Plans, then increases annually by 5% trend and 15% utilization

Non-Medical Expenses	$0.32	$0.35	$0.40	$0.47	$0.55
TOTAL AFFECT ON HEALTH INSURANCE PREMIUM	$1.81	$2.08	$2.43	$2.83	$3.31
EXPECTED MEMBER COST SHARING (not part of health insurance premium cost)	$0.11	$0.13	$0.15	$0.17	$0.20

Note: There is no member cost-sharing for MRI since it is a preventive service.

VII. APPENDIX THREE

PMPMs by Mandate, for each of Group and Individual Coverage

(Some totals may not add exactly due to rounding)

GROUP COVERAGE

PROJECTED 2011 COSTS

		PROJECTED 2011 PMPM AMOUNTS					
				= A - B		=C + D	
		A	B	C	D	E	F
		ALLOWED	COST SHARE	**PAID**	RETENTION	**PAID + RETENTION**	% of PREMIUM
1	Prescription Eye Drops--Early Refill for All Ages and Extra Bottle for Children	$0.15	$0.08	**$0.07**	$0.03	**$0.10**	0.0%
2	MRI for Breast Cancer Screening	$0.92	$0.00	**$0.92**	$0.18	**$1.10**	0.3%
3	Clinical Trials and Off-Label Prescribing for Multiple Sclerosis and Parkinson's Disease	$0.00	$0.00	**$0.00**	$0.00	**$0.00**	0.0%
4	Extension of Coverage for Gastric Bypass Surgery	$0.53	$0.03	**$0.50**	$0.11	**$0.61**	0.2%
	TOTAL	$1.60	$0.11	**$1.49**	$0.32	**$1.81**	0.5%

INDIVIDUAL COVERAGE

PROJECTED 2011 COSTS

		PROJECTED 2011 PMPM AMOUNTS					
				= A - B		=C + D	
		A	B	C	D	E	F
		ALLOWED	COST SHARE	**PAID**	RETENTION	**PAID + RETENTION**	% of PREMIUM
1	Prescription Eye Drops--Early Refill for All Ages and Extra Bottle for Children	$0.10	$0.05	**$0.05**	$0.03	**$0.08**	0.0%
2	MRI for Breast Cancer Screening	$0.62	$0.00	**$0.62**	$0.19	**$0.80**	0.3%
3	Clinical Trials and Off-Label Prescribing for Multiple Sclerosis and Parkinson's Disease	$0.00	$0.00	**$0.00**	$0.00	**$0.00**	0.0%
4	Extension of Coverage for Gastric Bypass Surgery	$0.36	$0.02	**$0.34**	$0.10	**$0.44**	0.2%
	TOTAL	$1.07	$0.07	**$1.00**	$0.31	**$1.31**	0.5%

VII. APPENDIX FOUR
TOTAL COST
(Some totals may not add exactly due to rounding)

GROUP + INDIVIDUAL COVERAGE
TOTAL COST CALCULATION
PROJECTED 2011 COSTS

		TOTAL COST CALCULATIONS BELOW ARE BASED ON **1,393,444** Fully Insrd + CT State Ees Plan				
		All Insureds + State EEs		**MEDICAL (PAID) COST ONLY**		
		ALLOWED	**ALLOWED + RETENTION**	**All Insureds + State EEs**	**State EEs Plan**	**Fully Insrd Only = All - State EEs**
1	Prescription Eye Drops--Early Refill for All Ages and Extra Bottle for Children	$ 2,405,871	$ 2,874,311	$ 1,122,740	$ 138,041	$ 984,699
2	MRI for Breast Cancer Screening	$ 14,756,010	$ 17,834,328	$ 14,756,010	$ 1,814,247	$ 12,941,763
3	Clinical Trials and Off-Label Prescribing for Multiple Sclerosis and Parkinson's Disease	$ -	$ -	$ -	$ -	$ -
4	Extension of Coverage for Gastric Bypass Surgery	$ 8,500,745	$ 10,320,213	$ 8,019,571	$ 986,004	$ 7,033,567
	TOTAL	$ 25,662,626	$ 31,028,851	$ 23,898,321	$ 2,938,292	$ 20,960,029

MEMBERSHIP COUNTS		= A + B		= C - D
A	B	C	D	E
FI Grp + State EEs	Indiv FI Only	All FI + State EEs	State EEs Only	All FI Only
1,220,577	172,867	1,393,444	164,334	1,229,110

Appendix IV

Ingenix Consulting

Financial and Socioeconomic Report

INGENIX | CONSULTING

Report for the State of Connecticut on the Financial and Socioeconomic Burden Related to Four Proposed Mandates

February 28, 2011

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INTRODUCTION AND SUMMARY FINDINGS

In this section of the report, the expected financial burden and socioeconomic aspects of the four proposed mandates will be considered both in the presence and absence of the mandate. A broader interpretation of the financial burden analysis was undertaken which includes socioeconomic factors in addition to the cost burden considerations. The medical aspects of the mandates as well as elaboration on the cost and effects of the mandates is covered in a separate actuarial report and therefore not included here.

