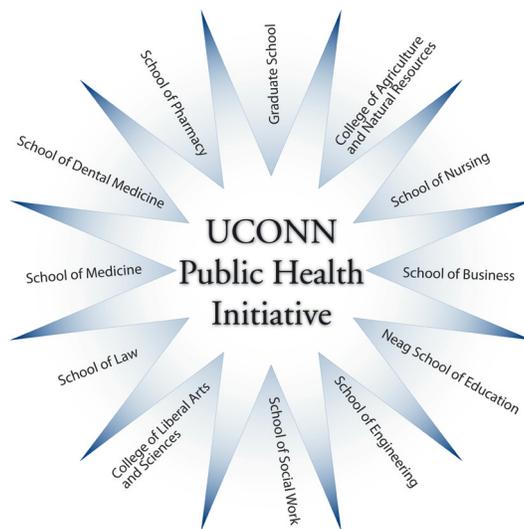


**Connecticut Mandated
Health Insurance Benefits
Reviews
2010
Volume IV**



University of Connecticut

Center for Public Health and Health Policy



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Connecticut Mandated Health Insurance Benefit Reviews

Volume IV. Introduction

Volume IV contains 13 of the forty-five comprehensive reviews of existing health insurance required benefits (mandates) completed by the University of Connecticut Center for Public Health and Health Policy pursuant to Public Act 09-179. (P.A. 09-179 is attached to this report as Appendix I.)

The mandates in Volume IV are found in Title 38a of the Connecticut General Statutes Annotated and apply to certain individual and group health insurance policies delivered, issued for delivery, renewed or continued in this state after the effective date of the respective statute. The types of policies to which health insurance mandates may apply as described in CGSA § 38a-469 include:

- Basic hospital expense coverage (Subsection 1)
- Basic medical-surgical expense coverage (Subsection 2)
- Hospital confinement indemnity coverage (Subsection 3)
- Major medical expense coverage (Subsection 4)
- Disability income protection coverage (Subsection 5)
- Accident only coverage (Subsection 6)
- Long term care coverage (Subsection 7)
- Specified accident coverage (Subsection 8)
- Medicare supplement coverage (Subsection 9)
- Limited benefit health coverage (Subsection 10)
- Hospital or medical service plan contract (Subsection 11)
- Hospital and medical coverage provided to subscribers of a health care center (Subsection 12)
- Specified disease coverage (Subsection 13).

Volume IV is intended to be read in conjunction with the General Overview and the actuarial report for these mandates prepared by Ingenix Consulting. The Ingenix Consulting report for this set of mandates is attached to this Volume as Appendix II.

The following table lists the mandates covered in this volume and the chapter in which each is reviewed; their statutory references (from CGSA Title 38a); and the applicable policy types. The order in which they are listed coincides with the order in which they are reviewed in the Ingenix Consulting report.

Index of Mandates: Volume IV				
Chapter	Description	Individual policy statute	Group plan statute	Policy Types Applicable (Subsection)
1	Experimental Treatments	§ 483c	§ 513b	Not indicated
2	Off-label Use of Cancer Drugs	§ 492b	§ 518b	Not indicated
3	Cancer Clinical Trials	§§ 504a-g	§§ 542a-g	1,2,4,11,12
4	Hypodermic Needles and Syringes	§ 492a	§ 518a	1,2,4,6,10,11,12
5	Prescription Drugs Removed from Formulary	§ 492f	§ 518f	1,2,4,11,12
6	Home Health Care	§ 493	§ 520	1,2,4,6,11,12
7	Ambulance Services	§ 498	§ 525	1,2,4,6,11,12
8	Prescription Drug Coverage/Mail Order Pharmacies	§ 510	§ 544	Not indicated
9	Co-payments Regarding In-Network Imaging Services	§ 511	§ 550	Not indicated
10	Comprehensive Rehabilitation Services (mandatory offer)	N/A	§ 523	1,2,4,6,11,12
11	Mobile Field Hospital	§ 498b	§ 525b	All 13 subsections
12	Pain Management	§ 492i	§ 518i	1,2,4,11,12
13	Maternity Benefits and Pregnancy Care Following Policy Termination	§ 547		1,2,4,11,12

Each chapter reviews a single mandate and includes five sections: Overview, Background, Methods, Social Impact, and Financial Impact. The Overview includes the statutory references and the language of the mandate, the effective date, the premium impact, and the extent to which the mandated benefit is included in self-funded plans. The Background describes the disease, condition, treatment or provider to which the mandate applies, provides information on the current research and other pertinent information for each mandate. The Methods section documents the research methods followed by the mandate review team. The Social Impact section addresses the sixteen criteria contained in section 1(d)(1) of P.A. 09-179. The Financial Impact section addresses the nine criteria contained in section 1(d)(2) of P.A. 09-179.

The following table summarizes the expected medical costs of each mandate in this volume for group plans. Medical cost is the primary component of health insurance premiums. See the Ingenix Consulting report (Appendix II) for further details.

Summary of Estimated Medical Costs of Mandates In 2010: Volume IV

Group Plans		
Mandate	Per Member Per Month (PMPM)	Percent of Premium
Experimental Treatments	\$0.00	0.00%
Off-label Use of Cancer Drugs	\$2.86	1.00%
Cancer Clinical Trials	\$0.00	0.00%
Hypodermic Needles and Syringes	\$0.05	0.02%
Prescription Drugs Removed from Formulary	\$0.02	0.01%
Home Health Care	\$1.47	0.50%
Ambulance Services	\$2.27	0.80%
Prescription Drug Coverage/Mail Order Pharmacies	\$0.00	0.00%
Co-payments Regarding In-Network Imaging Services	\$1.00	0.30%
Comprehensive Rehabilitation Services (mandatory offer)	\$2.42	0.80%
Mobile Field Hospital	\$0.00	0.00%
Pain Management	\$0.00	0.00%
Maternity Benefits and Pregnancy Care Following Policy Termination	\$0.00	0.00%
TOTAL	\$10.09	3.43%

Volume IV. Table of Contents

Chapter 1. Experimental Treatments	7
Overview.....	9
Background.....	10
Methods.....	11
Social Impact.....	12
Financial Impact.....	17
Chapter 2. Off-label Use of Cancer Drugs.....	21
Overview.....	23
Background.....	24
Methods.....	26
Social Impact.....	26
Financial Impact.....	36
Chapter 3. Cancer Clinical Trials	39
Overview.....	41
Background.....	42
Methods.....	43
Social Impact.....	44
Financial Impact.....	50
Chapter 4. Hypodermic Needles and Syringes	53
Overview.....	55
Background.....	56
Methods.....	57
Social Impact.....	57
Financial Impact.....	62
Chapter 5. Prescription Drugs Removed from Formulary	65
Overview.....	67
Background.....	68
Methods.....	70
Social Impact.....	71
Financial Impact.....	79
Chapter 6. Home Health Care	83
Overview.....	85
Background.....	88
Methods.....	89
Social Impact.....	90
Financial Impact.....	98
Chapter 7. Ambulance Services	101
Overview.....	103
Background.....	104
Methods.....	105
Social Impact.....	106
Financial Impact.....	112

Chapter 8. Prescription Drug Coverage/Mail Order Pharmacies	115
Overview.....	117
Background.....	118
Methods.....	119
Social Impact.....	120
Financial Impact.....	126
Chapter 9. Co-payments Regarding In-Network Imaging Services	131
Overview.....	133
Background.....	134
Methods.....	135
Social Impact.....	136
Financial Impact.....	139
Chapter 10. Comprehensive Rehabilitation Services	143
Overview.....	145
Background.....	146
Methods.....	148
Social Impact.....	149
Financial Impact.....	156
Chapter 11. Mobile Field Hospital.....	159
Overview.....	161
Background.....	161
Methods.....	162
Social Impact.....	163
Financial Impact.....	169
Chapter 12. Pain Management.....	173
Overview.....	175
Background.....	176
Methods.....	178
Social Impact.....	179
Financial Impact.....	183
Chapter 13. Maternity Benefits and Pregnancy Care Following Policy Termination	187
Overview.....	189
Background.....	190
Methods.....	194
Social Impact.....	194
Financial Impact.....	202

Appendix I. Public Act No. 09-179

Appendix II. Ingenix Consulting Actuarial and Economic Report

Appendix III. List of the forty-five health insurance mandates reviewed in volumes I-IV.

Volume IV

Chapter 1

Experimental Treatments

Review and Evaluation of Connecticut Statute

Chapter 700, §§ 38a-513b and 38a-483c

Coverage and Notice Regarding Experimental Treatments

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Chapter 1. Table of Contents

- I. Overview.....9
- II. Background..... 10
- III. Methods..... 11
- IV. Social Impact..... 12
- V. Financial Impact..... 17

I. Overview

The Connecticut General Assembly directed the Connecticut Insurance Department to review the health benefits required by Connecticut law to be included in group and individual health insurance policies as of July 1, 2009. The review was conducted following the requirements stipulated under Public Act 09-179. Reviews of required health insurance benefits are a collaborative effort of Connecticut Insurance Department (CID) and the University of Connecticut Center for Public Health and Health Policy (CPHHP).

Connecticut General Statutes, Chapter 700, §§ 38a-513b and 38a-483c state that each group or individual health insurance policy...

...delivered, issued for delivery, renewed amended or continued in this state on or after January 1, 2000, shall define the extent to which it provides coverage for experimental treatments.

- (b) No such health insurance policy may deny a procedure, treatment or the use of any drug as experimental if such procedure, treatment or drug, for the illness or condition being treated, or for the diagnosis for which it is being prescribed, has successfully completed a phase III clinical trial of the federal Food and Drug Administration.
- (c) Any person who has been diagnosed with a condition that creates a life expectancy in that person of less than two years and who has been denied an otherwise covered procedure, treatment or drug on the grounds that it is experimental may request an expedited appeal as provided in section 38a-226c and may appeal a denial thereof to the Insurance Commissioner in accordance with the procedures established in section 38a-478n.
- (d) For the purposes of conducting an appeal pursuant to section 38a-478n on the grounds that an otherwise covered procedure, treatment or drug is experimental, the basis of such an appeal shall be the medical efficacy of such procedure, treatment or drug. The entity conducting the review may consider whether the procedure, treatment or drug (1) has been approved by the National Institute of Health or the American Medical Association, (2) is listed in the United States Pharmacopoeia Drug Information Guide for Health Care Professionals (USP-DI), the American Medical Association Drug Evaluations (AMA-DE), or the American Society of Hospital Pharmacists' American Hospital Formulary Service Drug Information (AHFS-DI), or (3) is currently in a phase III clinical trial of the federal Food and Drug Administration.

In April 2010, CPHHP and Ingenix Consulting (IC) requested and received 2007 and 2008 claims data related to the mandated benefit from six 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 findings of this report are based on an actuarial analysis of received claims data and reviews of pertinent literature and other information related to the mandated benefit.

Current coverage

The experimental treatments mandate was enacted in 1999 and effective January 1, 2000 (P.A. 99-284).

Premium impact

Group plans: Three of the six insurers/MCOs provided claims data for group plans. On a 2010 basis,

medical cost is estimated to be \$0.01 per member per month (PMPM). Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services in 2010 in group plans is \$0.01 PMPM, which is less than 0.01 percent of estimated total costs in group plans. Estimated cost sharing in 2010 in group plans is \$0.00 PMPM.

Individual policies: Three of the six insurers/MCOs provided claims data for individual health insurance policies. On a 2010 basis, medical cost is estimated to be less than \$0.01 PMPM. Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services in 2010 in individual policies is less than \$0.01 PMPM, which is less than 0.01 percent of estimated total costs in individual policies. Estimated cost sharing in 2010 in individual plans is \$0.00 PMPM. Individual policies data is less credible than group data primarily due to small sample size.

Self-funded plans

Four health insurers/MCOs domiciled in Connecticut provided information about their self-funded plans, which represents an estimated 45 percent of the total population in self-funded plans in Connecticut. These four insurers/MCOs report that 16.3 percent of enrollees in their self-funded plans have coverage for the mandated services.

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

II. Background

An experimental treatment may be a drug, procedure, therapy, or device. According to the National Library of Medicine, an experimental treatment, also called an investigational treatment, investigational therapy or innovative therapy, refers a treatments undergoing a clinical trial or for which there is insufficient evidence to determine its effects on health outcomes.¹

A medical dictionary defines an experimental treatment as an unproven therapy that may or may not be superior to a current 'gold standard' therapy. Additional criteria for experimental treatments include that they are not generally accepted by the medical community as effective and proven; not recognized by professional medical organizations as conforming to accepted medical practice; not approved by the FDA or other requisite government body; are in clinical trials or need further study; are rarely used, novel, or unknown and lack authoritative evidence of safety and efficacy.²

The Connecticut statute under review prohibits health insurance policies from denying a procedure, treatment or drug as experimental if such procedure, treatment or drug has successfully completed an FDA Phase III clinical trial for the illness or condition being treated or for the diagnosis for which it is being prescribed.

There are 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 of administration and determine how new drugs 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. Phase II trials continue to test the safety of the drug, and begin to evaluate how well the new drug works. Phase II studies usually focus on a particular subtype of

¹ The National Library of Medicine. Medical Subject Heading. Available at: <http://www.nlm.nih.gov/mesh/MBrowser.html>. Accessed December 27, 2010.

² McGraw Hill Concise Dictionary of Modern Medicine. 2002. The McGraw-Hill Companies, Inc. Available at: <http://medical-dictionary.thefreedictionary.com/experimental+treatment>. Accessed December 27, 2010.

disease or condition (e.g., a particular type of cancer).

The Connecticut experimental treatments mandate concerns Phase III clinical trials. 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 particular disease centers (e.g., cancer centers) 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 disease or condition and subtype (e.g., type of 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.

The most common conditions and diseases treated with experimental treatments include:³

- Cancer
- Cardiology—stroke and cardiovascular disease
- Dentistry and oral health care
- Dermatology
- Infectious disease—HIV and infectious diseases
- Ophthalmology
- Psychiatry—anxiety disorders, cognitive behavior therapy, psychotherapy for depression
- Reproductive health—contraception, gynecology and infertility, early pregnancy termination, maternal and perinatal health
- Respiratory Medicine
- Surgery and anesthesia—anesthesia and pain, general surgery, plastic surgery, reconstructive surgery.
- Transplantation
- Other procedures—wound healing, palliative care, complementary medicine.

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 the following terms alone and/or in combination:

Therapy, therapies, investigational, treatment, treatments, experimental, innovative, clinical trials, high risk/special populations/patients, health services accessibility, health services needs, demand, barriers, blocks, adverse effects, effectiveness, efficacy, costs, cost analysis, economics, pharmaceutical, risk assessment, health insurance, benefit, cost savings, prevention, early detection, neoplasms, cardiovascular diseases, tooth diseases, oral health, dentistry, communicable diseases, diet therapy, drug therapy, nursing, radiotherapy, surgery, mental disorders, prevention and control, rehabilitation.

Resources searched include:

³ Machin D, Day S, Green S, (eds). 2006. Textbook of Clinical Trials.

- PubMed
- SCOPUS
- UpToDate
- Cochrane Systematic Review
- Lyman Maynard Stowe Library Catalog (University of Connecticut Health Center Library)
- Google

CPHHP staff conducted independent literature searches using PubMed and Google, with similar search terms as those 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 Medicine on matters pertaining to medical standards of care, current, traditional and emerging practices, and evidence-based medicine related to the benefit. Additionally, staff may have consulted practitioners in the community for additional and/or specialized information.

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 and the CID contracted with Ingenix Consulting (IC) to provide actuarial and economic analyses of the mandated benefit. Further details regarding the insurer/MCO claims data and actuarial methods used to estimate the cost of the benefit and economic methods used to estimate financial burden may be found in Appendix II.

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.

The estimated 1,393,444 persons in Connecticut in fully insured group and individual health insurance plans would have access to insurance coverage for experimental treatments as defined in the statute.⁴ Precise estimates of utilization rates are unknown, but are expected to be very low. Because experimental treatments are not FDA approved, there is no charge for them. The only potential medical costs that could occur are treatments required due to an adverse reaction or side effect of the experimental treatment. Few persons undergo experimental treatments and only a small percentage of these patients experience side effects or adverse reactions requiring treatment, thus utilization of the mandated services would appear to be very low.

Total costs reported by insurers/MCOs for the experimental treatments mandate are extremely low, which suggests that experimental treatments are utilized by very few persons in fully insured group and individual health insurance plans in Connecticut. For further information, please see Appendix II: Ingenix Consulting Actuarial and Economic Report, page 8.

⁴ 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 experimental treatments are available to the population, including, but not limited to, coverage under Medicare, or through public programs administered by charities, public schools, the Department of Public Health, municipal health departments or health districts or the Department of Social Services.

Medicare

Medicare generally does not provide coverage for experimental procedures, treatments or drugs. However, Medicare has an appeals process for individuals denied coverage for experimental treatments. Individuals may file an appeal if they believe that Medicare should have paid for an item or service. All beneficiaries, including those in traditional Medicare, a Medicare managed care plan, and a Medicare prescription drug plan have the right to appeal any decision about Medicare services.⁵

Under traditional Medicare, enrollees may file appeals in cases where it is believed that Medicare should have paid for, or did not pay enough for, an item or service.⁶ Under Medicare managed care plans, proper written notice is required in cases where services or payments are denied in whole or in part and enrollees have the rights to expedited appeals.⁷ Under Part D plans, a beneficiary can appeal a plan sponsor's decision not to provide or pay for a Part D prescription drug and in cases where serious medical harm is possible, expedited appeals are available.⁸

Public Programs Administered by Charities

No information was found that would indicate charities would be a source of funding for experimental treatments. Most drug and medical device manufacturers provide experimental treatments free of charge as part of compassionate care programs and as part of the research process.

Public Programs Administered by Public Schools

No information was found that would indicate public schools would be a source of funding for experimental treatments.

The Department of Public Health (DPH)

No information was found that would indicate the Connecticut Department of Public Health provides experimental treatments or provides funding for experimental treatments or therapies.

Municipal Health Departments

No information was found that would indicate local and municipal health departments in Connecticut provide experimental treatments or funding for experimental treatments or therapies.

The Department of Social Services (DSS)

Generally, Medicaid does not provide coverage for experimental treatments, drugs or clinical trials. According to the Department of Social Services, “[t]he department shall not pay for anything of an unproven, experimental or research nature...”⁹ However, if an experimental treatment or therapy is determined to be medically necessary it will be covered. Medicaid pays for medically necessary services appropriate for the patient/condition.¹⁰

⁵ Medicare Appeals and Grievances (<http://www.medicare.gov/basics/appeals.asp>).

⁶ *Ibid.*

⁷ Centers for Medicaid and Medicare Services (CMS) Overview of Medicaid Medicare Managed Care Appeals and Grievances Available at: <http://www.cms.gov/MMCAG/>.

⁸ Medicare Appeals and Grievances (<http://www.medicare.gov/navigation/medicare-basics/understanding-claims/medicare-appeals-and-grievances.aspx#AppealRightsOrigMedicare>).

⁹ DSS Provider Manual; Medical Services, p. 6.

¹⁰ Personal communication. Carolyn M. Treiss, Legislative Program Manger. Connecticut Department of Social Services. October 12, 2010.

There does not appear to be an appeals process in place as is the case for Medicare. Enrollees may submit a prior authorization request for an experimental treatment or drug. However, unless it can be proven that the experimental drug or service is medically necessary, it is unlikely that the prior authorization will be approved.

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

State of Connecticut law requires coverage and notice regarding experimental treatments as defined in the statute in fully insured group and individual health insurance plans as of January 1, 2000.¹¹ 2007 and 2008 claims data from six insurers/MCOs that cover 90 percent of the population in fully insured group and individual insurance plans in Connecticut showed evidence that claims are paid for the mandated services. Information received from three insurers/MCOs domiciled in Connecticut which represents an estimated 45 percent of the total population in self-funded plans in Connecticut shows that 16.3 percent of members in these self-funded plans have coverage for the benefit.

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.

Not applicable. Coverage is required and generally available for persons enrolled in fully insured group and individual health insurance plans.

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 and notice regarding experimental treatments is required to be included in fully insured group and individual insurance plans issued in Connecticut. Costs associated with experimental treatments are generally covered by the drug or device manufacturer; however, costs can vary due to several factors such as the type of treatment, procedure, or drug; disease being treated; required health professional services associated with the experimental treatment; and location of facility. Most experimental treatments, due to the fact that they are experimental, are not as costly as fully approved treatments, procedures, and drugs. Financial hardships due to experimental treatments are more likely to be experienced by those without insurance coverage than for the insured population.

Depending on the severity of disease and progression at time of diagnosis, a disease or condition that does not respond to approved treatments, procedures, and drugs often results in significant health and economic costs for the individual and their family, even for those with comprehensive health benefits. By the time experimental treatments are contemplated, family resources may be exhausted. Additionally, 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.

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

Medical librarians and CPHHP staff found no published literature regarding the level of public demand or level of demand from providers for experimental treatments as defined in the statute.

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.

A physician testified in favor of insurance coverage for the mandated services during the time legislation

¹¹ CONNECTICUT GENERAL STATUTES ANNOTATED § 38A-483C (INDIVIDUAL INSURANCE POLICIES); § 38A-513B (GROUP INSURANCE POLICIES).

for the mandated benefit was under consideration by the Connecticut General Assembly in March 1999.¹² Medical librarians and CPHHP staff found no other published literature regarding the level of demand from the public or from providers for insurance coverage for experimental treatments as defined in the statute.

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

According to the National Association of Insurance Commissioners, Connecticut is the only state that requires coverage and notice regarding experimental treatments in fully insured group and individual health insurance policies.¹³ CPHHP researchers found no evidence of the mandated benefit in any other state.

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

Internet searches and telephone inquiries found no relevant findings from state agencies and public organizations related to the social impact of mandated insurance coverage for experimental treatments as defined in the statute. Internet searches of and/or telephone inquiries were conducted with 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 Northeastern U.S. 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.*

Experimental treatments are generally attempted when standard-of-care treatments, methods or procedures have been attempted unsuccessfully. The alternative to an experimental treatment might include a different experimental treatment. Because the statute applies equally to all experimental treatments, any alternative experimental treatments would not be treated any differently by the insurer/MCO.

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 experimental treatments as defined in the statute fulfills a medical need that might not otherwise be met. Fully approved treatments, procedures, and drugs and disease management strategies for the specified disease or condition are frequently unsuccessful or the patient is near death when experimental treatments are contemplated. Experimental treatments can be more clinically effective than fully approved treatments, procedures, or drugs.

The statute is specific in defining experimental treatments and in describing processes for appeal and is thus 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 mandate could be replicated for other types of treatments. If denials of insurance coverage for treatments similar to experimental as defined in the statute were viewed as unfair or restricted access for a particular constituency, it is possible that mandated coverage could be proposed where currently, mandated coverage does not exist.

¹² Connecticut General Assembly. Report on Bills Favorably Reported By Committee. Public Health Committee. SB-1331. March 18, 1999.

¹³ National Association of Insurance Commissioners. 2008. NAIC Compendium of State Laws on Insurance Topics. Issued August 2008.

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

Because the experimental treatments and therapies are generally provided at no cost, the benefit is likely to have little impact on the availability of other benefits currently offered. The claims data provided by insurers/MCOs shows that costs associated with experimental treatments are extremely low. For further information, please see page 8 of the Ingenix Consulting Actuarial and Economic Report, attached as Appendix II.

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

Due to the low number of persons participating in experimental treatments and negligible financial effect on health insurance premiums, it is not anticipated that employers shifted or will shift to self-funded plans as a result of this single mandated benefit. It is also not anticipated that repeal of this single mandated benefit would lead to a shift from self-funded plans to fully insured plans among employers. Employers cognizant of the cumulative financial effects of mandated benefits and large enough to assume the risk of employee health care costs are more likely to consider shifting to self-funded 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.

Four insurers/MCOs domiciled in Connecticut provided information about coverage for experimental treatments in their self-funded plans, representing approximately 45 percent of the total population of Connecticut residents in self-funded plans. These four insurers/MCOs report that 16.3 percent of enrollees in their self-funded plans have coverage for the mandated services.

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

The experimental treatments mandate is a current benefit that has been included in the state employee health insurance and health benefits plans since 2000. Thus 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 Medicare¹⁴ 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.

State employee claims are included in the 2007 and 2008 claims data provided by insurers/MCOs for their fully insured group insurance enrollees. Because the state shifted to self-funded status on July 1, 2010 (during the time this report was being written), utilization under self-funded status is unknown. All self-funded plans, including those that provide coverage for state employees, are not regulated by the state insurance department and are exempt from state health insurance required benefit statutes.

In terms of financial impact, if the state employee health insurance/benefit plans continue to provide coverage for the required benefit, the IC actuarial analysis estimates the medical cost to the state employee

¹⁴ Personal communication. Scott Anderson, State of Connecticut Comptroller’s Office. September 14, 2010.

health insurance plan will total \$11,073 in 2010.¹⁵

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

Not applicable due to the nature of the mandated benefit. Experimental treatments by definition have not been proven to be safe and effective. They have not completed the full process of approval by the FDA or other regulatory agency as applicable to the type of treatment, procedure or therapy. However, the statute requires some degree of safety and effectiveness of experimental treatments in order for such treatments to be covered in fully insured group and individual health insurance plans. The statute requires experimental treatments to be appropriate for the illness or condition being treated or for the diagnosis for which it is being prescribed and requires the experimental treatment to have successfully completed a Phase III clinical trial of the federal Food and Drug Administration.

IV. Financial Impact

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

The mandate is not expected to materially alter the cost or availability of experimental treatments or costs associated with adverse events or side effects of experimental treatments over the next five years. Costs of mandated services are likely to increase (or decrease) at the same rate as any other medical service.

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

For those persons whose insurance plans would not otherwise cover experimental treatments as defined in the statute, the mandated health benefit may increase appropriate use of the service. For those covered by self-funded plans, using out-of-pocket funds, or receiving experimental treatments as defined in the statute from other sources, a mandated benefit may not increase appropriate use. Inappropriate use is not expected to be a potential factor due to the nature of the mandated service and low overall utilization.

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.

Not applicable due to the nature of the mandated benefit. Experimental treatments are generally administered following ineffective courses of standard treatments, thus they do not serve as alternatives to more or less expensive treatments, services, equipment, supplies or drugs. For further information, please see Appendix II, Ingenix Consulting Actuarial and Economic Report, page 40-41.

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 utilize the same utilization management methods and cost controls that are used for other covered benefits. The legislation does not prohibit insurers and MCOs from

¹⁵ The estimate is calculated by multiplying the estimated 2010 weighted average PMPM medical cost in fully insured plans in Connecticut by 12 to get an annual cost per insured life, and then multiplying that product by 163,334 covered lives, as reported by the State Comptroller's office. The actual cost of this 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 this mandated benefit would be in addition to the above amount. See Appendix II, Ingenix Consulting Actuarial and Economic Report, for further discussion.

employing utilization management, prior authorization, or other utilization tools at their discretion. The legislation also restricts experimental treatments as those that have successfully completed a phase III clinical trial of the federal Food and Drug Administration.

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 II, Ingenix Consulting Actuarial and Economic Report, page 15-16.

Group plans: When the medical cost of the mandate is spread to all insureds in group plans, medical costs are estimated to be \$0.01 PMPM and retention costs are estimated to be \$0.00 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$0.01 PMPM in 2010. Insurance coverage for the mandated benefit may be reasonably expected to increase group health insurance premiums accordingly, that is, \$0.12 per year per insured.

Individual plans: When the medical cost of the mandate is spread to all insureds in individual plans, medical costs are estimated to be \$0.00 PMPM and retention costs are estimated to be \$0.00 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$0.00 PMPM in 2010. Insurance coverage for the mandated benefit may be reasonably expected to increase individual health insurance premiums accordingly, that is, \$0.00 per year per insured.

For further information, please see Appendix II: Ingenix Consulting Actuarial and Economic Report.

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

Not applicable due to the nature of the mandated benefit. Experimental treatments, by definition, have not reached a fully proven level of safety or effectiveness based on scientific evidence (i.e., full FDA approval). Experimental treatments are also administered following ineffective courses of standard treatments, thus they do not serve as alternatives to more or less expensive treatments, services, equipment, supplies or drugs. For further information, please see Appendix II, Ingenix Consulting Actuarial and Economic Report, page 40-41.

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

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 of claims data received from insurers/MCOs in Connecticut shows an expected cost in 2010 of \$96,911 for medical costs associated with experimental treatments for Connecticut residents covered by fully insured group and individual health insurance plans.

Due to the nature of experimental treatments and the types of patients who undergo them, no prevention and early detection effects are anticipated.

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 experimental treatments 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 cost of the mandate (\$0.01 PMPM) suggests little difference in effects among different types of employers.

For further information regarding the differential effect of mandates on small group versus large group insurance, please see Appendix II: Ingenix Consulting Actuarial and Economic Report, page 30-31.

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 required benefit in its current form became effective January 1, 2000, it is unlikely that the mandate, taken individually, has any impact on cost-shifting between private and public payers of health care coverage at present.

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 of claims data received from insurers/MCOs in Connecticut shows an expected cost in 2010 of \$113,392 for coverage and notice regarding experimental treatments for Connecticut residents covered by fully insured group and individual health insurance plans.

For further information, please see Appendix II, Ingenix Consulting Actuarial and Economic Report.

Volume IV

Chapter 2

Off-label Drug Prescriptions for Cancer Treatment

Review and evaluation of CGSA §§ 38a-518b and 38s-492b
Mandatory coverage for off-label drug prescriptions for cancer treatment

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Chapter 2. Table of Contents

- I. Overview..... 23
- II. Background..... 24
- III. Methods..... 26
- IV. Social Impact..... 26
 - Table IV.2.1 State Mandates for Off-label Use of Prescription Drugs..... 29
- V. Financial Impact..... 36

I. Overview

In Public Act 09-179, An Act Concerning Reviews of Health Insurance Benefits Mandated in this State, the Connecticut General Assembly directed the Connecticut Insurance Department to review statutorily mandated health benefits existing on or effective on July 1, 2009. 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.

CGSA §§ 38a-518b and 381-492b mandate that group and individual health insurance policies issued, renewed or continued in this state provide coverage for off-label drugs prescribed for the treatment of cancer if the prescribed drug is recognized for treatment of the cancer for which it is prescribed in one of three drug reference compendia.

Specifically, CGSA § 38a-518b provides that...

...Coverage for off-label drug prescriptions. (a) Each group health insurance policy delivered, issued for delivery or renewed in this state on or after October 1, 1994, which provides coverage for prescribed drugs approved by the federal Food and Drug Administration for treatment of certain types of cancer 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 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 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 that 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.

(c) 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.
(P.A. 94-49, S. 1.)

§ 38a-492b mandates the same coverage in individual health insurance policies delivered, issued for delivery, renewed or continued in Connecticut.

In March 2010, CPHHP and Ingenix Consulting (IC) requested and received 2007 and 2008 claims data related to the mandated benefit from six 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 that claims data, a review of the legislative history, reviews of pertinent literature and the Ingenix Consulting report, this review found the following:

Current coverage

This mandate has been in effect since 1994 (P.A. 94-49).

Premium impact

Group plans: None of the Connecticut carriers was able to submit claims data on this mandate. They could not separate claims paid for cancer drugs prescribed off-label from those paid for other cancer drug prescriptions. Based on Ingenix Consulting data, it is estimated that, on a 2010 basis, the medical cost of this mandate is \$2.86 PMPM.¹⁶ Estimated total cost to insurers (insurance premium, administrative fees, and profit) of the mandated services on a 2010 basis in group plans is \$3.43 PMPM, which is 1.0 percent of estimated total premium costs in group plans. Estimated cost sharing on a 2010 basis in group plans is not available.

Individual policies: Four of the six insurers/MCOs provided claims data for individual health insurance policies. None of the Connecticut carriers was able to submit claims data on this mandate. They could not separate claims paid for cancer drugs prescribed off-label from those paid for other cancer drug prescriptions. Based on Ingenix Consulting data, it is estimated that, on a 2010 basis, medical cost is \$1.91 PMPM. Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services in 2010 in individual plans is \$2.48 PMPM, which is 0.9 percent of estimated total premiums in individual plans. Estimated cost sharing on a 2010 basis in individual plans is not available.

Self-funded plans

Data on how many self-funded plans provide coverage that equals or exceeds this mandate was not available.

It should be noted that most of this cost is duplicative of the cost that was reported in Volume I, Chapter 11 for mandated coverage of tumors and leukemia.

II. Background

“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.¹⁷ 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
- Given in a different dose than in the approved label.¹⁸

FDA approval is necessary in order for pharmaceutical companies to market new drug treatments. FDA approval is based on the results of the clinical trials that were submitted to the FDA as part of the approval process and it is often very narrow in its application. The FDA considers the marketing of an approved new drug for unapproved use to be an unapproved new drug with respect to that use (FD&C Act §§ 505(a), 301(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.¹⁹

¹⁶ Ingenix Consulting report, Appendix II, p. 8.

¹⁷ 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.

¹⁸ 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.

¹⁹ 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.

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.²⁰

However, 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.²¹ New clinical trials may establish a drug's effectiveness against other cancers of a similar type or against the same cancer at other stages than the stage for which it is approved. According to the National Cancer Institute, the standard of care for a particular type of cancer frequently involves the off-label use of one or more drugs.²²

Drug Compendia

Of the three compendia listed in Connecticut's mandate, only one is still in existence. The American Medical Association Drug Evaluations and the United States Pharmacopeia Drug Information for the Health Professional (U.S. Pharmacopeia) have been discontinued. The content of the U.S. Pharmacopeia was included in DrugPoints, a successor compendium.²³ 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.²⁴ 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.²⁵

Peer-reviewed Literature

Medicare Part B also allows reimbursement for off-label use of drugs in anticancer treatment if such use is medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in publications that have been identified for purposes of this subclause by the Secretary of Health and Human Services.²⁶ However, some authors have questioned whether peer review can ensure the quality of the evidence presented in an article.²⁷

Cancer drugs

For an in-depth discussion of chemotherapy, the most common type of off-label drug use for cancer, see *Chemotherapy Principles: An In-depth Discussion of the Techniques and Its Role in Cancer Treatment* on the web-site of the American Cancer Society.²⁸ This article describes how chemotherapy works and lists the

²⁰ *Ibid.*

²¹ 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.

²² 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.

²³ Abernethy A, Raman G, Balk E, *et al.* 2009. Systematic review: reliability of compendia methods for off-label oncology indications. *Ann Intern Med* 150(5):336.

²⁴ *Ibid.*

²⁵ 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.

²⁶ Social Security Administration. Compilation of Social Security Laws. Part E – Miscellaneous Provisions, Definitions. 42USC sec 1861(t)(2)(B)(ii)(II). Available at: http://www.ssa.gov/OP_Home/ssact/title18/1861.htm. Accessed on January 9, 2011.

²⁷ Curtiss F, Fairman K. 2009. Contradictory actions of off-label use of prescription drugs? The FDA and CMS versus the U.S. Justice Department. *Journal of Managed Care Pharmacy* 15(2):162.

²⁸ American Cancer Society. 2010. <http://www.cancer.org>.

many possible negative side effects associated with different chemicals used in it.

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, UptoDate, DynaMed, Cochrane Database, EMedicine, Micromedex, and Web Search using Google and Bing.

General search terms used included: off-label, drug labeling, cancer, neoplasm, social impact, insurance, health reimbursement, and economics.

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 Schools of Medicine and Pharmacy 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 requested and received 2007 and 2008 claims data from insurance companies and MCOs domiciled in Connecticut. None of the six companies were able to provide claims data on this mandate. Claims paid for off-label prescriptions for cancer are indistinguishable from claims paid for drugs approved by the FDA for that cancer.

CPHHP and the CID contracted with Ingenix Consulting (IC) to provide actuarial and economic analyses of the mandated benefit. Further details regarding the insurer/MCO claims data and actuarial methods used to estimate the cost of the benefit and economic methods used to estimate financial burden may be found in Appendix II.

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.

Estimates of the number of cancer drug prescriptions that are off-label vary between 30 percent and 50 percent of all cancer treatments.²⁹ The American Cancer Society reports that a 1991 study indicated that half of all chemotherapy drugs are used off-label and a 1997 study indicated that 60 percent of oncologists

²⁹ American Society of Clinical Oncology. 2006. Reimbursement for cancer treatment: coverage of off-label drug indications. *Journal of Clinical Oncology* 24:3206-3208.

had prescribed a chemotherapy drug off-label.³⁰ In addition, other drugs such as anti-depressants and anti-nausea drugs may also be prescribed off-label for cancer patients. A 2009 study by researchers at the University of Texas M.D. Anderson Cancer Center found that more than one-third of patients with metastatic breast cancer have received chemotherapy off-label.³¹

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

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 anticancer drugs and biologics for off-label uses if they were included in the same compendia that are listed in the Connecticut law (two of which are no longer in existence) or were supported by clinical evidence in peer-reviewed medical literature appearing in publications that have been identified for this purpose by the Secretary.³² 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. In 2008, CMS added three additional compendia to its list.

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.³³ In order 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.³⁴

Medicaid

The Social Security Act provides for coverage of off-label drugs in Title 19, § 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 that are included in the formulary [§ 1927(d)] and if coverage for the removed drug can be requested under prior authorization.

Connecticut Department of Public Health

No information was found on the CT DPH website regarding the off-label use of drugs for the treatment of cancer.

Partnership for Prescription Assistance

The Partnership for Prescription Assistance (PPA) program is a group of drug companies, health care

³⁰ 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.

³¹ University of Texas M.D. Anderson Cancer Center. 2009. Prevalence, impact of off-label chemotherapy in breast cancer evaluated. Science Daily. Retrieved March 8, 2010 from <http://www.sciencedaily.com/releases/2009/05/090514221929.htm>.

³² 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.

³³ 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 biologics in anticancer chemotherapeutic regimen. Available at: <http://www.cms.gov/manuals/Downloads/bp102c15.pdf>. Accessed on January 10, 2011.

³⁴ Center for Medicare Advocacy, Medicare Coverage for Off-label Drug Use (https://www.medicareadvocacy.org/InfoByTopic/PartDandPrescDrugs/10_09.16.OffLabelDrugCoverage.htm).

providers, patient advocacy organizations, and community groups. They help people who do not have prescription coverage and find assistance programs that are right for them. There are more than 475 public and private patient assistance programs, including more than 200 programs offered by drug companies.³⁵

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

These services have been mandated since 1994 in individual and group health insurance policies delivered, renewed or amended in Connecticut.

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.*

Cancer drugs are costly. If coverage were not available for off-label drugs for cancer treatments, it is likely that many patients would not be able to afford them and would choose not to use them.³⁶

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.*

Cancer drugs can cost up to \$10,000 per month. Assuming a conservative average annual cost of \$50,000, the actuarial report indicates that an off-label cancer drug can cost a family's entire annual income for families earning \$50,000 annually, if there is no insurance for it. These costs pose a significant financial burden for all income levels except for the very wealthy.³⁷

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

Approximately half of the uses for anti-cancer chemotherapy drugs are prescribed off-label, according to the American Society of Clinical Oncology.³⁸

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 American Society of Clinical Oncology published a statement in 2006 calling on the Secretary of Health and Human Services to ensure access to medically appropriate treatment for cancer as reflected in reports of studies in the medical literature, as well as in timely compendia listings.³⁹ They have also called 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.⁴⁰

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

The National Association of Insurance Commissioners lists 33 states that mandate insurance coverage for

³⁵ 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 on January 10, 2011.

³⁶ Ingenix Consulting report, Appendix II, p. 43.

³⁷ Ingenix Consulting report, Appendix II, p. 43.

³⁸ American Society of Clinical Oncology. 2006. Reimbursement for cancer treatment: coverage of off-label drug indications. *Journal of Clinical Oncology* 24:3206-3208.

³⁹ *Ibid.*

⁴⁰ 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.

off-label prescription drugs.⁴¹ Sixteen states limit the mandate to cancer treatments. Three states have mandates for cancer treatments and HIV/AIDS. Sixteen states have mandates that apply to treatments for any illness or to treatments for life-threatening illness (some states have more than one statute on off-label drug coverage). 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 which compendia are to be used.