In 2008, about two-thirds of Connecticut residents were covered[1] by private insurance (60.1% had employer based policies and 4.6% had individual policies); about a quarter were covered under public programs (Medicare 13.6% and Medicaid 11.5%); and 9.7% did not have any insurance. Among the privately insured, a third[2] were enrolled in HMO plans and the rest had PPO or other non-HMO coverage. Of those with HMO coverage, about 66% are fully insured. Of those with non-HMO coverage, about 45.6% are fully insured. Unless stated otherwise, the mandates discussed here, in general, apply to these fully insured group and individual policy holders only, that is, about 32% to 35% of the CT population. Although 60% of CT residents have private, employer-based group coverage, about half of that is self-funded (not fully insured) and is not subject to the state health insurance mandates. The charts below provide the overall coverage information as well as the demographics of the uninsured. Even though the state mandates are not applicable to this population, it provides us a baseline against which we can measure the impact of the mandates on the cost and financial burden.

FIGURE 1(a)

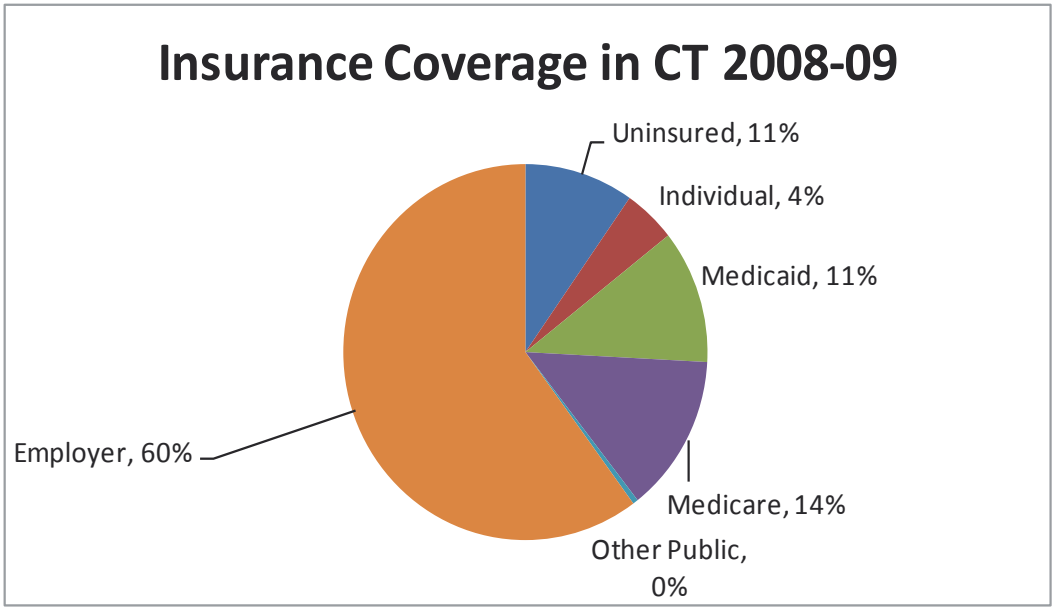


FIGURE 1(b)

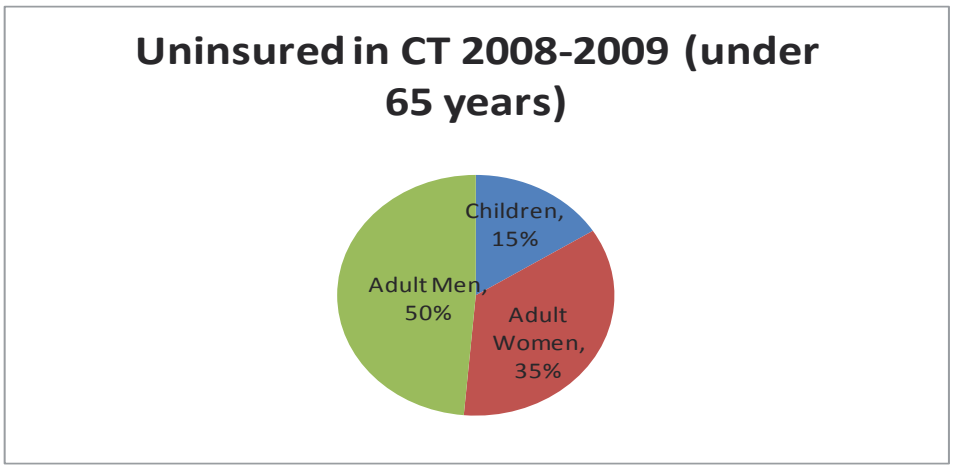
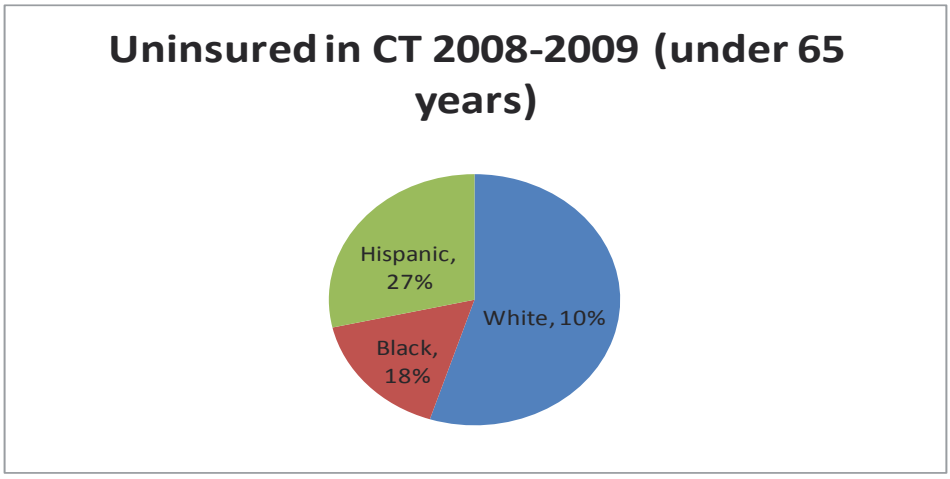


FIGURE 1(c)



Source: Urban Institute and Kaiser Commission on Medicaid and the Uninsured estimates based on the Census Bureau's March 2008 and 2009 Current Population Survey (CPS: Annual Social and Economic Supplements). Accessed February 20th, 2011
The totals in Fig 1(c) is less than 100% because 14% uninsured are of "Other" race/ethnicity
http://www.statehealthfacts.org/profileind.jsp?ind=125&cat=3&rgn=8

The healthcare landscape has changed significantly over the last few years. For instance, the high deductible plans are now common. America's Health Insurance Plans (AHIP) estimates that over ten million lives are covered in 2010 under Health Savings Account/High-deductible Health Plans (HSA/HDHP).[3] In Connecticut, 7.1% of the lives covered by commercial health insurance have a HSA plan. These plans have an inflation indexed minimum deducible for individual and family coverage (for 2010, the minimum family deductible is $2,400). Without some modification of benefit design, the high deductible in such plans can be a deterrent to services that are high value and much needed. For example, if one had to wait until a $2,400 deductible is satisfied in order to get a medically necessary service, the tendency might be to wait rather than pay. The tendency to wait is greater for people at a lower income level. It is possible that due to the increasing deductibles in particular, some of the proposed mandates may be less

readily accessed. Similarly, the impact of the mandates which work mainly through the pharmacy benefits of an insurance policy or have a significant pharmacy services component may be somewhat reduced by the penetration of fourth or even fifth copayment tiers. These higher tiers may require members to pay $100 or more for a prescription.

Insurers recognized this member propensity to delay care and countered with new and improved plan designs that are designed to encourage access to benefits that bring higher value for their cost. Preventive benefits are often covered without satisfying the deductible or even requiring any cost-sharing at all. Certain high value services may be generally 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 MRI for Breast Cancer screening involves what will likely be categorized as a preventive benefit under the federal Patient Protection andAffordable Care Act (PPACA). Under PPACA, preventive services must be covered with zero cost-sharing for the patient.

EXTRA REFILLS FOR EYE DROPS PRESCRIPTIONS

Eye drops are used for various eye disorders in adult and pediatric patients including infections, allergies, and chronic conditions. Some of these disorders are considered sight-threatening, such as glaucoma. This proposed mandate requires insurers to pay for an additional supply of eye drops for use at a child's alternative site of care as well as for any patient that has a need for an early refill.

The most common types of eye drops and medications prescribed for the school-going children are the treatment of pink-eye and other viral and bacterial infections, medications used for allergies, and those used for shortsightedness or myopia. Most of these medications are for short term acute use. For instance, a typical treatment course for pink-eye lasts seven days. The atropine therapy for myopia goes on for a longer period but the frequency of administering the drug can be once a week. We did not find evidence of lack of medication adherence or any clinical issues due to unavailability of children's eye medications at school. Probably the biggest impact in the absence of the proposed mandate may be that some children may have to occasionally miss school due to allergy (a child with pink-eye is advised not to go to school for the first one to three days of infection). There are a large number of OTC medications for temporary eye relief ranging in price from $2 to $20. Therefore we do not see any significant financial burden which will be alleviated by the passing of the proposed mandate as far as its extra prescription at school provision is concerned. If an extra prescription fill for school is mandated, there may be some increase in the utilization of the eye drops and even though it is hard to quantify that increase, the nature of use and the cost of the drugs suggest that the incremental cost to the insurer or the increase in the premium will be small. The potential cost impact is discussed in the actuarial part of the report in detail. Some of the indirect cost of the mandate will come in the form of administrative work on the part of the insurers (to accommodate the benefits set up in the system), for the pharmacy benefit managers (to allow for an extra fill in their claims processing system), and for the schools (the cost of disposing the unused medication).