Table IV.2.1 State Mandates for Off-label Use of Prescription Drugs		
State	Statute	Details
AL	§ 27-1-10.1	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. Does not require insurers to provide coverage for any experimental or investigational drug that the FDA has found to be contraindicated for treatment of a condition.
AZ	§ 20-2326	Shall not limit or exclude coverage of prescription drugs, prescribed as a cancer treatment, because the FDA approval is limited to treatment of a different type of cancer, if the off-label use is recognized as safe and effective in at least one standard medical reference compendia listed.
AR	§ 23-79-147	Shall not limit or exclude coverage of prescription drugs, prescribed as a cancer treatment, because the FDA approval is limited to treatment of a different type of cancer, if the off-label use is recognized as safe and effective in at least one standard medical reference compendia listed.
CA	Ins. §§ 10123.195; Health and Safety §1367.21	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.
CT	§§ 38a-518b; 38a-492b	Shall not limit or exclude coverage of prescription drugs, prescribed as a cancer treatment, because the FDA approval is limited to treatment of a different type of cancer, if the off-label use is recognized as safe and effective in at least one standard medical reference compendia listed.
FL	§ 627.4239	Shall not limit or exclude coverage of prescription drugs, prescribed as a cancer treatment, because the FDA approval is limited to treatment of a different type of cancer, if the off-label use is recognized as safe and effective in standard medical reference compendia or its use is recommended in medical literature.
GA	§§ 33-24-59.11; 33-53-2	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.
<i>Source:</i> NAIC's Compendium of State Laws on Insurance Topics		

⁴¹ National Association of Insurance Commissioners. 2010. Compendium of State Laws on Insurance Topics, vol. II-HB-10-12 *et seq.*

Table IV.2.1 State Mandates for Off-label Use of Prescription Drugs

State	Statue	Details
IL	215 ILCS 5/370r; 125/4-6.3; 375/6.4	Shall not limit or exclude coverage of prescription drugs, prescribed as a cancer treatment, because the FDA approval is limited to treatment of a different type of cancer, if the off-label use is recognized as safe and effective in at least one standard medical reference compendia listed.
IN	§§ 27-8-20-1 to 27-8-20-9	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
KS	§ 40-2,168	Shall not limit or exclude coverage of prescription drugs, prescribed as a cancer treatment, because the FDA approval is limited to treatment of a different type of cancer, if the off-label use is recognized as safe and effective in at least one standard medical reference compendia listed or in substantially accepted peer-review medical publication.
LA	§ 22:215.20	Any plan that covers the treatment of cancer shall not exclude coverage of prescription drugs used to treat cancers of a different type than approved by FDA, if recommended in medical literature or standard medical reference compendia, except for individually underwritten health insurance.
ME	tit. 24 §§ 2320-F; 2745-E; 2837-F; tit. 24 §2320-G; 2745-F; 2837-G; 4234-E 4234-D	Shall not limit or exclude coverage of prescription drugs, prescribed as a cancer treatment, because the FDA approval is limited to treatment of a different type of cancer, if the off-label use is recognized as safe and effective in at least one standard medical reference compendia listed or a medically recognized peer-reviewed journal. Policies that cover prescription drugs may not exclude coverage for any drugs prescribed for the treatment of HIV or AIDS because the drug has not been FDA approved for that indication, if it is a recognized use by standard medical reference compendia or a peer-reviewed medical journals
MD	Ins. § 15-804	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.
MA	ch. 175:47K to 175:47L; 176B:4N; 176G:4E ch. 175:47O to 175:47P; 176B:4P; 176G:4G	Policies that cover prescription drugs may not exclude coverage for any drugs prescribed for the treatment of cancer because the drug has not been FDA approved for that indication, if it is a recognized use by standard medical reference compendia or a peer-reviewed medical journal or by the commissioner. Policies that cover prescription drugs may not exclude coverage for any drugs prescribed for the treatment of HIV or AIDS because the drug has not been FDA approved for that indication, if it is a recognized use by standard medical reference compendia or peer-reviewed medical journals or by the commissioner.

Source: NAIC's Compendium of State Laws on Insurance Topics

Table IV.2.1 State Mandates for Off-label Use of Prescription Drugs

State	Statute	Details
MI	§§ 500.3406q; 550.1416c	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.
MN	§ 62Q.525	Shall not limit or exclude coverage of prescription drugs, prescribed as a cancer treatment, because the FDA approval is limited to treatment of a different type of cancer, if the off-label use is recognized as safe and effective in at least one standard medical reference compendia listed or a medically recognized peer-reviewed journal.
MS	§ 83-9-8	Shall not limit or exclude coverage of prescription drugs, prescribed as a cancer treatment, because the FDA approval is limited to treatment of a different type of cancer, if the off-label use is recognized as safe and effective in at least one standard medical reference compendia listed or a medically recognized peer-reviewed journal.
NE	§ 44-788	No policy that provides prescription drug coverage shall exclude coverage of a drug prescribed to treat cancer, AIDS, HIV or immunodeficiency syndrome because the FDA approval is limited to a different use, if the off-label use is recognized by medical literature.
NV	§§ 689A.0404; 689B.0365; 695B.1908; 695C.1733	If the policy includes prescription coverage for an FDA approved drug, must include coverage for any other use of the drug for cancer treatment, if the United States Pharmacopoeia Drug information or the American Hospital Formulary Service Drug Information recognize that use.
NH	§§ 415:6-g; 415:18-j; 420-A:2; 420-B:20	If provide coverage for prescription drugs, shall not exclude drug for other indication than approved by FDA if recommended in medical literature.
NJ	§§ 17:48-6h; 17B-26-2.1g; 17B:27-46.1g; 17:48E-35.5; 17:48A-7g § 26:1A-36.9	If provide coverage for prescription drugs, shall provide benefits for expenses incurred in prescribing drugs for treatment for that 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.
NC	§§ 58-51-59; 58-65-94; 58-67-78; 58-50-156	Shall not limit or exclude coverage of prescription drugs, prescribed as a cancer treatment, because the FDA approval is limited to treatment of a different type of cancer, if the off-label use is recognized as safe and effective in at least one standard medical reference compendia listed or a medically recognized peer-reviewed journal.
ND	§ 26.1-36-06.1	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 a listed reference compendia.

Source: NAIC's Compendium of State Laws on Insurance Topics

Table IV.2.1 State Mandates for Off-label Use of Prescription Drugs

State	Statue	Details
OH	§1751.66 § 3923.60	Shall not limit or exclude coverage of prescription drugs, prescribed as a cancer treatment, because the FDA approval is limited to treatment of a different type of cancer, if the off-label use is recognized as safe and effective in at least one standard medical reference compendia listed. No group or individual policy of sickness and accident insurance 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.
OK	tit. 63 § 1-2604	No individual policy of accident and health insurance issued that provides coverage for prescription drugs, nor any group blanket policy of accident and health insurance issued that provides coverage for prescription drugs shall exclude coverage of drugs for cancer treatment or the study of oncology because the off-label use of such drug has not been approved by FDA for that indication in one of the standard reference compendia listed.
OR	743.697	No insurance 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.
RI	§§ 27-55-1 to 27-55-3	No policy that covers prescription drugs shall drugs shall exclude coverage of drugs for cancer treatment or the study of oncology because the off-label use of such drug has not been approved by FDA for that indication in one of the standard reference compendia listed or medical literature.
SC	§ 38-71-275	No policy that covers prescription drugs shall exclude coverage of any such drug used for the treatment of cancer on the grounds that the drug has not been approved by FDA for the treatment of the specific type of cancer for which the drug has been prescribed; provided, that such drug is recognized for treatment of that specific type of cancer in one of the standard reference compendia or in the medical literature.
SD	§§ 58-17-100 to 58-17-106	If cover prescription drugs shall covers 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.
TN	§ 56-7-2352	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.
TX	I.C. Sec. 1369.004	If cover prescription drugs, shall covers 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-reviewed literature.

Source: NAIC's Compendium of State Laws on Insurance Topics

Table IV.2.1 State Mandates for Off-label Use of Prescription Drugs		
State	Statue	Details
VA	§ 38.2-3407.5	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.
	§ 2.2-2818	No policy that covers prescription drugs shall exclude coverage of any such drug used for the treatment of cancer on the grounds that the drug has not been approved by FDA for the treatment of the specific type of cancer for which the drug has been prescribed; provided, that such drug is recognized for treatment of that specific type of cancer in one of the standard reference compendia or in the medical literature.
WA	Reg. 284-30-450	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.

Source: NAIC's Compendium of State Laws on Insurance Topics

The Council on Affordable Health Insurance lists an additional five states with insurance mandates for off-label use of prescription drugs: Delaware, Missouri, New York, Vermont and New Mexico.⁴²

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

Internet searches and telephone inquiries found several studies from state agencies and public organizations related to the social impact of mandated insurance coverage for off-label drug prescriptions.

Maine: In December 2009, the Maine Bureau of Insurance reviewed the cumulative impact of mandates in Maine. The report notes that HMOs claim to already cover off-label drugs, in which case there would be no additional cost. However, the report notes that providers testified that claims have been denied on this basis. Maine's 1998 report states a "high-end cost" estimate of \$1 PMPM (0.6 percent of premium) if it is assumed there is currently no coverage for off-label drugs, which the 2009 reports estimates half this amount, or 0.3 percent.⁴³

Massachusetts: In July 2008, the Division of Health Care Finance and Policy (DHCFP) provided a Comprehensive Review of Mandated Benefits in Massachusetts. The report reviewed a mandate for off-label use of prescription drugs to treat HIV/AIDS and a mandate for off-label use of prescription drugs to treat cancer. DHCFP noted that to estimate of the costs of off-label drug use for HIV/AIDS would require a large, dedicated research effort, a comprehensive claims database, and extensive clinical definition of potential off-label use, associated diagnoses, etc. The report notes that using off-label prescriptions is an integral part of the community standard of care to treat AIDS and/or prevent HIV-related opportunistic infections. Further, health care providers also turn to off-label drugs when no licensed therapies are available to treat various AIDS conditions. According to DHCFP, AIDS providers have found that third-party payers are reluctant to reimburse for off-label drug use. Additionally, DHCFP noted that similar to the problem of how to measure costs associated with off-label use of prescription drugs to treat HIV/AIDS, it is also not

⁴² Council on Affordable Health Insurance. 2010. Health Insurance Mandates in the States, 2010.

⁴³ Maine Bureau of Insurance, 2009. Cumulative Impact of Mandates in Maine. <http://www.maine.gov/pfr/legislative/documents/mandatecumcost2009.pdf>. Accessed December 20, 2010.

feasible to measure off-label prescription drug use for the treatment of cancer in Massachusetts.⁴⁴

Wisconsin: In 2003, the State of Wisconsin Office of the Commissioner of Insurance reviewed Assembly Bill (AB) 364, relating to health insurance coverage of off-label drug prescriptions to treat cancer. Major findings of the report include that 227,000 adults in Wisconsin have been diagnosed with cancer in their lifetime, 116,000 of whom are over the age of 65. The report notes that total health care costs attributable to AB 364 are because there is not sufficient data to determine if such medication coverage would replace existing treatments or if it would be in addition to existing coverage. It is also not possible to determine what portion of the population that is afflicted with cancer would benefit from the passage of AB 364. Further, the report notes that the increase in costs could widen the disparity between insured plans and non-state regulated self-funded plans, decreasing the effectiveness and protections afforded by state regulation. Finally, the increase in costs, coupled with double-digit annual increases in health insurance premiums, could lead employers to discontinue prescription drug coverage in order to preserve other health benefits for their employees.⁴⁵

States searched for which no evidence of a review was found include Alabama, Alaska, Arizona, Arkansas, California, Colorado, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Maryland, Virginia, 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.

Cancer drugs are prescribed off-label because effective treatment options for cancer are often limited, prognoses are often grim, and submission of FDA applications for every combination of agent and cancer is impractical.⁴⁶

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 use of off-label drugs for the treatment of cancer as described in this mandate is a medical treatment and meets a medical need.

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 off-label drugs prescribed for other medical conditions. It may also have implications for benefit mandates on experimental treatments and clinical trials.

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

Mandates generally increase the cost of insurance in conjunction with medical trends. Individuals and groups may respond at time of renewal by purchasing a lower level of coverage with increased member cost-sharing, rather than by dropping coverage altogether. High levels of member cost-sharing can act as a barrier to access, especially for low-income members.

⁴⁴ Massachusetts Division of Health Care Finance and Policy, 2008. Comprehensive Review of Mandated Benefits in Massachusetts. Available at: http://www.mass.gov/Eeohhs2/docs/dhcfp/r/pubs/mandates/comp_rev_mand_benefits.pdf. Accessed December 20, 2010.

⁴⁵ State of Wisconsin Office of the Commissioner of Insurance, 2010. Review of Assembly Bill 364. Available at <http://oci.wi.gov/finimpct/sfiab364.pdf>. Accessed December 14, 2010.

⁴⁶ Abernethy A, Raman G, Balk E, *et al.* 2009. Systematic review: reliability of compendia methods for off-label oncology indications. *Ann Intern Med* 150(5):336.

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

Data on how many self-funded plans provide coverage that equals or exceeds this mandate was not available.

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

This is a currently mandated benefit and as such has been included in the state employee health insurance and health benefits plans, at least in part since 1994. Based on the IC estimated average cost PMPM, the total annual cost for this mandate in 2010 is estimated to be \$5,639,943.

(This has been calculated by multiplying the IC estimated 2010 PMPM medical cost in of they mandate by 12 to get an annual cost per insured life, and then multiplying that product by 163,334 covered lives, as reported by the State Comptroller's office.⁴⁷ The number of covered lives in the State plans includes both active employees and retirees who are not covered by Medicare.)

Caveat: This estimate is calculated using weighted averages for all claims paid by Connecticut-domiciled insurers and health maintenance organizations in the State. The actual cost of this 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.*

Off-label prescribing is widespread and is critical in treating cancer, where effective treatment options are often limited, and prognoses are often grim.⁴⁸ Drug compendia can be a mechanism for ensuring that patients have access to the newest, most effective drugs when evidence becomes available to support specific off-label uses.⁴⁹

According to the National Cancer Institute, use of a drug off-label may cause harm when the drug's effect against a kind of cancer has not been demonstrated and there is no medical reason to believe the drug might be an effective treatment for that kind of cancer. All drugs have side effects; the side effects of cancer drugs vary depending on the kind of cancer being treated. When a drug's effect against a type of cancer has not been demonstrated, and its side effects are unknown, the possible risks of giving the drug may outweigh the possible benefits.⁵⁰ The risks of using a drug off-label should be carefully weighed against the benefits of its use for a particular patient.

According to the American Cancer Society, chemotherapy (one of the most frequent types of off-label drug use) has many potential side effects, some of which can be life-threatening and some of which can be

⁴⁷ Personal communication with Scott Anderson, State Comptroller's office, September 14, 2010

⁴⁸ Abernethy A, Raman G, Balk E, *et al.* 2009. Systematic review: reliability of compendia methods for off-label oncology indications. *Ann Intern Med* 150(5);336.

⁴⁹ *Ibid.* p. 341.

⁵⁰ National Cancer Institute. 2010. Understanding the approval process for new cancer treatments: can off-label use be harmful? Available at: <http://newscenter.cancer.gov/clinicaltrials/learning/approval-process-for-cancer-drugs/allpages/print#Anchor-Ca-47238>. Accessed on January 10, 2011.

permanent.⁵¹ One of the biggest problems related to the widespread off-label prescribing of chemotherapy agents is the lack of information about such drug use for off-label conditions. 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.⁵²

There is some argument that allowing wide-spread off-label use of approved drugs gives manufacturers a disincentive to engage in the rigorous clinical trials that would establish the efficacy and effectiveness of the drug for those off-label uses.⁵³

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.

This mandate has been in effect since 1994 in Connecticut. Over the next five years, the cost is expected to rise from \$2.86 PMPM in 2010 to \$3.35 PMPM in 2014.⁵⁴

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

Cancer drugs tend to be higher priced than most pharmaceuticals⁵⁵ and they are also widely prescribed off-label. If there were no insurance coverage for such off-label prescriptions, utilization would likely be reduced due to affordability.

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.

Off-label prescribing is common in cancer treatment in part because there are frequently few FDA approved treatment options available.⁵⁶ In addition, many cancer treatments involve a combination of drugs, and it would be impractical to require FDA applications for every possible combination.⁵⁷

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

The mandate is limited to coverage for an off-label drug that is prescribed by a licensed health care provider for the treatment of cancer. It is also limited as to the circumstances under which it may be prescribed: it must be recognized as appropriate for treatment of that cancer in one of three named reference compendia. In addition, all other terms of the policy apply, so that utilization review, pre-authorization, and other

⁵¹ American Cancer Society. 2010. Chemotherapy Principles: An In-depth Discussion of the Techniques and Its Role in Cancer Treatment: what are the possible side effects of chemotherapy? Available at: <http://www.cancer.org/acs/groups/cid/documents/webcontent/002995-pdf.pdf>. Accessed on January 10, 2011.

⁵² 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.

⁵³ Ratner M, Gura T. 2008. Off-label or off-limits? *Nature Biotechnology* 26(8);871.

⁵⁴ Ingenix Consulting Summary Report.

⁵⁵ Ingenix Consulting report, Appendix II, p. 8.

⁵⁶ American Cancer Society. 2010. Off-label drug use: why are drugs used off-label? Available at: <http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Chemotherapy/off-label-drug-use>. Accessed on January 10, 2011

⁵⁷ Abernethy A, Raman G, Balk E, et al. 2009. Systematic review: reliability of compendia methods for off-label oncology indications. *Ann Intern Med* 150(5);336.

utilization management tools can be exercised by the carriers to avoid inappropriate use of the benefit.

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 II, Ingenix Consulting Actuarial and Economic Report, page 14.)

Group plans: When the IC estimated medical cost of this mandate is spread to all insureds in group plans, medical costs are estimated to be \$2.86 PMPM and retention costs are estimated to be \$0.57 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$3.43 PMPM in 2010, which is 1.0 percent of premium.

Individual plans: When the IC estimated medical cost of this mandate is spread to all insureds in individual plans, medical costs are estimated to be \$1.91 PMPM and retention costs are estimated to be \$0.57 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$2.48 PMPM in 2010, which is 0.9 percent of premium.

For further information, please see Appendix II: Ingenix Consulting Actuarial and Economic Report.⁵⁸

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.*

Some off-label prescriptions are for older, generic cancer treatments that are less expensive than new drugs, but many are for very expensive biologics.⁵⁹ This mandate is limited to off-label uses of FDA-approved drugs that are recognized in the specified drug compendia, some of which no longer exist. The mandate does not permit the use of peer-reviewed medical literature to support the off-label use of a cancer drug.

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. Cost sharing data for this mandate was unavailable from the Connecticut carriers. The IC actuarial analysis estimates an impact in 2010 of \$45,844,017 in paid medical costs from insurers/MCOs for off-label cancer drugs for Connecticut residents covered by fully insured group and individual health insurance.

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.*

The actuarial report found that this mandate is expected to have roughly the same effect on the allowed cost

⁵⁸ Ingenix Consulting report, Appendix II, p.8.

⁵⁹ Gillick M. 2009. Controlling off-label medication use. *Ann Intern Med* 150(5):344.

of small group plans as it does on large group plans.⁶⁰ 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.

Employees of small employers tend to pay a larger share of allowed costs through higher co-pays, deductibles and co-insurance, as well as a larger share of the premium.

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 Ingenix Consulting report estimates the impact of this mandate on the overall cost of the health care delivery system in the state in 2010 to be \$45,844,017. This includes only the medical cost included in premiums. It does not include member cost sharing (which also adds to the impact on the overall cost of the health care delivery system) because the insurers/MCOs were unable to provide data on this mandate.⁶¹

The estimated impact on the overall cost of the health care delivery system in the state assumes that the State of Connecticut plans continue to comply with this mandate even though these plans are now self-funded.

⁶⁰ Ingenix Consulting report, Appendix II, 30-31.

⁶¹ Ingenix Consulting report, Appendix II, p. 8.