As far as the early refill provision of the proposed mandate is concerned, insurers often have restrictions on quantity and refill intervals on medications. It is also known that inadvertent wastage of eye drops occurs due to technique and ability. If a patient prematurely depletes their supply, they could either pay cash for the early refill or wait until the refill is allowed, which creates a gap in care that may result in worsening of the disease. This gap in care could be particularly problematic for sight-threatening conditions. This issue has been recognized by the American Academy of Opthalmology[4] and a statement has been issued along with American Glaucoma society to bring awareness to the problem. The statement focuses on inadequate access to glaucoma treatment and the potential clinical outcomes of gaps in treatment: vision loss, surgical intervention. Potential factors affecting adherence to glaucoma treatment have been examined and include: population co-morbidities, severity of disease, cost of medication, and complexity of dosing regimen.[5]

The annual cost of eye medications for the treatment of glaucoma can be up to $2,000. Given the typical range of the member cost-share of the prescription cost of 20% to 50%, a patient with glaucoma may be spending between $400 and $1,000. In the absence of the proposed mandate, this cost burden is even higher since patients have to buy any early refills by paying the full cost of the drug. This cost burden increases with the age of the patient (glaucoma usually sets in around the age of 40 years, and its incidence increases with age), and with their socioeconomic status since lower income patients must spend a higher percentage of income. By mandating coverage of additional fills, a cost barrier to adherence may be lowered. The actuarial part of this report discusses the range of increased utilization and the associated increase in cost resulting from this mandate. Some of the indirect costs not quantified in this report include the cost of updating the insurers' systems to allow for the benefits mandated through this proposed law and the cost for PBMs to modify their refill-too-soon edits. However, given the high cost of surgery, productivity loss, loss in income etc. resulting from less than optimal adherence to the medication, the proposed mandate can provide significant benefit in terms of financial savings and quality of life for some residents of Connecticut with a few cents of incremental premium.

The impact of the proposed mandate on adults with common eye conditions other than glaucoma, for instance, cataract and diabetes related conditions, will be similar to that on the people with glaucoma. These conditions, however, are more prevalent in elderly populations and therefore the associated incremental cost of the mandate will be lesser for the fully insured population in the State. This is even more applicable for people with macular degeneration.

MRI FOR BREAST CANCER DIAGNOSIS

Breast cancer is the second leading cause for cancer-related deaths among women in Connecticut. According to the CT Department of Public Health, Connecticut had the third highest rate of new breast cancers in the nation in the 2000 – 2004 period[6]. During the same period, the state was ranked 26th in deaths from breast cancer. In 2008, 84% of the 40+ women in CT had a mammogram within the previous two years (the national average was 74%) and this number was 85% for women over fifty (the national average was 80%). White, non-Hispanic women were more likely to get breast cancer than other races or ethnicities. However, black non-Hispanic women were most likely to die from breast cancer, suggesting the possibility of a disparity in the quality of care. There was some regional variation in the incidence of the disease too. Based on the 2003-2007 data, the Southwest CT counties (Fairfield and New Haven) had the highest incidence of the disease.

CT already has a law mandating coverage of mammography and ultrasound for breast cancer screening. The existing law mandates a baseline mammography for women under forty and a yearly mammography from the age of 40 and above. Comprehensive ultrasound screening is also allowed under certain conditions. The services covered under this mandate are relatively inexpensive. A mammogram can cost the patient from nothing to around two hundred dollars depending on the test (traditional or digital) and the type of insurance. Ultrasounds can cost in the $250 to $300 range. The proposed new mandate requires coverage of MRI as a supplement to mammogram and ultrasound for breast cancer screening for women meeting specified conditions including a family history of breast cancer and/or the presence of dense breast tissue. The service covered under this mandate is similar to that recommended by national organizations like the American Cancer Society, the American College of Radiology, and the National Comprehensive Cancer Network. These organizations' recommendations[7 8 9] however, are more specific than the mandate. These recommendations will likely influence physician decisions with regard to the clinical necessity of a screening MRI and therefore it is expected that the proposed mandate will increase the utilization of MRI in CT. As discussed in the actuarial part of the report, additional factors likely to increase the utilization of MRIs for diagnosing breast cancer include the provisions in the health reform act related to the elimination of member cost sharing for preventative tests and the fact that CT already has a higher than national rate of MRI testing of breast cancer. Aging of the population will also be a minor factor in driving increased demand for this service.

Examples of MRI Screening Recommendations[7,8]

State of CT Mandate	American Cancer Society	American College of Radiology
Family history of breast cancer, her own prior breast cancer history, positive genetic testing, or other indications determined by her physician or advanced-practice registered nurse	BRCA mutation First-degree relative of BRCA carrier, but untested Li-Fraumeni syndrome and first-degree relatives Cowden and Bannayan-Riley-Ruvalcaba syndromes and first-degree relatives	BRCA1 or BRCA2 mutation carriers, untested first-degree relatives of BRCA mutation carrier
	Lifetime risk ~20-25% or greater, as defined by risk assessment tools that are largely dependent on family history	Women with $\geq$ 20% life-time risk for breast cancer on the basis of family history
	Radiation to the chest wall between the ages of 10 and 30 years	History of chest irradiation received between the ages of 10 and 30 years
		Personal history of breast cancer, ovarian cancer, or biopsy diagnosis of lobular neoplasia or atypical ductal hyperplasia
Presence of dense breast tissue		Women with dense breasts as the only risk factor

There are several factors which make a precise estimation of economic impact of this proposed mandate difficult. First, there is widespread recognition that preventative tests and screenings are cost effective in general. For this reason, insurers and employers generally do not impose any substantial financial barriers to these services. This is especially true for conditions like cancer where payer usually follow the relevant medical organizations' guidelines in making coverage decisions. Therefore, any projections of increased utilization due to the mandate can easily be overestimated if there is not a significant pent up demand for this service. Second, diagnostic tests usually are under- and over-utilized at the same time. As was reported in the Set 2 of the last phase of this project, there are significant socioeconomic and demographic disparities in the utilization of breast cancer screenings. In a study by the Centers for Disease Control and Prevention[10], women with insurance, higher income, and education reported a significantly higher rate of mammography in the previous two years. This and other studies suggest that lack of health awareness and education among the poor and the less educated may be a barrier to early detection of breast cancer. Similarly, the tendency of overutilization of breast and prostate cancer screenings in certain subsets of populations

CLINICAL TRIALS AND OFF-LABEL USE OF MS AND PARKINSON'S DISEASE MEDICATIONS

This mandate, similar to previous oncology mandates, requires the coverage of the cost of routine care for patients enrolled in clinical trials and coverage of off-label prescribing for Multiple Sclerosis and Parkinson's disease. Similar to cancer, there is not a cure for Multiple Sclerosis (MS) or Parkinson's disease (PD), and patients often experience symptoms, co-morbidities, and disability as a result of their chronic disease. Fortunately, fewer people are affected with MS and PD as compared to cancer. The National MS Society estimates 400,000 patients are affected with MS within the US. Most patients are diagnosed between the ages of 20 and 50 and are Caucasian women. In contrast, Parkinson's disease affects mainly an older male population; the average age of onset is 60 years. The NIH has estimated that 500,000 people in the US are affected with Parkinson's disease.

The off-label use of a prescription medication does not necessarily imply inappropriate medical use of the medication. An understanding of a drug's approval process as well as the roles of and incentives to various stakeholders[14] in this process is essential in order to understand the distinction between the two and to understand the context of the mandate on off-label use. The use of an FDA approved drug (regardless of the indication for which it is approved) is driven by the clinical decisions of a doctor. Doctors use clinical judgment, experience, treatment guidelines, etc. to make decisions about treatments and prescriptions. On the other hand, a drug developer/manufacturer has to follow strict protocols for clinical trials and FDA guidelines to obtain approval for a drug. Given the high cost and other factors associated with clinical trials, a drug developer typically applies for approval of a new drug for a narrowly focused condition in order to minimize its cost and maximize the approval probability. Once approved by the FDA for a specific condition, it is less costly for a drug manufacturer to let the medical community experiment with other uses for that drug rather than conduct more (costly) clinical trials or go through a lengthy FDA approval process for additional indications. By law, drug manufacturers are not allowed to directly market the off-label use of their products. Eventually, a drug manufacturer may apply for FDA approval for additional uses of a product once the drug has been in use to treat illnesses beyond the original approval. The above process means that there is almost always a lag between many off-label uses of certain drugs and the eventual FDA approval for some of these indications. In the meanwhile, payers like private insurers, Medicare, and Medicaid are faced with the decision of whether to pay for the off-label use of these drugs.

Multiple sclerosis (MS) is a chronic, sometimes debilitating disease that attacks the central nervous system. Treatment for MS is limited. As there is no cure for the disease, available treatment methods are available to modify the disease course (disease modifying medications). Disease modifying medications are intended for long-term management of the disease. The FDA currently has approved eight disease modifying agents: Avonex, Betaseron, Copaxone, Extavia, Gilenya, Novantrone, Rebif, and Tysabri.[15] Most of these drugs are used to treat relapsing forms of MS. Not all of these drugs are FDA are approved to treat each of the four types of MS (relapsing remitting,

secondary progressive, primary progressive, progressive relapsing) and some physicians may prescribe these drugs off-label for their MS patients. The cost of disease modifying medications is high, ranging from $3400-$4400 (Average wholesale price /package). Off-label drug use in the treatment of MS with drugs not approved for any type of MS has occurred for a number of years. For example, in treating symptoms of MS, physicians frequently prescribe off-label drugs.[16] Modafinil (brand name, Provigil), is an FDA approved drug for the treatment of narcolepsy, but relieves MS fatigue in some studies. A literature review shows that use of modafinil for the treatment of MS-related fatigue has demonstrated benefit in all uncontrolled studies but has conflicting results from 2 controlled studies.[17] Though the medication may be effective in certain off-label use, one must also consider safety and toxicity. For example, the disease modifying agents are associated with significant toxicity. When physicians prescribe off-label medications, they must weigh the benefit of the medication versus the toxicity risk.