Volume IV

Chapter 3

Cancer Clinical Trials: Routine Patient Care Costs

Review and Evaluation of Connecticut Statute

Chapter 700, §§ 38a-542a-g and 38a-504a-g

Cancer Clinical Trials: Coverage for Routine Patient Care Costs

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Chapter 3. Table of Contents

- I. Overview..... 41
- II. Background..... 42
- III. Methods..... 43
- IV. Social Impact..... 44
- V. Financial Impact..... 50

I. Overview

The Connecticut General Assembly directed the Connecticut Insurance Department to review the health benefits required by Connecticut law to be included in fully insured group and individual health insurance policies as of July 1, 2009. The review was conducted following 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).

Connecticut General Statutes, Chapter 700, §§ 38a-504a-g and 38a-542a-g state that each individual and group health insurance policy,

...shall provide coverage for the routine patient care costs...associated with cancer clinical trials...As used in this section...‘cancer 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 in human beings...

...routine patient care costs’ means: (1) Coverage for 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 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, provided such drugs have been approved for sale by the federal Food and Drug Administration.

In April 2010, CPHHP and Ingenix Consulting (IC) requested 2007 and 2008 claims data related to the mandated benefit from six 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). Due to the structure of the mandated benefit, insurers/MCOs were unable to isolate claims for routine patient care costs associated with cancer clinical trials in their claims databases. The findings of this report are based on an actuarial analysis of received claims data and reviews of pertinent literature and other information related to the mandated benefit.

Current coverage

This mandate went into effect on January 1, 2002 (P.A. 01-171).

Premium impact

For both fully insured group plans and individual health insurance policies, the actuarial analysis estimates the net effect of the mandate to be *de minimus*.

Self insured plans

Coverage of the benefit in self-funded plans is unknown.

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

II. Background

Clinical trials are research studies that allow physicians and scientists to investigate ways to improve 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 find out whether promising approaches to prevention, diagnosis, and treatment are safe and effective. For cancer patients and their families and physicians, decisions on therapy are largely based on what is known about treatment outcomes for patients with similar types and stages of cancer. 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 cancer clinical trials is currently underway. Investigators are researching many different types of cancer, treatments, drugs, prevention strategies, detection methods, and quality of life of cancer patients in attempts to improve prevention of cancer, increase rates of survival, and 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.⁶²

There are several different types of cancer 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 certain cancer. Screening trials test the best way to detect cancer, especially in its early stages. Quality of Life trials (also called Supportive Care trials) explore ways to improve comfort and quality of life for cancer patients.⁶³

There are also several different phases of cancer 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 cancer. Phase II trials continue to test the safety of the drug, and begin to evaluate how well the new drug works. Phase II studies usually focus on a particular type of cancer. Phase III trials test a new drug, a new combination of drugs, or a new surgical procedure in comparison to standard cancer therapy to evaluate tumor 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 cancer centers 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 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, cancer 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. Due to their own financial constraints and the high cost

⁶² 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.

⁶³ National Cancer Institute. Clinical Trials. United States National Institutes of Health. Available at: <http://www.cancer.gov/clinicaltrials>. Accessed September 23, 2010.

of existing cancer treatments, clinical trial sponsors generally do not cover routine health care costs for trial participants. Insurance coverage of medically necessary routine patient care costs for persons enrolled in cancer 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 cancer patients, and affect the progress of cancer research on the whole.

Organizations that chart state health insurance mandates report differing numbers of states that require the mandate. The National Cancer Institute reports 33 states require insurance policies to cover the routine health care costs for persons enrolled in clinical trials;⁶⁴ the National Association of Insurance Commissioners reported 17 states required coverage in 2006.⁶⁵ A recent review found 25 states with active cancer clinical trials legislation and one state with an expired statute.⁶⁶

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. Search terms included health knowledge, attitudes, practice; health care costs; health care disparities; insurance, health, reimbursement; insurance coverage; cost effectiveness analysis; clinical trials, economics, legislation, jurisprudence; cancer; biomedical research; demography; research support; insurance benefits; cancer therapy.

CPHHP staff conducted independent literature searches using the Cochrane Review, Scopus, and Google Scholar under the search terms of cancer clinical trials and routine patient care costs/cancer clinical trials. 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 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 2007 and 2008 claims data from six insurance companies and MCOs domiciled in Connecticut. The insurers/MCOs were unable to provide claims data for routine costs associated with cancer clinical trials for their fully insured group and individual plan participants or for the self-funded plans they administer.

CPHHP and the CID contracted with Ingenix Consulting (IC) to provide actuarial and economic analyses of the mandated benefit. Further details regarding the insurer/MCO claims data and actuarial methods used to estimate the cost of the benefit and economic methods used to estimate financial burden may be found in

⁶⁴ National Cancer Institute. 2010. States that require health plans to cover patient care costs in clinical trials. United States National Institutes of Health. Available at: <http://www.cancer.gov/clinicaltrials/developments/laws-about-clinical-trial-costs>. Accessed September 24, 2010.

⁶⁵ National Association of Insurance Commissioners. 2006. NAIC Compendium of State Laws on Insurance Topics.

⁶⁶ Taylor PL. 2010. State payer mandates to cover care in US oncology trials: Do science and ethics matter? *Journal of the National Cancer Institute* 102:1-15.

IV. Social Impact

1. The extent to which cancer clinical trials are utilized by a significant portion of the population.

The Connecticut Department of Public Health (DPH) compiles cancer statistics and information for Connecticut. DPH documents 8,469 cases of invasive cancer in 2006 among adults age 20-64 and 152 cases of invasive cancer in 2006 among children age 0-19.⁶⁷ An estimated three percent of adults and 71 percent of children with invasive cancer enter a clinical trial each year.^{68,69,70} Based on cancer incidence in Connecticut and estimated participation in clinical trials, and estimated 254 adults (age 20-64) and 108 (age 0-19) children enter a cancer clinical trial each year.⁷¹ Of these, 118 adults and 50 children are estimated to be covered by group and individual insurance policies subject to the mandated benefit.⁷²

The actuarial analysis 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. The diagnosis code includes participation in any clinical trial (not specifically a cancer clinical trial); however, the majority of clinical trials occurring in the United States are related to cancer. For further information, please see Appendix II: Ingenix Consulting Actuarial and Economic Report, page 9.

Demographic disparities are apparent in cancer clinical trials enrollment. For example, relative to white patients, participation in surgical oncology clinical trials is lower among racial/ethnic minorities; men are less likely to enroll in surgical oncology clinical trials than women; and patients 65-74 years of age are less likely to enroll than patients 20-44 years of age.⁷³ Enrollment in surgical oncology clinical trials is very low across all demographics.

2. The extent to which routine patient care costs associated with cancer clinical trials 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

In 2000, Medicare policy changed to include coverage of routine patient care costs of clinical trials.⁷⁴ 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. Medicare does not pay for some clinical trial treatments, tests that collect information only for the

⁶⁷ Connecticut Department of Public Health. 2008. Cancer incidence in Connecticut, 2006. Available at: <http://www.ct.gov/dph/lib/dph/ctr/pdf/CancerIncidenceinConnecticut2006.pdf>. Accessed September 24, 2010.

⁶⁸ Stein PM. 2006. Clinical trials. In *The Gale Encyclopedia of Cancer*, JL Longe, ed. Gale: Detroit, MI.

⁶⁹ National Cancer Institute. 2005. Doctors, patients face different barriers to clinical trials. U.S. National Institutes of Health. Available at: <http://www.cancer.gov/clinicaltrials/developments/doctors-barriers0401>. Accessed September 27, 2010.

⁷⁰ Umutyay A, Chiechi C, Beckett LA, et al. 2008. Overcoming barriers to cancer clinical trial accrual: impact of a mass media campaign. *Cancer* 112(1): 212-9.

⁷¹ US Census. 2008 Population estimates for the USA and Connecticut. Available at: <http://www.census.gov/popest/states/NST-ann-est.html>. Accessed September 24, 2010.

⁷² 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.

⁷³ Stewart JH, Bertoni AG, Staten JL, et al. 2007. Participation in surgical oncology clinical trials: gender-, race/ethnicity- and age-based disparities. *Annals of Surgical Oncology* 14(12): 3328-34.

⁷⁴ 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.

trial, and coinsurance and deductibles.⁷⁵

Public Programs Administered by Charities

The American Cancer Society (ACS) does not offer health care insurance, and does not have the means to provide all the people who need it with financial assistance. It does offer answers to financial and insurance questions and funds research on the causes of cancer and its potential prevention and treatment.⁷⁶

There is a wide array of cancer charities throughout the country that offer financial assistance for cancer patients and their families. Charitable cancer organizations are in general supported by private contributions, thus resources are not unlimited. Eligibility for financial assistance is generally based on need.

The ACS and other cancer charities 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.

Public Programs Administered by Public Schools

No information was found that would indicate public schools would be a source of funding for routine patient care costs associated with cancer clinical trials. While school-based health centers 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 with cancer due to their involvement with other health care providers and facilities as a result of their cancer diagnosis.

The Department of Public Health (DPH)

No information was found regarding the availability of funding for routine patient care costs associated with cancer clinical trials through the Connecticut Department of Public Health. A search of “cancer clinical trials” on the DPH website yielded an overview of Public Act 07-67, which summarizes the insurance mandate under review. The summary includes information on insurance coverage for routine patient care costs, as well as qualifications for out-of-network care coverage. No other information was available regarding this mandate on the DPH website.

Municipal Health Departments

No information was found regarding the availability of funding for routine patient care costs associated with cancer clinical trials through local and municipal health departments in Connecticut. Because local and municipal health departments generally focus on public health endeavors, it would seem unlikely that they would provide funding for medical care for individuals.

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 cancer clinical trials would be covered.

3. The extent to which insurance coverage is already available for routine patient care costs associated with cancer clinical trials.

State of Connecticut law requires coverage for routine patient care costs associated with cancer clinical trials

⁷⁵ National Cancer Institute. 2009. Clinical trials and insurance coverage. National Institutes of Health. Available at: <http://www.cancer.gov/clinicaltrials/education/insurance-coverage/page3>. Accessed September 23, 2010.

⁷⁶ American Cancer Society. 2007. “Access to Health Care”. Available at: http://www.cancer.org/docroot/subsite/accesstocare/content/Frequently_Asked_Questions.asp. Accessed June 1, 2010.

in fully insured group and individual health insurance plans as of January 1, 2002.⁷⁷ Coverage in self-funded plans in Connecticut is unknown because insurers/MCOs domiciled in Connecticut were unable to isolate claims for routine patient care costs associated with cancer clinical trials. 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.⁷⁸ It would seem likely that coverage for the mandated benefit in self-funded plans in Connecticut is similar to that in Maryland.

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 is required and generally available for persons enrolled in fully insured group and individual health insurance plans in Connecticut. Persons enrolled in fully insured group and self-funded plans represent the vast majority of covered lives. The uninsured and underinsured represent the largest population groups in Connecticut that may lack access the subject mandated benefit. 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.

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 routine patient care costs associated with cancer clinical trials is required to be included in fully insured group and individual insurance plans issued in Connecticut. Depending on the level of cost-sharing and personal financial resources available, that coverage may or may not be sufficient for the insured’s family to avoid unreasonable financial hardship. There is a range of costs for routine patient care costs associated with cancer clinical trials; several factors contribute such as the type of clinical trial, type of cancer being treated, and location of facility. Financial hardships due to routine patient care costs for those without insurance coverage for the mandated benefit may be significant.

Depending on the severity of disease and progression at time of diagnosis, a cancer diagnosis often results in significant health and economic costs for the individual and their family, even for those with comprehensive health benefits. If a cancer diagnosis is delayed, disease progression may have advanced to a point where it requires more intensive treatment or results in premature mortality. 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.

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.

Further discussion of financial and socioeconomic effects of the mandated benefit may be found in Appendix II: Ingenix Consulting Actuarial and Economic Report, page 37-39.

6. The level of public demand and the level of demand from providers for routine patient care associated with cancer clinical trials.

Because clinical trials may provide patients with life-threatening conditions the best opportunities for

⁷⁷ CONNECTICUT GENERAL STATUTES ANNOTATED § 38A-504A-G (INDIVIDUAL INSURANCE POLICIES); § 38A-542A-G (GROUP INSURANCE POLICIES).

⁷⁸ 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.

finding effective treatment, it is expected that the mandated 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”).⁷⁹ 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.

7. The level of public demand and the level of demand from providers for insurance coverage for routine patient care costs associated with cancer clinical trials.

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. Several members of the public and providers testified in favor of insurance coverage for the mandated services during the time legislation for the mandated benefit was under consideration by the Connecticut General Assembly.⁸⁰

Public and provider demand for the services and for insurance coverage of the services is also indicated by the large number of states that mandate coverage for patient care costs associated with cancer clinical trials as described below.

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

Washington DC and 32 states including Connecticut require coverage for patient care costs for patients enrolled in cancer clinical trials.⁸¹ Washington DC and 22 states require coverage for “routine” patient care costs associated with cancer clinical trials, using similar statutory language as in Connecticut.⁸² The remaining ten states use different statutory language but cover essentially the same patient costs.⁸³ For example, Massachusetts requires coverage for “patient care service,” defining patient care service as “a health care item or service that is furnished to an individual enrolled in a qualified clinical trial, which is consistent with the usual and customary standard of care for someone with the patient’s diagnosis, is consistent with the study protocol for the clinical trial, and would be covered if the patient did not participate in the clinical trial.”⁸⁴ Similarly, North Carolina requires coverage for “medically necessary costs of health care services... associated with participation in a covered clinical trial, including those related to health care services typically provided absent a clinical trial...”⁸⁵ Although these states’ statutes do not include the phrase “routine patient care costs,” the statutes require coverage of essentially the same patient care costs as Connecticut’s mandate for routine patient care costs associated with cancer clinical trials.

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

⁷⁹ National Cancer Institute. 2005. Doctors, patients face different barriers to clinical trials. U.S. National Institutes of Health. Available at: <http://www.cancer.gov/clinicaltrials/developments/doctors-barriers0401>. Accessed September 27, 2010.

⁸⁰ Connecticut General Assembly. Report on Bills Favorably Reported By Committee. Public Health Committee. SB-325. March 22, 2001.

⁸¹ 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.

⁸² California, Colorado, Delaware, Florida, Georgia, Indiana, Iowa, Kentucky, Maine, Michigan, Missouri, Nebraska, New Hampshire, New Jersey, New Mexico, Ohio, Oregon, South Carolina, Texas, Vermont, West Virginia and Wyoming.

⁸³ Arizona, Louisiana, Maryland, Massachusetts, Nevada, North Carolina, Rhode Island, Tennessee, Virginia and Wisconsin.

⁸⁴ Commonwealth of Massachusetts. General Laws, Chapter 175, Section 110L.

⁸⁵ General Assembly of North Carolina. Session 2001. Senate Bill 199. Ratified Bill.

CPHHP staff found several studies from state agencies and public organizations related to the social impact of the mandated benefit. 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.

Reviews completed in Maine, Maryland, and Pennsylvania provide no analysis of relevant social costs.^{86,87,88} A Louisiana review based on 2005-2007 claims data also provides no analysis of social costs but lists 22 states that require insurance coverage for the benefit.⁸⁹

Reviews completed in Massachusetts and Wisconsin provide analyses of social costs of the mandated benefit. In 2008, Massachusetts reported that approximately 10 million adults in the United States have cancer, and despite the fact that sometimes the best hope for a person with a serious illness is to become a subject in a clinical drug trial, only 3 to 5 percent of cancer patients take part in clinical trials each year. Massachusetts found that financial considerations and misconceptions about the nature of clinical trials, along with insurance hurdles, contribute to the reluctance of many cancer patients to join clinical trials and, often, their doctors' reluctance to suggest that they participate.⁹⁰

In 2005, Wisconsin reported that there is a small pool of individuals with cancer who are actually eligible to participate in cancer clinical trials. For Wisconsin, it was noted that approximately 1-2 percent of cancer patients were participating in cancer clinical trials. Health insurance coverage seems to have a direct effect on participation in cancer clinical trials with over 71 percent of clinical trials participants having health insurance coverage, self-funded coverage included. This number jumps to over 94 percent when Medicare, Medicaid and military participants are included. Wisconsin report authors suggest it would appear that the biggest deterrent to participating in a cancer clinical trial is having no insurance coverage at all.⁹¹

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

The subject 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 applicable alternatives is not attempted.

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 cancer clinical trials fulfills a medical need that might not otherwise be met. Treatment options and disease management strategies for cancer are not

⁸⁶ 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 September 29, 2010.

⁸⁷ Maine Insurance Department. 2009. Cumulative Impact of Mandates in Maine. Available at: <http://www.maine.gov/pfr/legislative/documents/mandatecumcost2009.pdf>. Accessed September 29, 2010.

⁸⁸ Pennsylvania Health Care Cost Containment Council. Mandated benefits review-Senate Bill 1198-review. Available at: <http://www.phc4.org/reports/mandates/SB1198/review.htm>. Accessed September 30, 2010.

⁸⁹ Office of Health Insurance. Louisiana Department of Insurance. Mandated benefits healthcare study 2005-2007. Available at: <http://www.lidi.state.la.us/Documents/Health/MandatedHealthcareBenefitsStudy.pdf>. Accessed September 30, 2010.

⁹⁰ Bachman SS, Highland J, Nordahl K, *et al.* 2008. Comprehensive review of mandated benefits in Massachusetts. Report to the legislature. Division of Health Care Finance and Policy, Commonwealth of Massachusetts. Available at: http://www.mass.gov/Eoehhs2/docs/dhcfp/r/pubs/mandates/comp_rev_mand_benefits.pdf. Accessed September 29, 2010.

⁹¹ Gomez J. 2005. Social and financial impact report – Senate Bill 288/Assembly Bill 617. Office of the Commissioner of Insurance, State of Wisconsin. Available at: <http://oci.wi.gov/finimpct/sfisb288.pdf>. Accessed September 29, 2010.

always successful. Cancer clinical trials attempt to identify treatments and disease management methods that are more effective than those currently available while giving persons with advanced cancers treatment opportunities that they would otherwise not have access to. Required insurance coverage for routine patient care costs associated with cancer 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, development of more effective cancer treatments with fewer side effects is facilitated, contributing to the public good.

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 mandate (i.e., required coverage for routine health care costs for clinical trials enrollees) could be replicated for non-cancer clinical trials, for example, 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-cancer 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.

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-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-funded plans and the extent to which the benefit is currently being offered by employers with self-funded plans.

Due to the low number of persons participating in cancer clinical trials, it is not anticipated that employers shifted or will shift to self-funded plans as a result of this single mandated benefit. It is also not anticipated that repeal of this single mandated benefit would lead to a shift from self-funded plans to fully insured plans among employers. Employers cognizant of the cumulative financial effects of mandated benefits and large enough to assume the risk of employee health care costs are more likely to consider shifting to self-funded 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 in self-funded plans in Connecticut is unknown because insurers/MCOs domiciled in Connecticut were unable to isolate claims for routine patient care costs associated with cancer clinical trials. 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.⁹² If coverage for the mandated benefit in self-funded plans in Connecticut is similar to that in Maryland, it is likely that the mandate has little to no direct effect on employers shifting to self-funded plans.

⁹² 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.

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

Required coverage of routine patient care costs associated with cancer clinical trials is a current benefit that has been included in the state employee health insurance and health benefits plans at least in part since 2002. Thus 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 Medicare⁹³ 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.

Because the state shifted to self-funded status on July 1, 2010 (during the time this report was being written), utilization under self-funded status is unknown. All self-funded plans, including those that provide coverage for state employees, are not regulated by the state insurance department and are exempt from state health insurance required benefit statutes.

16. The extent to which credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community determines that the routine patient care costs associated with cancer clinical trials are safe and effective.

The subject 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.

IV. Financial Impact

1. The extent to which the mandated health benefit may increase or decrease the cost of routine patient care costs associated with cancer clinical trials over the next five years.

Medical librarians found one 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.⁹⁴ 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.⁹⁵

2. The extent to which the mandated health benefit may increase the appropriate or inappropriate use of routine patient care costs associated with cancer clinical trials over the next five years.

For those persons whose insurance plans would not otherwise cover routine patient care costs associated with cancer clinical trials, the mandated health benefit may increase appropriate use of the service. For those covered by self-funded plans, use out-of-pocket funds, or receive routine patient care costs associated with cancer clinical trials from other sources, a mandated benefit may not increase 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 cancer clinical trials. Additionally, the legislation requiring the coverage references eligibility guidelines for cancer clinical trials.

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.

⁹³ Personal communication. Scott Anderson, State of Connecticut Comptroller's Office. September 14, 2010.

⁹⁴ 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.

⁹⁵ *Ibid.*

The subject 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.

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 utilize the same utilization management methods and cost controls that are used for other covered benefits. 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 cancer clinical trials and “routine patient care costs.” Utilization and cost impact is limited due to the small number of beneficiaries enrolled in cancer clinical trials.

5. The extent to which insurance coverage for routine patient care costs associated with cancer clinical trials may be reasonably expected to increase or decrease the insurance premiums and administrative expenses for policyholders.

The design of many oncology clinical research trials is to provide an additional treatment or drug in addition to the standard recommended treatment for the patient’s type and stage of cancer. In effect, the “routine patient care costs” for trial participants is the standard recommended treatment for the patient’s type and stage of cancer. The cost of such “routine” treatment is not insignificant; cancer is a high cost disease to treat and for which to provide continuity of care. Connecticut requires health insurance coverage for cancer treatment, thus it is not anticipated that the health insurance mandate for routine patient care costs associated with cancer clinical trials increases or decreases health insurance premiums and administrative expenses for policyholders.

Connecticut insurers/MCOs were unable to provide claims data associated with the routine health care costs for their members participating in cancer clinical trials. Actuarial analysis found a very small number of enrollees in cancer clinical trials in Connecticut and estimated the costs of routine patient care for clinical trials participants to be *de minimus*. For further discussion, please see Appendix II: Ingenix Consulting Actuarial and Economic Report, page 15-16.

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

The subject 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.

7. The impact of insurance coverage for routine patient care costs associated with cancer clinical trials 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. Insurers/MCOs in Connecticut were unable to

provide claims data for the routine patient care costs associated with cancer clinical trials, thus no actuarial analysis of claims data is available.

Economic benefits of the mandate may accrue to employers in terms of worker productivity. The economic benefits to business of employees with cancer returning to work or on-the-job productivity may offset some of the costs of routine patient care associated with cancer clinical trials covered by the mandate.

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 routine patient care costs associated with cancer clinical trials on the cost of health care for small employers. Because Connecticut mandates coverage for cancer treatment and “routine patient care costs” for trial participants is the standard recommended treatment for the patient’s type and stage of cancer, it is unlikely that the subject mandate results in different effects among different types of employers.

For further information regarding the differential effect of the mandates on small group versus large group insurance, please see Appendix II: Ingenix Consulting Actuarial and Economic Report, page 31.)

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 required benefit became effective January 1, 2002, it is unlikely that the mandate, taken individually, has any impact on cost-shifting between private and public payers of health care coverage at present.

Additionally, due to the low number of cancer patients enrolling in clinical trials in Connecticut and in the insured population, the mandated benefit is not estimated to have an impact on cost-shifting between private and public payers.

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. Because insurers/MCOs were unable to isolate claims for routine patient care costs associated with cancer clinical trials, actuarial analysis of claims data was not available. For several reasons including those described above, the actuarial analysis suggests the cost of the mandate to be *de minimus*.

For further information, please see Appendix II, Ingenix Consulting Actuarial and Economic Report.

Volume IV

Chapter 4

Hypodermic Needles and Syringes

Review and evaluation of CGSA §§ 38a-518a and 38a-492a

Mandatory coverage for Hypodermic Needles and Syringes

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Chapter 4. Table of Contents

- I. Overview..... 55
- II. Background..... 56
- III. Methods..... 57
- IV. Social Impact..... 57
- V. Financial Impact..... 62

I. Overview

In Public Act 09-179, An Act Concerning Reviews of Health Insurance Benefits Mandated in this State, the Connecticut General Assembly directed the Connecticut Insurance Department (CID) to review statutorily mandated health benefits existing on or effective on July 1, 2009. 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.

CGSA §§ 38a-518a and 38a-492a mandate that group and individual health insurance policies issued, renewed or continued in this state provide coverage for hypodermic needles and syringes when prescribed for administration of medications. Specifically, CGSA § 518a provides that:

Mandatory coverage for hypodermic needles and syringes. Every group 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 or renewed in this state on or after July 1, 1992, shall provide coverage for hypodermic needles or syringes prescribed by a prescribing practitioner, as defined in subdivision (22) of section 20-571, for the purpose of administering medications for medical conditions, provided such medications are covered under the policy. Such benefits shall be subject to any policy provisions that apply to other services covered by such policy.
(P.A. 92-185)

§38a-492a mandates the same coverage in individual health insurance policies delivered, issued for delivery, renewed or continued in Connecticut.

In March 2010, CPHHP and Ingenix Consulting (IC) requested and received 2007 and 2008 claims data related to the mandated benefit from six 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 that claims data, a review of the legislative history, reviews of pertinent literature and the Ingenix Consulting report, this review found the following:

Current coverage

This mandate has been in effect since 1992 (P.A. 92-185).

Premium impact

Group plans: On a 2010 basis, the medical cost of this mandate is estimated to be \$0.05 PMPM. Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services on a 2010 basis in group plans is \$0.06 PMPM, which is less than 0.1 percent of estimated total premium costs in group plans. Estimated cost sharing on a 2010 basis in group plans is \$0.04 PMPM.

Individual policies: Four of the six insurers/MCOs provided claims data for individual health insurance policies. On a 2010 basis, medical cost is estimated to be \$0.01 PMPM. Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services in 2010 in individual plans is *de minimis*. Individual data is less credible than group data primarily due to small sample size.

Self-funded plans

Information received from five insurers/MCOs domiciled in Connecticut representing an estimated 47

percent of the total self-funded population in Connecticut shows that 86 percent of members in self-funded plans have coverage for this benefit.

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

II. Background

The mandate specifies coverage for hypodermic needles and syringes as prescribed for the administration of medications for medical conditions. Presumably, needles and syringes would be prescribed by a provider so that the patient or a family member could administer the medication without needing to visit the provider or have a nurse come to the home every time the medication needed to be administered.

Available treatments for many chronic conditions include options that involve the self-administration of injectable medications by the patient or a family member.⁹⁶ The most common of these are the self-administration of insulin by people with diabetes and the self-administration of epinephrine to treat or prevent anaphylactic shock due to severe allergic reactions. Other conditions include multiple sclerosis, infertility (for *in vitro* fertilization), erectile dysfunction, rheumatoid arthritis, osteoporosis, hepatitis C, acromegaly (severe diarrhea associated with certain cancers), deep vein thrombosis and migraine headaches.⁹⁷ Self-injections may be required daily, several times daily, every few days or episodically, depending on the condition and the treatment plan.

The mandate specifies hypodermic needles and syringes. In the eighteen years since the mandate became effective, a number of alternative delivery devices have also been developed for self-administration of medications. These medications may be available in multi-dose vials that are administered via prescribed needles and syringes. They may also be available in pre-filled syringes or pen devices, some of which require a separate purchase of pen needles and some of which do not. In the case of insulin, continuous delivery systems (insulin pumps) are available that use infusion sets implanted in the skin rather than needles and syringes or pens.⁹⁸ The insulin pump and infusion sets are generally considered durable medical equipment.

⁹⁶ UpToDate. 2010. Search results for “self-injected medications”. Available at http://www.uptodate.com/patients/content/search.do?search=self+injected+medications&source=USER_INPUT&searchOffset=0&_NEXTITEM=&_EVENTNAME=Go&_EVENTARG=undefined&_POSTBACK=true&_DESTINATION=&_xCoordHolder=0&_yCoordHolder=0. Accessed on December 28, 2010.

⁹⁷ Communication from Devra Dang, PharmD, BCPS, CDE; Associate Clinical Professor, University of Connecticut School of Pharmacy. Dated December 23, 2010.

⁹⁸ Communication from Devra Dang, PharmD, BCPS, CDE, Associate Clinical Professor, University of Connecticut School of Pharmacy. Dated December 23, 2010.

III. Methods

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 from 2000-2010 under search terms including hypodermic needles, syringes, prescriptions, self-administration, self-administered injectable drug. More information was supplemented from available texts, government reports and non-profit organization reports.

Resources searched include:

- PubMed
- Scopus
- EMedicine
- CINAHL
- Web Search through Google

CPHHP staff conducted independent literature searches using Google 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.

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, and non-profit and community-based organization websites.

With the assistance of the CID, CPHHP and Ingenix Consulting requested and received 2007 and 2008 claims data from insurance companies and MCOs domiciled in Connecticut. Six insurers/MCOs provided hypodermic needles and syringes claims data for their fully insured group and individual health insurance plan participants. Five insurers/MCOs also provided information about coverage for hypodermic needles and syringes in the self-funded plans they administer.

CPHHP and the CID contracted with Ingenix Consulting (IC) to provide actuarial and economic analyses of the mandated benefit. Further details regarding the insurer/MCO claims data and actuarial methods used to estimate the cost of the benefit and the economic methods used to estimate financial burden may be found in Appendix II.

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.

People who have Type 1 diabetes and some who have Type 2 diabetes are the most common users of self-injectable medication. People who have severe allergies or multiple sclerosis may self-inject medication such as epinephrine (for allergic reactions) or glatiramer acetate (for multiple sclerosis). People with infertility, erectile dysfunction, hepatitis C, severe diarrhea associated with certain cancers, rheumatoid arthritis, osteoporosis, and deep vein thrombosis may also self-inject their medications.

In a 2006 report, the Connecticut Department of Public Health reported that approximately 163,000 adults age 18 and older have diabetes in Connecticut.⁹⁹ This is 6.2 percent of the population. Five to ten percent of this population has Type 1 diabetes.

Connecticut Department of Public Health indicates that approximately 1 in 5 Connecticut residents have some form of arthritis.¹⁰⁰ The CDC reports that the prevalence of rheumatoid arthritis in the U.S. is 0.6 percent.¹⁰¹ CT DPH reports that there were approximately 12,226 people in Connecticut with chronic or resolved hepatitis C in 2008.

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 Part B does not cover insulin, syringes and needles. However, an external insulin pump may be covered as durable medical equipment.¹⁰² Medicare Part B beneficiaries pay 100 percent for insulin (unless used in a pump), syringes, and needles.¹⁰³ Part D prescription drug programs may cover certain medical supplies used to inject insulin such as syringes, needles and gauzes.¹⁰⁴

Medicaid

Medicaid covers diabetic supplies, including insulin, needles and syringes.¹⁰⁵ Poor or elderly people who are eligible for both Medicare and Medicaid receive benefits first through Medicare Part B and Part D, and then Medicaid pays the remainder.¹⁰⁶ Connecticut's Pharmaceutical Assistance Contract to the Elderly and Disabled (ConnPACE) also covers prescription drugs, insulin and insulin syringes.¹⁰⁷

Manufacturers

Some manufacture of needles and syringes, such as Becton Dickinson, provide free needles and syringes to community health clinics to help those in need.¹⁰⁸

Municipal health departments/health districts

The city of New Haven Health Department and AIDS Project Hartford operates a needle exchange program that provides clean needles to addicts in exchange for used ones to prevent the spread of HIV.^{109,110} The Department of Public Health also lists AIDS Project Greater Danbury, the city of Bridgeport, and the city of

⁹⁹ Connecticut Department of Public Health. 2006. The burden of diabetes in Connecticut, 2006 Surveillance Report.

¹⁰⁰ Connecticut Department of Public Health. 2010. Arthritis. Available at: http://www.ct.gov/dph/cwp/view.asp?a=3135&q=393096&dphNav_GID=1601&dphPNavCtr=#47037. Accessed on December 29, 2010.

¹⁰¹ Centers for Disease Control and Prevention. 2010. Arthritis. Available at: <http://www.cdc.gov/arthritis/basics/rheumatoid.htm>. Accessed on December 29, 2010.

¹⁰² Medicare Coverage Guidelines for Diabetes – Insulin and Syringes (Connecticut).

¹⁰³ *Ibid.*

¹⁰⁴ American Diabetes Association, Living with Diabetes. Available at: <http://www.diabetes.org/living-with-diabetes/treatment-and-care/health-insurance-options/65-and-older/medicare-part-d.html>.

¹⁰⁵ DSS Provider Fee Schedule: MEDS - Medical/Surgical Supplies

¹⁰⁶ Helga Neiss. Diabetes Supplies Insurance and Medicare Coverage, June 2, 2006. (<http://www.cga.ct.gov/2006/rpt/2006-R-0339.htm>).

¹⁰⁷ *Ibid.*

¹⁰⁸ Becton Dickinson. 2009. BD and Direct Relief International Team Up to Provide Free Diabetes Insulin Injection Products to Americans Impacted by the Economic Downturn. Available at: http://www.bd.com/contentmanager/b_article.asp?Item_ID=24064&ContentType_ID=1&BusinessCode=20001&d=BD+Worldwide&s=&dTitle=&dc=&dcTitle=. Accessed on January 6, 2011.

¹⁰⁹ City of New Haven. Health Department. AIDS services. Available at: <http://cityofnewhaven.com/Health/Aids.asp>. Accessed January 6, 2011.

¹¹⁰ AIDS Project Hartford. Harm Reduction. Available at: <http://www.aphct.org/>. Accessed January 6, 2011.

Stamford as also providing a needle exchange program.¹¹¹

Public Programs administered by Public Schools

No information was found that would indicate public schools provide funding for hypodermic needles and syringes.

Department of Public Health

The Department of Public Health administers the Syringe Exchange Programs (SEPs) in Connecticut by the Department's Public Health AIDS and Chronic Diseases Division.¹¹²

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

Connecticut General Statutes, §§ 38a-518a and 38a-492a require fully insured private insurance policies delivered, renewed or amended in Connecticut to cover hypodermic needles and syringes. This mandate has been in effect since January 1, 1992 for individual and group policies.

Connecticut's public insurance programs also cover hypodermic needles and syringes.

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.

The cost of hypodermic needles and syringes has decreased since 1992, when this mandate was enacted. Lack of insurance coverage is unlikely to prevent persons from obtaining necessary health care treatment. In addition, self-injectable medications are increasingly available in pre-filled single dose syringes, with the cost of the syringe included in the cost of the drug itself.¹¹³

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.

The cost of hypodermic needles and syringes does not impose a significant burden. Even without insurance coverage, a box of 100 single unit disposable needle-syringes costs as little as \$25.¹¹⁴ For people with diabetes, the most frequent users of self-injectable medications, this is about one month's supply. It would be covered by the mandate for coverage of diabetes equipment and supplies (see Volume I, Chapter 7) if this mandate did not exist.

For other self-injectable medications, the cost of the drug is usually significantly higher than the cost of the needles and syringes.¹¹⁵

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

This mandate was included in the law that decriminalized the sale of hypodermic needles and syringes without a prescription in Connecticut (P.A. 92-185). Self-injectable medications are used to treat a wide variety of diseases and conditions.

¹¹¹ Department of Public Health. Connecticut Syringe Exchange Summary FY 2009. Available at: http://www.ct.gov/dph/lib/dph/government_relations/2010_reports/sepann0809.pdf. Accessed January 6, 2011.

¹¹² Department of Public Health. Connecticut Syringe Exchange Summary FY 2009. Available at: http://www.ct.gov/dph/lib/dph/government_relations/2010_reports/sepann0809.pdf. Accessed January 6, 2011.

¹¹³ Ingenix Consulting report, Appendix II, p. 44.

¹¹⁴ Ingenix Consulting report, Appendix II, p 44.

¹¹⁵ *Ibid.*

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 American Diabetes Association, in its Standards of Medical Care in Diabetes – 2010, calls for third-party payer coverage of various components of its recommended diabetes care, including equipment and supplies such as needles and syringes for self-injection of insulin.¹¹⁶

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

Mandates for coverage of hypodermic needles and syringes were not found for other states. However, 44 states and the District of Columbia mandate insurance coverage of equipment and supplies, including syringes, for diabetes treatment.¹¹⁷

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

No mandated benefit reviews from other states were found.

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

If members cannot purchase or obtain hypodermic needles and syringes for self-injection of prescribed medications, the alternative is to require the administration of such medication by licensed medical professionals, either in the provider's office or the patient's home (as by a visiting nurse), or to use other treatment options that may not be the preferred treatment for that individual. Some medications now are available in pre-filled syringes and pens that do not require separately purchased hypodermic needles and syringes. In these cases, the cost of the syringe or pen is included in the cost of the drug and would be covered by the pharmacy benefit.

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 mandate is limited to hypodermic needles and syringes that are prescribed for the administration of prescribed medications for the treatment of medical conditions. Therefore, it meets a medical need and is consistent with the role of health insurance and managed care.

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

The technology of delivery systems for medications continues to evolve. As an example, insulin can be delivered by subcutaneous injections using hypodermic needles and syringes, by pre-filled pens with or without removable needles, or by continuous delivery systems such as insulin pumps.¹¹⁸

The mandate does not specify these other delivery systems.

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

Mandates generally increase the cost of insurance in conjunction with medical trends. Individuals and groups may respond at time of renewal by purchasing a lower level of coverage with increased member cost-

¹¹⁶ American Diabetes Association. 2010. Standards of Medical Care in Diabetes – 2010. *Diabetes Care*, vol. 33, Supp. 1 p.

¹¹⁷ National Association of Insurance Commissioners. 2010. Compendium of State Laws on Insurance Topics, vol. II.

¹¹⁸ Valentine V, Kruger D. 2010. Considerations in insulin delivery device selection. *Diab Tech and Ther* 12(supp 1):S98-S100. Available at: <http://www.liebertonline.com/doi/pdfplus/10.1089/dia.2010.0007>. Accessed on January 6, 2011.

sharing, rather than by dropping coverage altogether. High levels of member cost-sharing can act as a barrier to access, especially for low-income members.

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

Information received from five insurers/MCOs domiciled in Connecticut representing an estimated 47 percent of the total self-funded population in Connecticut shows that 86 percent of members in self-funded plans have coverage for this benefit.

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

Because the State plans were fully insured in 2007 and 2008, claims data from the carriers and cost projections based on that data include the data from the State plans. Assuming that the State plans will continue to comply with this mandated health benefit, the total annual medical cost for this mandate in 2010 is estimated to be \$98,600. This has been calculated by multiplying the 2010 PMPM cost by 12 to get an annual cost per insured life, and then multiplying that product by 163,334 covered lives, as reported by the State Comptroller's office. (This includes those retirees and their dependents who are not receiving Medicare.)¹¹⁹

Caveat: This estimate is calculated using weighted averages for all claims paid by Connecticut-domiciled insurers and health maintenance organizations in the State. The actual cost of this 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.

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.

People with Type 1 diabetes have been self-injecting insulin for several decades. This is the most common delivery system for insulin, although other delivery systems exist and are becoming more common.¹²⁰

The risks associated with self-injection using needles and syringes include inaccurate dosing due to errors in drawing the medication, bubbles in the syringe or incomplete administration of the medication due to patient error; and scarring or infection at the injection site.¹²¹ There is also potential for re-use of the syringe and needle, which increases the potential for infection.

¹¹⁹ Personal Communication with Scott Anderson, Connecticut State Comptroller's Office, September 14, 2010.

¹²⁰ American Diabetes Association. 2010. Insulin routines. Available at: <http://www.diabetes.org/living-with-diabetes/treatment-and-care/medication/insulin/insulin-routines.html>. Accessed on January 7, 2011.

¹²¹ Asakura T, Seino H, Nakano R, *et al.* 2009. A comparison of the handling and accuracy of syringe and vial versus pre-filled insulin pen (FlexPen). *Diabetes Technology and Therapeutics* 11(10):657-61.

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 cost of syringes and hypodermic needles has decreased significantly since the mandate was passed.¹²² However, delivery systems are continuing to evolve and it is unclear whether this mandate will apply to some of the new systems.

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

The mandate may increase the appropriate use of alternative treatments for many diseases/conditions. As alternate delivery systems are developed and become more widely used, the mandate may become out-dated.

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.