Parkinson's disease (PD) is a slowly progressing, degenerative disease that is the most common form of Parkinsonism, a group of motor system disorders. While there is no cure for PD, there are some treatment methods available to manage its symptoms. Several potential Parkinson's treatments that are approved and/or are in use for other conditions include the following[18]:

Medication	**Current Use**	**Potential Off-Label Use**
Abilify	Antipsychotic.	Psychosis associated with PD
Keppra	Antiepileptic	Levodopa-induced dyskinesia in PD
Zonegran	Antiepileptic	PD symptoms including tremor and dyskinesias
Namenda	Alzheimer's Disease	Cognitive impairment and dementia in PD

MS and PD represent an economic burden to society, the patient, and the insurer, due to their chronic and potentially progressive course. The estimated per person annual cost range for MS and Parkinson's disease is $6,500 - $78,000 and $10,000 - $12,500 respectively.[19] [20] As noted above, the off-label medication use may impact the overall costs of caring for MS and PD patients. This mandate, however, may not have significant cost burden on insurers if they are currently allowing off- label medication use. Also, insurers may already have step-edits or prior authorization policies in place that would allow off-label use under certain conditions. The cost impact for patients under this mandate would represent their cost-sharing for the off-label drug use.

This cost burden impacts all income levels, except for the very rich, albeit in different ways. A lower income family may simply have to forego the treatment in the absence of this mandate, whereas a higher income family may have to choose between foregoing the therapy and substantial financial burden, even bankruptcy if their insurance plan lacks an out-of-pocket maximum. As the actuarial analysis of this mandate shows, the payers (health insurance carriers and HMOs) have to bear a financial burden due to this mandate. In a sense, these private insurers, as well as Medicare and Medicaid, could be

perceived as contributing indirectly to the funding of "clinical trials" for drug manufacturers by covering the off-label use of medications for MS and PD.

Clinical trials are a useful mechanism to propagate scientific research and, for trial participants, they can provide treatment alternatives which would not be otherwise available. However, there are a number of barriers to trial participation. Cost burden is one such barrier. The cost of participating in a clinical trial can be divided into three major categories. The cost of investigational treatment, drug, device, or service is the first item and is usually covered by the entity sponsoring the trial. The cost of transportation, living expenses, etc. for the trial participant and the family is the second major cost item. Usually the participant would cover this cost although several non-profit organizations provide some support. The last major cost item is the cost of treatment not related to the trial's target investigational treatment. This mandate requires the insurers to cover this last cost item commonly known as the "cost of routine care".

In the complex, multi-payer health care system in the U.S., various stakeholders pay for the research and advancement of the treatment of Multiple Sclerosis and Parkinson's disease. Drug manufacturers have a clear financial stake and are therefore expected to pay for the investigational expenses of the clinical trials. The trial participants have the most to gain in terms of access to alternative and sometimes lifesaving treatments. These participants pay a small part of the trial cost in the form of transportation and living expenses associated with trials. Insurers will generally continue to cover the routine care costs of those in clinical trials, which, in some rare instances, may include adverse reactions to treatments or drugs under study in the trial. In Connecticut and a number of states, the law requires that this cost be paid by the insurers for cancer. It is not clear whether the mandate has caused an increase in the participation in clinical trials or not. As mentioned above, a number of studies have shown cost as a significant barrier to participation in trials. On the other hand, researchers at Yale[21] studied the enrollment data for a number of states before and after the states adopted mandates covering for routine care in clinical trials. The results of these studies were not conclusive.

According to ClinicalTrials.gov, there are over 700 recorded research trials for each of these diseases. Forty such trials were recorded within CT for MS and 70 for Parkinson's disease. This represents an opportunity for patients to have access to the latest advances for their disease.

GASTRIC BYPASS SURGERY

Obesity is a well-recognized epidemic within the US. According to the CDC, more than 1/3 of US adults and 17% of children are obese[22]. According to the Kaiser Family Foundation, 56% of adults in CT are overweight or obese (the national average is about 61%). Health disparities related to the prevalence of obesity exist, with blacks and Hispanics more likely than non-Hispanic whites to be obese. In the year 2009, CT had 69% adult male overweight or obese as compared to 44% female. There are 10% more overweight and obese blacks in the state than whites and over 8% more Hispanics are overweight or obese than whites. Obesity is associated with various health consequences such as, heart disease, type-2 diabetes, cancers, high-blood pressure, liver and gallbladder disease, reproductive health complications, stroke, sleep apnea, osteoarthritis, and death. Healthcare costs related to obesity are expected to rise with the increasing prevalence of obesity. Patients, insurers, and society will bear the cost of this epidemic. It is has been estimated that in 2008 the annual medical burden of obesity could be as high as $147 billion. For private and government payers in 2006, obese individuals had per capita medical spending that was 42% more than normal weight individuals[23].