To the extent that there are a range of treatment options for a particular disease or condition, this mandate may make the option for self-injected medications a more viable option for some patients. Whether self-injection of medication is a more expensive or a less expensive alternative to other treatment options will depend on the cost of the medication to be injected. Some of the self-injected medications are very expensive, e.g. growth hormone (\$500-\$700 per month) or some osteoporosis therapies (\$700 or more per month).¹²³

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

The statutes specifically state that this benefit is subject to any policy provisions that apply to other services covered by such policy. It is anticipated that insurers and MCOs will employ the same utilization management methods and cost controls that are used for other covered benefits, such as price negotiations with suppliers, utilization review, prior authorization, or other utilization tools at their discretion.

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 costs and retention costs. Medical costs are the amounts insurers/MCOs pay 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 II, Ingenix Consulting Actuarial and Economic Report, page 15.)

Group plans: When the medical cost of the mandate is spread to all insureds in group plans, medical costs are estimated to be \$0.05 PMPM and retention costs are estimated to be \$0.01 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$0.06 PMPM in 2010, which is less than one tenth of one percent of premium.

Individual plans: When the medical cost of the mandate is spread to all insureds in individual plans, medical costs are estimated to be \$0.01 PMPM and retention costs are estimated to be \$0.00 PMPM in

¹²² Ingenix Consulting report, Appendix II, p. 44.

¹²³ *Ibid.*

2010. Thus the total effect on insurance premiums is estimated at \$0.01 PMPM in 2010, which is *de minimis*. (Note: Individual data is less credible than group data primarily due to small sample size.)

It is unclear how much of this cost would be covered by employers and insurance carriers even without the mandate since coverage for hypodermic needles and syringes is provided by a large percentage of self-funded plans that are not subject to the mandate.

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.*

Some medications can only be given by injection, such as insulin, which is the only option for treating Type 1 diabetes. In the case of other conditions, self-injected medications may be one of several options available to the treating physician. In that case, the cost of the medication will determine whether self-injection is a more or less expensive alternative to other treatments.

A systematic literature review of the cost-effectiveness of vials/syringes versus pen devices indicated improved adherence to injection guidelines utilizing an insulin pen. The insulin pens also had decreased costs with utilization compared to vials/syringes.¹²⁴ However, insulin delivery through an inhaler (Exubera) was found not to be cost-effective. Compared to other delivery options, more insulin is required when utilizing an inhaler, and thus is more costly. Some benefit might be gained for individuals with trouble injecting insulin.¹²⁵

There is growing research on the use of needle-free injectors (NFI) that utilize a high-velocity liquid jet to puncture the skin and deliver a drug.¹²⁶ An evaluation of NFI indicated it can be a useful tool for enhanced drug delivery into skin.¹²⁷ Although these may be a cost-effective alternative to needles and syringes, the authors found no scientific evidence in peer reviewed journals or other reputable sources to substantiate the cost-effectiveness of these devices.

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 payments by the insureds. Actuarial analysis of claims data received from insurers/MCOs in Connecticut shows an expected impact in 2010 of \$1,487,254 for hypodermic needles and syringes for Connecticut residents covered by fully insured group and individual health insurance plans.

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.*

¹²⁴ Asche CV, Shane-McWhorter L, Raparla S. 2010. Health economics and compliance of vials/syringes versus pen devices: a review of the evidence. *Diabetes Technology and Therapeutics* 12(Suppl 1): S101-8.

¹²⁵ Black C, Cummins E, Royle P, *et al.* 2007. The clinical effectiveness and cost-effectiveness of inhaled insulin in diabetes mellitus: a systematic review and economic evaluation. *Health Technology Assessment* 11(33):1-126.

¹²⁶ Anahtar MN. 2008. Needle-free injectors as a sustainable alternative to syringes. *MIT International Review* Spring 2008.

¹²⁷ Inoue N, Todo H, Iidaka D, *et al.* 2010. Possibility and effectiveness of drug delivery to skin by needle-free injector. *International Journal of Pharmaceutics* 391(1-2):65-72.

In general, the cost of mandates may be part of a premium increase or a redesign of benefits. If the premium increases, the employer may decide to absorb that cost or increase the employee's payments toward the premium. If benefits are redesigned, coverage for other benefits that are not mandated may be dropped. Alternatively, firms may increase employee cost-sharing at the point of service level with increased co-payments or deductibles. To some degree, both the employer and the employee are sensitive to increasing prices. As health insurance costs rise, the employer and/or the employee may opt out of offering/purchasing health insurance.

Small employers tend to be more sensitive to price changes than large employers. Also, small employers are more likely to offer less comprehensive insurance coverage at lower cost. As a result, mandates constitute a larger portion of the health insurance premium for small employers. Any increase in mandates constitutes a higher percentage rise for small employers compared to large employers. This particular benefit is not likely to be a large enough increase to change firm behavior but the combined expense of all mandates may cause small employers to discontinue providing health insurance to their employees.

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 mandate on the overall cost of health care delivery in the state is \$1,638,333.¹²⁸ 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.

¹²⁸ Ingenix Consulting Summary Report.

Volume IV

Chapter 5

Prescription Drugs Removed from Formulary

Review and Evaluation of Connecticut Statute

Chapter 700, §§ 38a-518f and 38a-492f

Mandatory Coverage for Certain Prescription Drugs Removed from Formulary

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Chapter 5. Table of Contents

- I. Overview.....67
- II. Background.....68
 - Figure IV.5.1. Type of Formulary Used by Employers.....69
- III. Methods.....70
- IV. Social Impact.....71
 - Table IV.5.2. Retail Prescription Drugs Utilization.....71
- V. Financial Impact.....79

I. Overview

In Public Act 09-179, An Act Concerning Reviews of Health Insurance Benefits Mandated in this State, the Connecticut General Assembly directed the Connecticut Insurance Department (CID) to review statutorily mandated health benefits existing on or effective on July 1, 2009. This report is part of that review and was conducted following the requirements stipulated under Public Act 09-179. This review was a collaborative effort of Connecticut Insurance Department and the University of Connecticut Center for Public Health and Health Policy (CPHHP).

Connecticut General Statutes, Chapter 700, §§ 38a-518f and 38a-492f mandate that group and individual health insurance policies issued, renewed or continued in this state provide coverage for certain prescription drugs removed from the formulary if these drugs were deemed medically necessary by a health care provider, if the drugs were covered by the insurance policy prior to the removal of the drug from the formulary, and if the insured used these drugs to treat a chronic illness prior to the removal of the drug from the formulary.

Specifically, Connecticut General Statutes, Chapter 700, § 38a-518f provides that:

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 or continued in this state on or after January 1, 2000, that provides coverage for outpatient prescription drugs shall not deny coverage for an insured for any drug that the insurer removes from its list of covered drugs, or otherwise ceases to provide coverage for, if (1) the insured was using the drug for the treatment of a chronic illness prior to the removal or cessation of coverage, (2) the insured was covered under the policy for the drug prior to the removal or cessation of coverage, and (3) the insured's attending health care provider states in writing, after the removal or cessation of coverage, that the drug is medically necessary and lists the reasons why the drug is more medically beneficial than the drugs on the list of covered drugs. Such benefits shall be subject to the same terms and conditions applicable to all other benefits under such policies.

§ 38a-492f mandates the same coverage in individual health insurance policies delivered, issued for delivery, renewed or continued in Connecticut.

In May 2010, CPHHP and Ingenix Consulting (IC) requested 2007 and 2008 claims data related to the mandated benefit from six 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 available claims or other data, a review of the legislative history, reviews of pertinent literature and the Ingenix Consulting report, this review found the following:

Current coverage

This mandate has been in effect since January 1, 2000 (P.A. 99-284, S. 38, 60.).

Premium impact

Group plans: There is no claims data on which to base an estimate of the cost of the mandate.

Individual policies: There is no claims data on which to base an estimate of the cost of the mandate.

Self-funded plans

Five health insurers/MCOs domiciled in Connecticut provided information about their self-funded plans, which represents an estimated 47 percent of the total population in self-funded plans in Connecticut. These five insurers/MCOs report that 20 percent of enrollees in their self-funded plans have coverage for the mandated services.

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

II. Background

Advances in medications in the past several decades have contributed greatly to the prevention, management and cure of many debilitating diseases. Frequently, medications reduce mortality, limit health complications, allow patients to remain productive, and avert more costly health care services such as hospitalization and surgery.¹²⁹ However, pharmaceutical costs are one of the fastest growing medical expenses increasing nearly six times from 1990 to present.¹³⁰ The increase in prescription drug expenditures is due in part to greater pharmaceutical research budgets, increased spending on advertising, the aging population, the rise of chronic diseases, the introduction of “lifestyle medications” (e.g. medications for baldness, acne, wrinkles, etc.), and increased use of newer, higher priced brand name drugs.¹³¹

U.S. residents spent approximately \$234 billion on prescription drugs in 2008, which represents 10 percent of national health expenditures.¹³² Prescription drug utilization increased 39 percent from 1999 to 2009 resulting in 3,679,671,222 prescriptions being filled at retail pharmacies in the U.S and 46,489,823 prescriptions being filled at retail pharmacies in Connecticut.¹³³ Per capita, Connecticut residents filled 13.2 prescriptions at retail pharmacies in 2009 with women and senior citizens accessing medications at higher rates than men and younger residents.

Based on 2007 claims data 69 percent (829,041) of the 1,197,282 individuals covered in group medical plans also had prescription drug coverage. Similarly, 2008 claims data show that 70 percent (804,438) of the 1,155,892 individuals covered in group medical plans also had prescription coverage.¹³⁴

In 2003, nearly all (90 percent) of private sector health plans used some sort of drug formulary. Figure IV.5.1 displays the percent of each type of formulary used by employers.^{135,136}

Increased coverage and rising expenditures for prescription drugs have led to greater use of cost containment

¹²⁹ Goldman DP, Joyce GF, Zheng Y. 2007. Prescription drug cost sharing: Associations with medication and medical utilization and spending and health. *Journal of the American Medical Association* 298(1): 61-69.

¹³⁰ Valluri S, Seoane-Vazquez E, Rodriguez-Monguio R, et al. 2007. Drug utilization and cost in a Medicaid population: a simulation study of community vs. mail order pharmacy. *BMC Health Services Research* 7: 122-131.

¹³¹ Kaiser Family Foundation. Prescription Drug Costs. Available at: <http://www.kaiseredu.org/Issue-Modules/Prescription-Drug-Costs/Background-Brief.aspx>. Accessed January 2, 2011.

¹³² Kaiser Family Foundation. 2010. Prescription Drug Trends. Available at: <http://www.kff.org/rxdrugs/upload/3057-08.pdf>. Accessed January 2, 2011.

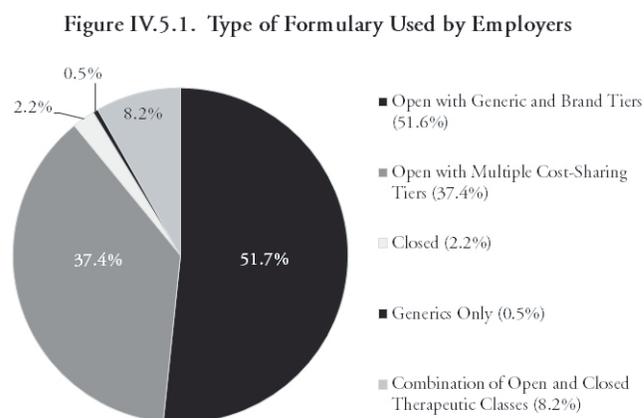
¹³³ Kaiser Family Foundation. State Health Facts. Available at: <http://www.statehealthfacts.org/profileind.jsp?ind=265&cat=5&rgn=8>. Accessed January 2, 2011.

¹³⁴ Ingenix Consulting Actuarial and Economic Report. Appendix II: p. 14.

¹³⁵ Hoadley J. 2004. The Effect of Formularies and Other Cost Management Tools on Access to Medications. Health Policy Institute, Georgetown University. Available at: <http://www.kff.org/medicare/upload/The-Effect-of-Formularies-and-Other-Cost-Management-Tools-on-Access-to-Medications-An-Analysis-of-the-MMA-and-Proposed-Regulations.pdf>. Accessed January 10, 2011.

¹³⁶ The Prescription Drug Benefit Cost and Plan Design Survey Report, 2008-2009 edition. Pharmacy Benefit Management Institute, Inc., 2003. Available at: http://www.pbmi.com/2008_report/pdfs/Revised_Report_20112009.pdf. Accessed January 10, 2011.

measures. Health plans and prescription benefit management companies (PBMs) use prescription drug formularies to manage the appropriate use of Food and Drug Administration (FDA) approved drugs. A drug formulary is defined as “a continually updated list of medications and related information, representing the clinical judgment of physicians, pharmacists and other experts in the diagnosis and/or treatment of disease and promotion of health.”¹³⁷ Additionally, a drug formulary system is “an ongoing process whereby a health care organization through its physicians, pharmacists, and other health care professionals, establishes policies on the use of drug products and therapies, and identifies drug products and therapies that are the most medically appropriate and cost-effective to best serve the health interests of a given patient population.”¹³⁸



Drug formularies can be structured as either “Open Formularies” or “Closed Formularies.” An open formulary is nonrestrictive and generally grants access to all or most FDA approved drugs. A closed formulary tends to limit the number of medications that the plan will reimburse. Formularies typically group covered drugs into tiers based on the amount of co-payment. Co-payments vary by health plan and are designed as incentives for patients to consider costs of the drugs they are prescribed. Tier 1 drugs are typically generic with low co-payments. Tier 2 includes preferred brand name drugs that generally do not have a generic substitute and have a higher co-payment. Tier 3 consists of non-preferred brand name drugs which may have a generic substitute. The drugs in this tier have a high co-payment. Some formularies have a fourth tier that offers “lifestyle” drugs (e.g. medications for baldness, acne, wrinkles, etc.) or expensive biologics (drugs produced from biological materials rather than chemical compounds).

Perspectives vary on the impact of drug formularies on treatment costs and health outcomes. On the one hand, well-designed prescription drug formularies have been shown to reduce drug expenditures and overall medical cost and increase access to health care.¹³⁹ For example, cost savings associated with the Department of Defense’s three tier Uniform Formulary are estimated to be \$986 million in cost avoidance and rebates representing an approximate 13 percent reduction.¹⁴⁰ Moderate cost sharing increases in a three-tier formulary adoption was found to have little effect on medication continuation among the elderly.¹⁴¹ In addition, a study examining prescription patterns of patients initiating chronic therapy in three-tier pharmacy benefit plans found greater adherence and reduced substitution with generic drugs than preferred and non-preferred drugs.¹⁴² These findings suggest that cost savings are greater when generic drugs are prescribed due to lower drug costs, lower co-payments, improved health associated with greater adherence, and reduced physician workload with fewer drug substitution requests.

¹³⁷ Coalition Working Group. 2000. Principles of a Sound Drug Formulary System. Available at: <http://www.pbm.va.gov/LinksAndOtherResources/FormularyPrinciplesCoalition.pdf>. Accessed January 2, 2011.

¹³⁸ *Ibid.*

¹³⁹ Killilea T, Funk L. 2006. Cost efficiency and formulary considerations for statin therapy. *The American Journal of Managed Care* 12(11): 325-332.

¹⁴⁰ Trice S, Devine J, Mistry H, et al. 2009. Formulary management in the Department of Defense. *Journal of Managed Care Pharmacy* 15(2): 133-146.

¹⁴¹ Huskamp HA, Deberka PA, Landrum MB, et al. 2007. The effect of three-tier formulary adoption on medication continuation and spending among elderly retirees. *Health Research and Educational Trust* 42 (5): 1926-1942.

¹⁴² Shrank WH, Hoang T, Ertner SL, et al. 2006. The implications of choice: Prescribing generic or preferred pharmaceuticals improved medication adherence for chronic conditions. *Journal of the American Medical Association* 166: 332-337.

Health care providers and consumers have raised concerns that restrictions placed on prescribing may contribute to reduced quality medical care.¹⁴³ For example, a study of antihypertensive medications found that patients taking restricted drugs filled fewer prescriptions and were more likely to be non-adherent than unrestricted patients.¹⁴⁴ Similar results were found in studies examining the effects of switching to a three-tier formulary on patients prescribed antidepressants, ACE inhibitors, statins, and proton-pump inhibitors.¹⁴⁵¹⁴⁶ These findings suggest an association between formulary restrictions and unintended health consequences such as a greater number of office visits, and the increased likelihood of hospitalization.¹⁴⁷ Most health plans allow exceptions to formulary drug restrictions to facilitate effective patient care.

III. Methods

CPHHP staff conducted literature searches using the Cochrane Review, Pubmed, Google, PsycInfo, and Google Scholar using the following search terms: prescription drug formularies/systems/decisions, pharmacy and therapeutic committee, pharmacy benefit management, health care cost management, generic drugs/efficacy/safety, brand-name drugs/efficacy/safety, drug utilization, patient safety. 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 faculty from the University of Connecticut, School of Pharmacy 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 requested 2007 and 2008 claims data from insurance companies and MCOs domiciled in Connecticut. No claims data was provided due to the nature of the mandate. However, five insurers/MCOs provided information on the self-funded plans they administer.

CPHHP and the CID contracted with Ingenix Consulting to provide actuarial and economic analyses of the mandated benefit. Further details regarding the actuarial methods used to estimate the cost of the benefit and economic methods used to estimate financial burden may be found in Appendix II.

¹⁴³ Simon GE, Psaty BM, Hrachovec JB, *et al.* 2005. Principles for evidence-based drug formulary policy. *Journal of General Internal Medicine* 20: 964-968.

¹⁴⁴ Goldman DP, Joyce GF, Zheng Y. 2007. Prescription drug cost sharing: Associations with medication and medical utilization and spending and health. *Journal of the American Medical Association* 298(1): 61-69.

¹⁴⁵ Hodgkin D, Parks TC, Simoni-Wastila L, *et al.* 2008. The effect of a three-tier formulary on antidepressant utilization and expenditures. *Journal of Mental Health Policy Economics* 11(2): 67-77.

¹⁴⁶ Huskamp HA, Deverka PA, Epstein AM, *et al.* 2003. The effect of incentive based formularies on prescription drug utilization and spending. *New England Journal of Medicine* 349: 2224-2232.

¹⁴⁷ Goldman DP, Joyce GF, Zheng Y. 2007. Prescription drug cost sharing: Associations with medication and medical utilization and spending and health. *Journal of the American Medical Association* 298(1): 61-69.

IV. Social Impact

1. *The extent to which the service is utilized by a significant portion of the population.*

Pharmaceutical costs are one of the fastest growing medical expenses increasing nearly six times from 1990 to present.¹⁴⁸ The increase in prescription drug expenditures is due in part to greater pharmaceutical research budgets, increased spending on advertising, the aging population, the rise of chronic diseases, the introduction of “lifestyle medications,” (e.g. medications for baldness, acne, wrinkles, etc.) and increased use of newer, higher priced brand name drugs.¹⁴⁹ U.S. residents spent approximately \$234 billion on prescription drugs in 2008, which represents 10 percent of national health expenditures.¹⁵⁰ Prescription drug utilization increased 39 percent from 1999 to 2009 resulting in 3,679,671,222 prescriptions being filled at retail pharmacies in the United States, and 46,489,823 prescriptions being filled at retail pharmacies in Connecticut.¹⁵¹ Per capita, Connecticut residents filled 13.2 prescriptions at retail pharmacies in 2009 with women and senior citizens accessing medications at higher rates than men and younger residents (Table IV.5.1.)

	Connecticut	U.S.
Total Number of Retail Prescription Drugs Filled at Pharmacies	46,489,823	3,679,671,222
Retail Prescription Drugs Filled at Pharmacies (Annual per Capita)	13.2	12.0
Retail Prescription Drugs Filled at Pharmacies (Annual per Capita by Gender)		
Male	10.7	9.4
Female	15.3	14.4
Retail Prescription Drugs Fill at Pharmacies (Annual Per Capita by Age)		
0-18 years	4.2	3.9
19-64 years	12.4	11.3
65+ year	31.7	31.2

Based on 2007 claims data 69 percent (829,041) of the 1,197,282 individuals covered in group medical plans also had prescription drug coverage. Similarly, 2008 claims data show that 70 percent (804,438) of the 1,155,892 individuals covered in group medical plans also had prescription coverage. In 2003, nearly all (90 percent) of private sector health plans used some sort of drug formulary.¹⁵²

2. *The extent to which the service 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*

¹⁴⁸ Valluri S, Seoane-Vazquez E, Rodriguez-Monguio R, et al. 2007. Drug utilization and cost in a Medicaid population: a simulation study of community vs. mail order pharmacy. *BMC Health Services Research* 7: 122-131.

¹⁴⁹ Kaiser Family Foundation. Prescription Drug Costs. Available at: <http://www.kaiseredu.org/Issue-Modules/Prescription-Drug-Costs/Background-Brief.aspx>. Accessed January 2, 2011.

¹⁵⁰ Kaiser Family Foundation. 2010. Prescription Drug Trends. Available at: <http://www.kff.org/rxdrugs/upload/3057-08.pdf>. Accessed January 2, 2011.

¹⁵¹ Kaiser Family Foundation. State Health Facts. Available at: <http://www.statehealthfacts.org/profileind.jsp?ind=265&cat=5&rgn=8>. Accessed January 2, 2011.

¹⁵² Hoadley J. 2004. The Effect of Formularies and Other Cost Management Tools on Access to Medications. Health Policy Institute, Georgetown University. Available at: <http://www.kff.org/medicare/upload/The-Effect-of-Formularies-and-Other-Cost-Management-Tools-on-Access-to-Medications-An-Analysis-of-the-MMA-and-Proposed-Regulations.pdf>. Accessed January 10, 2011.

Department of Social Services.

Medicare

Centers for Medicare and Medicaid Services (CMS) sets guidelines for when and how sponsors may make changes to their formularies. Positive changes “require no CMS approval and enhance the formulary by adding new drugs, reducing cost sharing, or removing utilization controls.”¹⁵³ On the other hand, negative changes “restrict the formulary by removing drugs, increasing cost sharing, or adding utilization controls.”¹⁵⁴ Negative changes require CMS approval.

When certain prescription drugs are removed from the formulary, Medicare requires drug plans to inform a beneficiary at least 60 days before a drug that he or she uses is removed from a formulary or if a drug’s cost is changing.¹⁵⁵ A written notification of a formulary change must include:

1. the name of the drug,
2. the type of change made to the formulary,
3. the reason for the change,
4. alternative drugs in the same class,
5. expected cost sharing for alternative drugs, and
6. information on obtaining a coverage determination or an exception for coverage of the affected drug.¹⁵⁶

If a beneficiary’s doctor thinks he or she needs a drug that has been removed from the formulary, the beneficiary, or his doctor, can apply for an exception or appeal the decision.¹⁵⁷

Public Programs Administered by Charities

No information was found that would indicate public programs administered by charities provide services for coverage of certain prescription drugs removed from the insurers’ formulary. However, most major pharmaceutical manufacturers offer limited drug assistance programs that may provide free medications through physician offices and community health centers. Pharmaceutical manufacturers’ websites advertise programs for the unemployed, uninsured, and underinsured who qualify, as well as for insured individuals during appeals processes if their plans deny coverage for the medications they need. There are significant barriers to accessing free medications. For example, guidelines for qualifications can be onerous and time-consuming; individuals need a “medical home” and an established relationship with a provider; paperwork may be burdensome; and patients may need to activate a coupon prior to going to the pharmacy and coupons may be only valid for a one month supply. Examples of pharmaceutical manufacturers with drug assistance programs include Pfizer, Bristol-Myers Squibb, Eli Lilly and Company, Wyeth-Ayerst Laboratories, SmithKline Pharmaceuticals, Inc., Ortho-McNeil Pharmaceutical, Abbott Laboratories, Roche Laboratories, Inc., Novartis Pharmaceuticals, and Glaxo Wellcome Inc.^{158, 159}

¹⁵³ Levinson DR. 2009. Depart of Health and Human Services, Office of the Inspector General. Midyear Formulary Changes in Medicare Prescription Drug Plans. Available at: <http://oig.hhs.gov/oei/reports/oei-01-08-00540.pdf>. Accessed January 2, 2011.

¹⁵⁴ *Ibid.*

¹⁵⁵ US Railroad Retirement Board. 2005. Medicare Prescription Drug Plans. Available at: http://www.rrb.gov/opa/qa/pub_0511.asp. Accessed January 2, 2011.

¹⁵⁶ Levinson DR. 2009. Depart of Health and Human Services, Office of the Inspector General. Midyear Formulary Changes in Medicare Prescription Drug Plans. Available at: <http://oig.hhs.gov/oei/reports/oei-01-08-00540.pdf>. Accessed January 2, 2011.

¹⁵⁷ *Ibid.* The form to apply for a formulary exception is available at: <https://www.cms.gov/MedPrescriptDrugApplGriev/Downloads/ModelCoverageDeterminationRequestForm.pdf>. Accessed January 2, 2011.

¹⁵⁸ Pfizer. 2010. Helpful Answers Program website. Available at: <http://www.pfizerhelpfulanswers.com/pages/Programs/medicines.aspx?p=2>. Accessed November 16, 2010.

¹⁵⁹ Pheil P. 2010. Patient Assistance Programs Listed by Psychotropic Medication. Mental Health Today (online newsletter). Available at:

Public Programs Administered by Public Schools

No information was found that would indicate public schools provide services for coverage of certain prescription drugs removed from the insurers' formulary.

The Department of Public Health (DPH)

The study found no information on the provision of drugs removed from formulary through the Connecticut Department of Public Health. Searches on the DPH website yielded in no information on formularies. Although six Community Health Centers in the Connecticut region subscribe to the 340B Pricing Plan for prescription drugs, these drugs are only limited to outpatient prescriptions, and there is no mention of coverage for certain prescription drugs removed from formularies.

Municipal Health Departments

No information was found that would indicate municipal health departments provide services for certain prescription drugs removed from the insurers' formulary.

The Department of Social Services (DSS)

Medicaid uses a Preferred Drug List (PDL) similar to Medicare's formulary. The PDL "is a listing of prescription products selected by the Pharmaceutical and Therapeutics Committee as efficacious, safe and cost effective choices when prescribing for Medicaid patients."¹⁶⁰ Most but not all drugs that need a prescription are covered. Over-the-counter drugs are also covered for clients under 21 years of age with a doctor prescription for it. Doctors must prescribe either generic drugs or drugs on the Preferred Drug List when they are available.¹⁶¹

When a doctor thinks that a certain brand name drug is necessary rather than the generic brand, the doctor can ask for prior authorization.¹⁶² In emergency situations, the pharmacist may telephone the Department to obtain verbal authorization, and a written request for authorization must be submitted within 15 working days following verbal authorization.¹⁶³

Federally-Qualified Community Health Centers

Federal statutes and regulations require that federally-qualified community health centers (FQHC) provide a comprehensive array of services either directly, or through contracts or cooperative agreements.¹⁶⁴ Most FQHCs in Connecticut participate in the Federal 340B Drug Program. Section 340B requires manufacturers to sell any drug provided in an outpatient setting to eligible entities at or below the 340B statutory ceiling price, including prescription drugs and over-the-counter drugs, if a prescriber writes a prescription for the drug.

A sliding fee scale program is offered for patients who do not have insurance or whose income is insufficient to pay for care. Even if patients do not qualify for a sliding fee discount, most FQHCs will offer patients the option to establish payment arrangements over a reasonable period of time.¹⁶⁵ Patients typically will not

<http://www.mental-health-today.com/medsassist.htm>. Accessed November 16, 2010.

¹⁶⁰ Connecticut Department of Social Services. Connecticut Medicaid Preferred Drug List. Available at: https://www.ctdssmap.com/CTPortal/Portals/0/StaticContent/Publications/CT_PDL_medicaid.pdf. Accessed November 16, 2010.

¹⁶¹ Connecticut Department of Social Services. DSS Provider Manual, Pharmacy. Available at: https://www.ctdssmap.com/CTPortal/Information/Get%20Download%20File/tabid/44/Default.aspx?Filename=ch7_iC_pharm_V1.0.pdf&URI=Manuals/ch7_iC_pharm_V1.0.pdf. Accessed November 16, 2010.

¹⁶² *Ibid.*

¹⁶³ *Ibid.*

¹⁶⁴ Connecticut Department of Public Health. 2009. Community Health Centers Programs and Services. Available at: <http://www.ct.gov/dph/cwp/view.asp?a=3138&q=405340#healthservices>. Accessed December 23, 2010.

¹⁶⁵ Connecticut Department of Public Health. 2009. Community Health Centers Programs and Services. Available at:

be turned away due to an inability to pay. FQHCs also take other measures for patients who cannot afford care. For example, one FQHC in Connecticut, Cornell Scott Hill Health Center, created a Pharmacy Fund to help patients who, despite a sliding fee discount, still cannot afford medications.¹⁶⁶ Cornell Scott Hill Health Center seeks donations from individuals, corporations and foundations to support the Pharmacy Fund.¹⁶⁷

3. *The extent to which insurance coverage is already available for the service.*

Connecticut law requires coverage for certain prescription drugs removed from insurers' formulary in fully insured group and individual health insurance plans that provide coverage for outpatient prescription drugs as of January 1, 2000 (P.A. 99-284, S. 38, 60.). Five health insurers/MCOs domiciled in Connecticut provided information about their self-funded plans, which represents an estimated 47 percent of the total population in self-funded plans in Connecticut. These five insurers/MCOs report that 20 percent of enrollees in their self-funded plans have coverage for the mandated services.

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 is required and generally available for persons enrolled in fully insured group and individual health insurance plans that include coverage for outpatient prescription drugs. Twenty percent of members in self-funded plans have coverage for the benefit. Persons enrolled in fully insured and self-funded group plans represent the vast majority of covered lives. Levels of patient cost-sharing vary greatly depending on the prescription drug benefit plan and the cost of the drug prescribed. Medicare and Medicaid generally cover prescription medications.

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, Connecticut law requires coverage for certain prescription drugs removed from formulary in fully insured group and individual plans that include coverage for outpatient prescription drugs. Depending on the level of cost-sharing and personal financial resources available, that coverage may or may not be sufficient for the insured's family to avoid unreasonable financial hardship.

Further discussion of financial and socioeconomic effects of the mandated benefit may be found in Appendix II: Ingenix Consulting Actuarial and Economic Report, pages 44-45.

6 and 7. *The level of public demand and the level of demand from providers for the service and level of public demand and the level of demand from providers for insurance coverage for the service.*

With rising expenditures for prescription drugs, restricting medications using formularies was introduced as a cost containment measure to benefit the consumer and insurance companies. Health care providers and consumers have raised concerns that restrictions placed on prescribing may contribute to a reduction in the quality of medical care.¹⁶⁸ Restricting certain medications may pressure patients to use less expensive medications that may also be less effective.

8. *The likelihood of achieving the objectives of meeting a consumer need as evidenced by the*

<http://www.ct.gov/dph/cwp/view.asp?a=3138&q=405340#healthservices>. Accessed December 23, 2010.

¹⁶⁶ Cornell Hill Health Center. Pharmacy Services. Available at: <http://www.hillhealthcenter.com/services/medical/pharmacy.shtml>. Accessed December 23, 2010.

¹⁶⁷ *Ibid.*

¹⁶⁸ Simon GE, Psaty BM, Hrachovec JB, et al. 2005. Principles for evidence-based drug formulary policy. *Journal of General Internal Medicine* 20: 964-968.

experience of other states.

According to the National Association of Insurance Commissioners, no states have a mandated insurance benefit similar to Connecticut's that require policies in fully insured plans that provide coverage for outpatient prescription drugs that have been removed from the formulary.¹⁶⁹

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

Thirty states now require a fiscal note or an additional review process for any new required health insurance benefit prior to enactment.¹⁷⁰ Internet searches and telephone inquiries found one study from state agencies and public organizations related to the social impact of mandated insurance coverage for certain prescription drugs removed from formulary.

Massachusetts: In May 2009, the Division of Health Care Finance and Policy reviewed SB 433, an Act Regarding Continuity of Prescription Drug Coverage. The mandate was intended to address issues of continuity of prescription drug coverage when a member changes from one health insurance carrier to another. The report found that the mandate would provide greater continuity of medication coverage for patients and avoid repeating similar prior authorizations steps that were already completed. This would help save patients and physicians the time of going through repetitive prior authorization procedures.¹⁷¹

States searched for which no evidence of a review was found include California, Colorado, Maryland, Maine, 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.*

To facilitate effective patient care, most health plans allow exceptions to formulary drug restrictions. For example, prior authorization is a process whereby an off-formulary medication may be purchased at a formulary rate (typically at the highest tier co-payment) if the prescribing physician obtains advanced approval by the insurance company prior to dispensing. "Step Therapy" is the practice of requiring a physician and patient to try a lower cost medication; if it is found to be inappropriate, then more costly medications are tried. "Dispensing Limits" requires prior approval if the prescribed quantity of the drug exceeds the predefined limit within a given time period.

Other alternatives to obtaining prescription drugs that have been removed from an insurers' formulary include over-the-counter medicine, home remedies, complementary and alternative medicine (CAM), obtaining medications via foreign markets, paying for medications out-of-pocket, and forgoing treatment altogether.

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 mandate requires insurance carriers to continue covering a prescribed drug after that medication has been removed from its formulary so long as specific conditions are met. A prescription drug formulary, by

¹⁶⁹ NAIC Compendium of State Laws on Insurance Topics. National Association of Insurance Commissioners. August 2008.

¹⁷⁰ 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.

¹⁷¹ Massachusetts Division of Health Care Finance and Policy. 2009. Paper Related to Proposed Legislation Entitled: An Act Regarding Continuity of Prescription Drug Coverage Senate Bill 433. Available at: http://www.mass.gov/Eeohhs2/docs/dhcfp/r/pubs/09/prescription_drug_continuity_mb_report.pdf. Accessed December 14, 2010.

nature, is consistent with the role of health insurance and the concept of managed care. Insurance carriers evaluate their formulary by therapeutic class to make sure they have adequate coverage for each class. Periodically, an insurer may drop or replace certain drugs. Changes to a drug formulary can be made due to drug safety, medical efficacy, or financial reasons.¹⁷²

The mandate allows continued coverage for a drug removed from formulary if the member was using the drug prior to cessation of coverage, and if the member was covered under that policy. Additionally, the member's physician must provide a statement of medical necessity to the carrier as to why the drug is beneficial for the patient compared to others covered under the policy.

There are many therapeutic classes of drugs for which the patient's response to therapy may be drug specific. Not all drugs in a class will perform equally well for an individual patient. This type of patient specific response to therapy may occur with psychiatric medications (antidepressants, antipsychotic drugs), neurologic treatments (anti-seizure medications), and other classes.¹⁷³

A clear medical and broader social need is met by the mandate if a change in a prescription causes a patient to clinically deteriorate. A study of three patients taking brand-name psychotropic pharmaceuticals who switched to a generic equivalent clinically deteriorated after starting treatment with the generic drug. The three individual cases led the researchers to conclude that "bioequivalence parameters selected by regulatory agencies do not always translate to therapeutic equivalence in patients."¹⁷⁴ A study of seven patients diagnosed with schizophrenia was also noted to have clinically deteriorated after switching from a brand-name drug to a generic equivalent.¹⁷⁵ For some therapies there may be important clinical differences between brand-name drugs and their generic equivalent.

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

The mandate is narrow in scope. It is therefore difficult to anticipate any comparable benefit for other situations.

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-mandated benefits currently offered. However, the availability of any benefits 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. Due to the difficulty of isolating claims data related to this benefit, the impact of this specific mandate on the availability of other benefits is difficult to estimate.

For further information, see Appendix II: Ingenix Consulting Actuarial and Economic Report, page 22.

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

Individuals enrolled in self-funded plans are expected to demand access to prescription drugs removed from formulary in the same manner as individuals covered in fully insured plans. Therefore, it is not anticipated

¹⁷² IC Report – Set 4.

¹⁷³ *Ibid.*

¹⁷⁴ Margolese HC, Wolf Y, Desmarais JE, *et al.* 2010. Loss of response after switching from brand name to generic formulations: three cases and a discussion of key clinical considerations when switching. *International Clinical Psychopharmacology* 25(3):180-2.

¹⁷⁵ Mofsen R, Balter J. 2001. Case reports of the reemergence of psychotic symptoms after conversion from brand-name clozapine to a generic formulation. *Clinical Therapeutics* 23(10):1720-31.

that employers will shift to self-funded plans as a result of this single mandate. It is also not anticipated that repeal of this single mandate would lead to a shift from self-funded plans to fully insured plans among employers. Employers cognizant of the cumulative financial effects of mandated benefits and large enough to assume the risk of employee health care costs are the more likely to consider shifting to self-funded 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 considering a shift to self-funded plans are likely to weigh these and other factors prior to reaching a decision. Employers also may shift to plans with higher coinsurance amounts to keep premiums at a more affordable level (“benefit buy down”). This can result in employees not taking up coverage and thus being uninsured or not accessing care when it is needed because of high deductibles.

Five health insurers/MCOs domiciled in Connecticut provided information about their self-funded plans, which represents an estimated 47 percent of the total population in self-funded plans in Connecticut. These five insurers/MCOs report that 65 percent of enrollees in their self-funded plans have coverage for the mandated services.

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

This mandate is a current benefit that has been included in the state employee health insurance and health benefits plans since January 1, 2000. Thus 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 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.¹⁷⁶

Because the state shifted to self-funded status on July 1, 2010 (during the time this report was being written), utilization under self-funded status is unknown. All self-funded plans, including those that provide coverage for state employees, are not regulated by the state insurance department and are exempt from state health insurance required benefit statutes. However, enrollees in self-funded plans, including state employees, are expected to demand access to prescription drugs through their local community pharmacies in the same manner as persons covered in fully insured plans.

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

When properly designed and implemented, drug formularies promote rational, clinically appropriate, safe and cost-effective drug therapy.¹⁷⁷ For example, a study examining prescription patterns of patients initiating chronic therapy in three-tier pharmacy benefit plans found greater adherence and reduced substitution with generic drugs than preferred and non-preferred drugs.¹⁷⁸ These findings suggest that lower co-payments for generic drug prescriptions increase access to medications for a greater number of patients and improve medication adherence, which result in effective treatments and improved health outcomes.

However, health care providers and consumers have raised concerns that restrictions placed on prescribing

¹⁷⁶ Personal communication. Scott Anderson, State of Connecticut Comptroller’s Office. September 14, 2010.

¹⁷⁷ Killilea T, Funk L. 2006. Cost efficiency and formulary considerations for statin therapy. *The American Journal of Managed Care* 12(11): 325-332.

¹⁷⁸ Shrank WH, Hoang T, Ettner SL, et al. 2006. The implications of choice: Prescribing generic or preferred pharmaceuticals improved medication adherence for chronic conditions. *Journal of the American Medical Association* 166: 332-337.

may contribute to the reduction of quality medical care.¹⁷⁹ Restricting certain medications may pressure patients to use less expensive medications that may be less effective. For example, a study of antihypertensive medications found that patients taking restricted drugs filled fewer prescriptions and were more likely to be non-adherent than unrestricted patients.¹⁸⁰ Formulary restrictions have been linked to unintended health consequences such as a greater number of office visits, and the increased likelihood of hospitalization.¹⁸¹ To facilitate effective patient care, most health plans allow exceptions to formulary drug restrictions.

Many generic drugs have been found to be bioequivalent (i.e., equal in chemical composition) and less expensive than their brand name counterpart. However, drugs can be considered bioequivalent and still have differences. The FDA requires that generic drugs have at least 80 percent and not more than 125 percent of the active ingredient of the brand-name formulation.¹⁸² In addition, excipients, ingredients used in pharmaceutical preparations, can be categorized as either exceptional or non-exceptional. Exceptional excipients (e.g. preservatives pH adjusters, antioxidants, thickening agents, buffers, and substances to adjust tonicity) are allowed to vary between a generic drug and its brand-name counterpart.¹⁸³ The variation in excipients used and level of active ingredients may explain why equal effects on average may not ensure consistent results for individual patients.¹⁸⁴

Some classes of drugs are more interchangeable than others.¹⁸⁵ For example, estrogen and statins, are relatively homogeneous and prescription substitutions may reduce costs without disrupting health benefits. In contrast, antidepressant and antipsychotic drugs are significantly heterogeneous and switching medications may disrupt stable and effective treatment. Further, in certain high-risk conditions such as stroke, epilepsy, or immunosuppressive therapy in transplant, a small variation in efficacy or safety between medications may have fatal consequences.¹⁸⁶ Changing these types of drugs could require a great deal of clinical reevaluation and could cause substantial distress and potential harm to some patients. In addition, supplementary costs may be incurred when substituting medications due to added office visits, laboratory work, and medication waste.¹⁸⁷ Therefore, requiring patients to switch to an alternative medication based solely on formulary requirements may not be medically sound.