The causes as well as the solutions for solving obesity are complex. Treatment for obesity may include a combination of diet, exercise, behavior modification, pharmacotherapy, and in some cases bariatric surgery. This mandate requires coverage of gastric bypass surgery, one type of bariatric surgery. Medicare as well as other national payers cover various bariatric surgery procedures under certain conditions. As stated in the actuarial report the average national cost for gastric bypass surgery is approximately $25,000. The patient undergoing gastric bypass surgery may incur costs in the form of co-pays and co-insurance associated with physician fees, hospital fees, and testing.

If this proposed mandate is approved, insurers in CT would be required to cover gastric bypass surgery. Some private insurers already cover this service under certain conditions related to BMI and other obesity related thresholds. They usually require some documentation of failure to control obesity through diet and exercise programs. Given some of the ambiguity around the proposed mandate, there is a possibility that an unconditional coverage may generate moral hazard issues and associated increase in utilization of the service. Even in the absence of moral hazard driven utilization, long term trends in the use of bariatric surgery and in the prevalence of obesity will cause the use of this service to increase. About three fourth of the procedures performed during 2006-2008 were for people with commercial insurance. Therefore any increased utilization due to various drivers of bariatric bypass surgery is going to impact the premiums and the economics of the private insurance sector more than the public sector.

Studies show that obesity reduction services like bariatric surgery do not pose a cost burden in the long run. The downstream savings associated with bariatric surgery can be significant and are estimated to offset the cost of the surgery within 2-4 years[24] [25]. The cost-effectiveness of bariatric surgery has also been evaluated. The cost per quality-

adjusted life year gained for gastric bypass surgery as compared to no treatment has ranged[26] [27] from $5,600-$18,500.

The impact of the proposed mandate may be limited by the disparities which exist in the utilization of bariatric services including gastric bypass surgery. These disparities exist in two dimensions. First, obesity and its related health complications are more prevalent in lower socioeconomic strata and in racial and ethnic minorities. Second, these same segments of the population are less likely to utilize bariatric services. One study has found that people eligible for bariatric surgery (based on obesity and other markers) were significantly more likely to be below the poverty line etc. At the same time, people who went through these surgeries were predominately white, high income, and with private insurance[28].

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Appendix V

Glossary of Terms and Acronyms

Term	Definition
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.
Autoimmune disease	An illness that occurs when the body tissues are attacked by its own immune system.
Bariatric surgery	A surgery on the stomach and/or intestines to help a person with extreme obesity lose weight.
Blepharitis / Blepharoconjuntivitis	Inflammation of the eyelash follicles due to infection
Bradykinesia	A slowness in initiating movement.
Body Mass Index	The body mass index is a person's weight in kilograms divided by their height in meters squared and indexed as underweight, normal weight, overweight and obesity.
BPD/DS	A type of bariatric procedure. Biliopancreatic diversion with duodenal switch
BMI	Body Mass Index.
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 mestastasized nor invaded neighboring cells.
Cataract	A clouding of the lens of the eye or its surrounding transparent membrane that obstructs the passage of light
Central nervous system	The part of the nervous system including the brain and spinal cord.
Class III obesity	A BMI greater than or equal to 40 where an individual generally exceeds normal weight by 100 or more pounds. Also referred to as extreme obesity.
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.
CID	Connecticut Insurance Department.
Clinical trials:	Trials to evaluate the effectiveness and safety of medications or medical devices by monitoring their effects on large groups of people.
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.
Conjunctivitis	ocular bacterial infection

Term	Definition
Conversion	The conversion of coverage under a group master contract to coverage under an individual contract. The chance to convert is 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 contract.
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.
Corneal ulcer	An open sore on the cornea, the thin transparent structure overlying the iris, which is the colored part of the eye
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	Raising the prices charged to other payers to cover the cost of providing services for which the reimbursement received does not fully cover the cost.
Comorbidity	The co-occurring presence of two or more disease processes.
CPHHP	University of Connecticut Center for Public Health and Health Policy.
Dacryocystitis	Infection of the tear duct
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.
DSS	Department of Social Services.
Dopamine	An important neurotransmitter in the brain that contributes to relaying brain signals to the rest of the body and is important to muscle function.
Dry eye disease / Dry eye syndrome	A condition associated with inadequate tear production and marked by redness of the conjunctiva, by itching and burning of the eye, and usually by filaments of desquamated epithelial cells adhering to the cornea
Dumping syndrome	A group of symptoms that occur when food or liquid enters the small intestine too rapidly resulting in cramps, nausea, diarrhea and/or dizziness.
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.

Term	Definition
Extreme obesity	See Class III obesity.
Gastric	Having to do with the stomach.
Gastric bypass	The most common type of bariatric surgery. See Roux-en-Y gastric bypass and bariatric surgery.
Glaucoma	A disease of the eye marked by increased pressure within the eyeball that can result in damage to the optic disk and gradual loss of vision
Group Coverage	A type of health insurance in which members receive coverage through an insurance contract that covers an entire group, usually an employer group. Employees usually have the option of covering other members of their families as well.
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.
Hyperplasia	A condition in which there is an increase in the number of normal cells in a tissue or organ.
IC	Ingenix Consulting.
Individual Coverage	A type of health insurance in which there is a contract directly between an insurer and an individual who may purchase self-only coverage or may add other members of their family for additional premium cost.
Keratitis / Keratoconjuntivitis	Inflammation of the cornea due to bacterial or viral infection
Laparoscopic adjustable gastric band (LAGB)	A silicone® band implanted using laparoscopy to help a person lose weight by narrowing the opening between the stomach pouch and the rest of the stomach.
Laparoscopic surgery	A surgical procedure using a laparoscope to see structures within the abdomen and pelvis, generally reducing the need for a large surgical incision.
Magnetic Resonating Image (MRI)	A noninvasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radio waves
Mammography	X-ray examination of the breasts (as for early detection of cancer).
Managed care	At the very least, 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 noncontracted providers (unless authorized to do so), and some type of authorization system.

Term	Definition
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	Benefits that a health plan is required to provide. Mandated benefits are generally benefits above and beyond routine insurance-type benefits, they are typically mandated by state laws, and the types of benefits mandated vary widely from state to state. Common examples include in vitro fertilization, defined days of inpatient mental health or substance abuse treatment, and other special-condition treatments. Self-funded plans are exempt from state mandated benefits under ERISA.
Malabsorption	Impaired absorption by the intestines of nutrients from food. Lack of absorption may be general or specific to sugars, fats, vitamins, etc.
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. The medical cost ratio is dependent on the amount of money brought in as well as the cost of delivering care; thus, if premium rates are too low, the ratio may be high even though the cost of delivering care is not out of line.
Medical trend	The change in the cost of medical care driven by changes in utilization and unit costs of covered services.
Meibomianitis	An inflammation of the meibomian glands, a group of oil-secreting (sebaceous) glands in the eyelids. These glands have tiny openings to release oils onto the surface of the cornea
Member	An individual covered under a managed care plan. Members include subscribers and dependents.
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.
Mestastisis	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.
Multiple Sclerosis (MS)	An autoimmune disease of the central nervous system marked by numbness, weakness, loss of muscle coordination, and problems with vision, speech, and bladder control.
Myelin	A key substance that serves as a nerve insulator and helps in the transmission of nerve signals.
Obesity	The state of being well above one's normal weight as classified by BMI. Obesity is divided into Class I (BMI 25.0-29.9), Class II (30.0-34.9) and Class III obesity (40 or greater).

Term	Definition
Ocular	Of or relating to the eye
Ocular hypertension	A situation in which the pressure inside the eye, called intraocular pressure, is higher than normal.
Off-label	Of, relating to, or being an approved drug legally prescribed or a medical device legally used by a physician for a purpose (as the treatment of children or of a certain disease or condition) for which it has not been specifically approved (as by the United States Food and Drug Administration).
Parkinson's Disease (PD)	A slowly progressive neurologic disease caused by degeneration of an area of the brain called the basal ganglia, and by low production of the neurotransmitter dopamine.
Parkinsonism	A form of Parkinson Disease that is not related to dopamine.
Primary-progressive MS (PPMS)	A type of multiple sclerosis where symptoms progress slowly and steadily from onset without periods of remission.
Progressive-relapsing MS (PRMS)	A relatively rare type of multiple sclerosis where people experience both steadily worsening symptoms and attacks during periods of remission.
Neurotransmitter	A chemical that is released from a nerve cell sending an impulse from a nerve cell to another nerve, muscle, organ, or other tissue.
Per member per month (PMPM)	Specifically applies to revenue or cost for each enrolled member each month.
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. The term rating refers to the development of rates by a health plan.
Tremor	Involuntary muscle movement in the hands, arms, head, face, vocal cords, trunk and legs that may be a sign of a neurologic disorder.
Relapsing-remitting MS	A type of multiple sclerosis characterized by periods of symptom flare-ups followed by periods of remission.
RRMS	Relapsing-remitting MS.
Roux-en-Y gastric bypass	A surgical procedure which may be done for severe obesity. The size of the stomach pouch is reduced to hold less food and food skips the duodenum thus reducing the absorption of fat which is high in calories.
Secondary-progressive MS (SPMS)	A type of multiple sclerosis where relapses and partial recoveries occur by disability does not fade away between cycles.

Term	Definition
Self-funded plan	In a self-funded plan, the risk for medical cost is assumed by the employer rather than an insurance company or managed care plan. Under the Employee Retirement Income Security Act, self-funded plans are exempt from state laws and regulations. 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.
State of domicile	The state in which an insurance company or MCO is licensed as its primary location. For example, the state of domicile for an insurer may be Virginia, but the insurer might also be licensed and doing business in Maryland and the District of Columbia. MCOs, on the other hand, because of their local networks, are domiciled and licensed in a single state. The unique nature of their local service delivery requires them to be domiciled in each market they operate in. In many states, the insurance commissioner will defer primary regulation of an insurance company to the insurance department in the state of domicile as long as all minimum standards of the state are met.
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.
Termination date	The day that health plan coverage ceases to be in effect.
Tumor	An abnormal benign or malignant new growth of tissue that possesses no physiological function and arises from uncontrolled usually rapid cellular proliferation.

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