Recognizing the complexity of balancing health care quality and medical expenditures, the AMA, Department of Veterans Affairs, Academy of Managed Care Pharmacy, the National Business Coalition on Health, and other national health care organizations published Principles of a Sound Drug Formulary System in 2000.¹⁸⁸ The document was designed as a guide when developing a formulary system to provide appropriate therapeutic alternatives for improving or maintaining health and promoting cost-effective measures. The premise of this document is that the cost of a medication should be considered only after

¹⁷⁹ Simon GE, Psaty BM, Hrachovec JB, *et al.* 2005. Principles for evidence-based drug formulary policy. *Journal of General Internal Medicine* 20: 964-968.

¹⁸⁰ Goldman DP, Joyce GF, Zheng Y. 2007. Prescription drug cost sharing: Associations with medication and medical utilization and spending and health. *Journal of the American Medical Association* 298(1): 61-69.

¹⁸¹ *Ibid.*

¹⁸² Center for Drug Evaluation and Research. 2003. Guidance for Industry: Bioavailability and Bioequivalence Studies for Orally Administered Drug Products — General Considerations. United States Food and Drug Administration.

¹⁸³ Borgherini G. 2003. The bioequivalence and therapeutic efficacy of generic versus brand-name psychoactive drugs. *Clinical Therapeutics* 25(6): 1578-1592.

¹⁸⁴ Simon GE, Psaty BM, Hrachovec JB, *et al.* 2005. Principles for evidence-based drug formulary policy. *Journal of General Internal Medicine* 20: 964-968.

¹⁸⁵ *Ibid.*

¹⁸⁶ Borgherini G. 2003.

¹⁸⁷ Simon GE, Psaty BM, Hrachovec JB, *et al.* 2005.

¹⁸⁸ Coalition Working Group. 2000. Principles of a Sound Drug Formulary System. Available at: <http://www.pbm.va.gov/LinksAndOtherResources/FormularyPrinciplesCoalition.pdf>. Accessed January 2, 2011.

safety, efficacy, and therapeutic need and that treatments should be evaluated in terms of impact on total health care costs.

In addition, the Academy of Managed Care Pharmacy (AMCP) developed the Format for Formulary Submissions as a set of guidelines that can be used by manufactures of pharmaceuticals, biologics and vaccines to support reimbursement and formulary placement consideration of a new drug or new formulation of an existing drug.¹⁸⁹ The Format helps manufacturers standardize relevant drug safety data that pharmacy and therapeutics committees (P & T) can use in their decision making.

Pharmacy and therapeutics committees (P & T) are another safeguard to ensure the safety and effectiveness of formularies. Institutions such as hospitals and health insurance companies that prescribe, dispense or finance pharmaceuticals have a P & T. P & Ts are an administrative body that oversee the formulary system of an organization and typically consist of primary care and specialty physicians, pharmacists and other health care professionals. They were developed to address creating and maintaining a drug formulary, establishing and implementing policies on the use of drugs, ensuring the delivery of safe and effective drug therapy, and curbing the rising costs associated with pharmaceutical therapies.¹⁹⁰ P & Ts meet regularly to keep a formulary current; constantly assessing peer reviewed pharmacotherapy literature and other sources to evaluate the safety, effectiveness and cost of new and existing drugs.

IV. Financial Impact

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

The mandate is not expected to materially alter the availability or cost of prescription drugs over the next five years. Prescription drugs can be a high-volume, high-cost service and the presence of the insurance mandate is not expected to have any additional effect on its cost. The cost of the service is likely to increase (or decrease) at the same rate as any other medical service

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

There are differing perspectives regarding the impact that continuing to cover medications that have been removed from a formulary may have on the appropriate or inappropriate use of medications. Some studies suggest that a well-designed prescription drug formulary may increase access and medication adherence while reducing drug expenditures and overall medical cost.¹⁹¹ However, other studies have found an association between formulary restrictions and reduced medication adherence, greater number of office visits, and the increased likelihood of hospitalization.¹⁹² In addition, generic and brand-name drugs may not be consistently interchangeable. Although they may be considered pharmaceutically equivalent on average slight variations in formulation may result in significantly different effects on individuals.

3. The extent to which the mandated health benefit may serve as an alternative for more expensive or less expensive treatment, service or drug(s).

¹⁸⁹ Academy of Managed Care Pharmacy. 2009. The AMCP format for formulary submissions –version 3.0.

¹⁹⁰ Suh DC, Okpara IRN, Agnese WB, et al. 2002. Application of Pharmacoeconomics to formulary decision making in managed care organizations. *The American Journal of Managed Care* 8(2): 161-169.

¹⁹¹ Killilea T, Funk L. 2006. Cost efficiency and formulary considerations for statin therapy. *The American Journal of Managed Care* 12(11): 325-332.

¹⁹² Goldman DP, Joyce GF, Zheng Y. 2007. Prescription drug cost sharing: Associations with medication and medical utilization and spending and health. *Journal of the American Medical Association* 298(1): 61-69.

Most health plans allow exceptions to formulary drug restrictions through processes such as prior authorization, “Step Therapy,” and “Dispensing Limits.” In addition, there are many alternative approaches to traditional drug therapy such as acupuncture, yoga, biofeedback, and guided imagery. Recent interest in the benefits of natural products to treat a variety of ailments has contributed to the growth of herbal remedies. The National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health has evaluated the use of St. John’s wort, valerian, and Omega-3 fatty acids.¹⁹³ The NIH findings indicate limited support for the efficacy of alternative approaches similar to or greater than traditional approaches.

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 utilize the same utilization management methods and cost controls that are used for other covered benefits. The legislation does not prohibit insurers and MCOs from employing utilization management, prior authorization, pharmacy benefit managers (PBMs), or other utilization tools at their discretion.

5. The extent to which insurance coverage for the service 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).

Due to the difficulty of isolating claims data related to this benefit, an estimate of the increase or decrease in insurance premiums and administrative expenses for policyholders is not available. However, this mandate is not expected to significantly increase or decrease the insurance premiums or administrative expenses. When the cost of continuing to cover a prescribed drug after that medication has been removed from its formulary is spread across the entire insured population the effect on premiums is likely to be extremely small.

For further information, please see the Appendix II: Ingenix Consulting Actuarial and Economic Report.

6. The extent to which the service is more or less expensive than an existing treatment, service or drug(s), 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.

Perspectives vary regarding the relative expense of continuing to cover medications that have been removed from a formulary in comparison to existing treatments, services or drugs. Some studies suggest that a well-designed prescription drug formulary may increase access and medication adherence while reducing drug expenditures and overall medical cost.¹⁹⁴ However, other studies have found an increase in health care costs association with formulary restrictions due to reduced medication adherence, greater number of office visits, and the increased likelihood of hospitalization.¹⁹⁵

Generic formulations of brand name drugs are generally chemically equivalent and less expensive. However,

¹⁹³ National Center for Complementary and Alternative Medicine. Mental Health. Available at <http://nccam.nih.gov/health/mentalhealth.htm>. Accessed November 17, 2010.

¹⁹⁴ Killilea T, Funk L. 2006. Cost efficiency and formulary considerations for statin therapy. *The American Journal of Managed Care* 12(11): 325-332.

¹⁹⁵ Goldman DP, Joyce GF, Zheng Y. 2007. Prescription drug cost sharing: Associations with medication and medical utilization and spending and health. *Journal of the American Medical Association* 298(1): 61-69.

the drugs may not be universally interchangeable since equal effects on average do not ensure consistent outcomes for all patients, or subgroups.¹⁹⁶ In addition, certain classes of drugs such as antidepressant and antipsychotic are more chemically heterogeneous. Changing these types of drugs could require a great deal of clinical intervention, or may cause substantial distress and potential harm to some patients.¹⁹⁷ Further, in certain high-risk conditions such as stroke, epilepsy, or immunosuppressive therapy in transplant, a small variation in efficacy or safety between medications may have fatal consequences.¹⁹⁸ In cases such as these, the higher cost of off-formulary prescription drugs may prohibit patient access to quality health care and may contribute to severe health consequences.¹⁹⁹

7. The impact of insurance coverage for the service 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. Due to the difficulty of isolating claims data related to this benefit no estimate of the total cost of health care associated with this mandated benefit is available.

In terms of potential benefits or savings to insurers and employers resulting from prevention or early detection of disease or illness, continued coverage of prescriptions following their removal from drug formularies limit complications that can arise for certain individuals when a change in prescription is required.

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.

No published literature was found regarding the effect of this mandate on the cost of health care for small employers. Although small employers may be more sensitive to premium increases than other employers, the lack of data from the carriers does not allow for estimated costs of the mandate among different types of employers.

For further information, please see the Appendix II: Ingenix Consulting Actuarial and Economic Report, page 31.

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. Due to the nature of this benefit, it is not expected to have an impact on cost-shifting between private and public payers either in the

¹⁹⁶ Simon GE, Psaty BM, Hrachovec JB, *et al.* 2005. Principles for evidence-based drug formulary policy. *Journal of General Internal Medicine* 20: 964-968.

¹⁹⁷ Borgherini G. 2003. The bioequivalence and therapeutic efficacy of generic versus brand-name psychoactive drugs. *Clinical Therapeutics* 25(6): 1578-1592.

¹⁹⁸ *Ibid.*

¹⁹⁹ Borgherini G. 2003.

past or at present.

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. Due to the difficulty of isolating claims data related to this benefit no estimate of the financial impact of the mandated services on the overall cost of the health delivery system in the state is available.

For further information, please see Appendix II, Ingenix Consulting Actuarial and Economic Report.

Volume IV

Chapter 6

Home Health Care

Review and evaluation of Connecticut General Statutes

Chapter 700, §§ 38a-493 and 38a-520

Mandatory coverage for home health care. Deductibles. Exception from deductible limits for medical savings accounts. Archer MSAs and health savings accounts.

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Chapter 6. Table of Contents

- I. Overview..... 85
- II. Background..... 88
- III. Methods..... 89
- IV. Social Impact..... 90
- Figure IV.6.1. Utilization of Home Health Care Services by Insurance Type
 (US Population <65 years old)..... 93
- V. Financial Impact..... 98

I. Overview

The Chairs of the Insurance and Real Estate Committee of the Connecticut General Assembly directed the Connecticut Insurance Department to review statutorily mandated health benefits existing on or effective on July 1, 2009, pursuant to section (b) of Public Act 09-179, An Act Concerning Reviews of Health Insurance Benefits Mandated in this State. Each review was conducted following the requirements stipulated under Public Act 09-179 as a collaborative effort of Connecticut Insurance Department (CID) and the University of Connecticut's Center for Public Health and Health Policy (CPHHP). The CID and CPHHP contracted with the actuarial firm Ingenix Consulting (IC) to conduct an actuarial and economic analysis for each mandate.

This chapter evaluates the financial and social impact of the requirement for fully insured group and individual health insurance policies to cover home health care as specified under Connecticut General Statutes, Chapter 700, § 38a-493 and § 38a-520. The statute, § 38a-520, reads as follows:

Each group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (6), (11) and (12) of section 38a-469 delivered, issued for delivery or renewed in this state on or after October 1, 1975, shall provide coverage providing reimbursement for home health care to residents in this state.

- (b) For the purposes of this section, “hospital” means an institution which is primarily engaged in providing, by or under the supervision of physicians, to inpatients (1) diagnostic, surgical and therapeutic services for medical diagnosis, treatment and care of injured, disabled or sick persons, or (2) medical rehabilitation services for the rehabilitation of injured, disabled or sick persons, provided “hospital” shall not include a residential care home, nursing home, rest home or alcohol or drug treatment facility, as defined in section 19a-490. For the purposes of this section and section 38a-494, “home health care” means the continued care and treatment of a covered person who is under the care of a physician but only if (A) continued hospitalization would otherwise have been required if home health care was not provided, except in the case of a covered person diagnosed by a physician as terminally ill with a prognosis of six months or less to live, and (B) the plan covering the home health care is established and approved in writing by such physician within seven days following termination of a hospital confinement as a resident inpatient for the same or a related condition for which the covered person was hospitalized, except that in the case of a covered person diagnosed by a physician as terminally ill with a prognosis of six months or less to live, such plan may be so established and approved at any time irrespective of whether such covered person was so confined or, if such covered person was so confined, irrespective of such seven-day period, and (C) such home health care is commenced within seven days following discharge, except in the case of a covered person diagnosed by a physician as terminally ill with a prognosis of six months or less to live.
- (c) Home health care shall be provided by a home health agency. The term “home health agency” means an agency or organization which meets each of the following requirements: (1) It is primarily engaged in and is federally certified as a home health agency and duly licensed, if such licensing is required, by the appropriate licensing authority, to provide nursing and other therapeutic services, (2) its policies are established by a professional group associated with such agency or organization, including at least one physician and at least one registered nurse, to govern the services provided, (3) it provides for full-time

supervision of such services by a physician or by a registered nurse, (4) it maintains a complete medical record on each patient, and (5) it has an administrator.

- (d) Home health care shall consist of, but shall not be limited to, the following: (1) Part-time or intermittent nursing care by a registered nurse or by a licensed practical nurse under the supervision of a registered nurse, if the services of a registered nurse are not available; (2) part-time or intermittent home health aide services, consisting primarily of patient care of a medical or therapeutic nature by other than a registered or licensed practical nurse; (3) physical, occupational or speech therapy; (4) medical supplies, drugs and medicines prescribed by a physician, an advanced practice registered nurse or a physician assistant and laboratory services to the extent such charges would have been covered under the policy or contract if the covered person had remained or had been confined in the hospital; (5) medical social services, as hereinafter defined, provided to or for the benefit of a covered person diagnosed by a physician as terminally ill with a prognosis of six months or less to live. Medical social services are defined to mean services rendered, under the direction of a physician by a qualified social worker holding a master's degree from an accredited school of social work, including but not limited to (A) assessment of the social, psychological and family problems related to or arising out of such covered person's illness and treatment; (B) appropriate action and utilization of community resources to assist in resolving such problems; (C) participation in the development of the overall plan of treatment for such covered person.
- (e) The policy may contain a limitation on the number of home health care visits for which benefits are payable, but the number of such visits shall not be less than eighty in any calendar year or in any continuous period of twelve months for each person covered under a policy, except in the case of a covered person diagnosed by a physician as terminally ill with a prognosis of six months or less to live, the yearly benefit for medical social services shall not exceed two hundred dollars. Each visit by a representative of a home health agency shall be considered as one home health care visit; four hours of home health aide service shall be considered as one home health care visit.
- (f) Home health care benefits may be subject to an annual deductible of not more than fifty dollars for each person covered under a policy and may be subject to a coinsurance provision which provides for coverage of not less than seventy-five per cent of the reasonable charges for such services. Such policy may also contain reasonable limitations and exclusions applicable to home health care coverage. A "high deductible health plan," as defined in Section 220(c)(2) or Section 223(c)(2) of the Internal Revenue Code of 1986, or any subsequent corresponding internal revenue code of the United States, as from time to time amended, used to establish a "medical savings account" or "Archer MSA" pursuant to Section 220 of said Internal Revenue Code or a "health savings account" pursuant to Section 223 of said Internal Revenue Code shall not be subject to the deductible limits set forth in this subsection.
- (g) No policy, except any major medical expense policy as described in subsection (j), shall be required to provide home health care coverage to persons eligible for Medicare.
- (h) No insurer, hospital service corporation or health care center shall be required to provide benefits beyond the maximum amount limits contained in its policy.

- (i) If a person is eligible for home health care coverage under more than one policy, the home health care benefits shall only be provided by that policy which would have provided the greatest benefits for hospitalization if the person had remained or had been hospitalized.
- (j) Each major medical expense policy delivered, issued for delivery or renewed in this state on or after October 1, 1989, shall provide coverage in accordance with the provisions of this section for home health care to residents in this state whose benefits are no longer provided under Medicare or any applicable individual or group health insurance policy.

(P.A. 90-243, §104)

CGSA § 38a-493 mandates the same coverage in individual health insurance policies delivered, issued for delivery, or renewed in Connecticut.

To evaluate this mandate, in March 2010, CPHHP and IC requested and received 2007 and 2008 claims data related to the mandated benefit from six insurers and managed care organizations (carriers) 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). Six carriers provided data for group plans and four of the six carriers provided claims data for individual policies. However, the claims data for individual policies is considered less credible than the group plan data due to the lower response rate and fewer covered lives represented by the claims. Five carriers also provided information about the extent to which home health care is included under their self-funded plans. It is anticipated that the self-funded plans managed by the sixth carrier offer coverage comparable to the other five carriers. Projected costs for 2010 were estimated from the IC actuarial analysis of carrier claims data from 2007 and 2008. The financial impacts presented likely overstate the impact of the mandate on premiums and the total cost because the claims data reflects all home health care among the fully insured, rather than the change in utilization and cost of the benefit following implementation of the mandate.

Overall, the projected 2010 cost to Connecticut's health care system for providing home health care to the population enrolled in fully insured plans is \$29,848,475. This amount includes \$23,088,061 in total medical claims, \$4,779,927 in retention (administrative expenses plus profit) and \$1,980,486 in cost sharing. On average, out-of-pocket cost sharing is expected to comprise 6.6 percent of the dollars spent on home health care for the fully insured population.

Current coverage

The mandate originally went into effect on October 1, 1975. Most Connecticut residents with a health plan have home health care services as a covered benefit.

Premium impact

The projected 2010 average per member per month (PMPM) premium for all covered home health care provided to fully insured members is summarized below. The gross cost presented is expected to be higher than the "new" cost or change in cost that may have occurred following the mandate. However, since home health care is primarily available as a substitute for inpatient hospital care, the actual contribution of the mandate to premiums is expected to be cost neutral or cost saving.

Group plans: The medical cost is estimated to be \$1.47 PMPM. The estimated total premium (carrier paid medical claims, administrative fees, and profit) of the mandated services in 2010 in group plans is \$1.76 PMPM, which is 0.5 percent of the estimated total cost for group plans. Estimated cost sharing in 2010 in group plans is \$0.13 PMPM.

Individual policies: The weighted average paid medical cost of home health care claims is estimated to be \$0.75 PMPM. The estimated total premium of the mandated services in 2010 in individual plans is \$0.97 PMPM, which is approximately 0.4 percent of estimated total costs in individual plans. Estimated cost sharing in 2010 in individual policies is \$0.07 PMPM.

Self-funded plans

Responses indicate that approximately 89 percent of self-funded groups, covering 90.1 percent of self-funded members, offer home health care to an equal or greater extent than the Connecticut mandate requires of fully insured groups.

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 II.

II. Background

In this chapter, home health care refers to hospital care or hospice services received in the home. This definition is consistent with the provisions for home health care specified under the Connecticut statute being reviewed in this chapter. Home-based hospital care includes a myriad of medical and ancillary care services such as physician care; nursing care; home health aide services; physical, occupational or speech therapy; prescribed medical supplies, drugs, medicines and laboratory services (e.g., blood and urine tests); and medical social services. These services are typically requested by a physician after consulting with the patient and coordinated as a component of hospital discharge planning. The alternative for home care is for such services to be performed at a hospital or other medical facility.

The role of different health care providers in hospital care at home can be summarized as follows. Nursing care is the most common form of home health care and typically utilized after a major surgery. The nurse(s) adhere to a physician-designed home care treatment plan that may include: wound care, ostomy care, intravenous therapy, administering medication, pain control, and overall health monitoring.²⁰⁰ Physicians may also visit the home to diagnose a patient, monitor an illness, or review health care needs. Home health aides may help the patient with basic personal needs (bathing, dressing, walking, etc). In addition, homemakers may help with meal preparation, grocery shopping, laundry and other daily tasks.²⁰¹ However, home health aide services and homemaker services deemed nonmedical usually must be funded out of pocket.

Rehabilitative services such as occupational, physical and speech therapy may also be provided in the home. Physical therapists can assist a patient in regaining lost musculoskeletal function through the use of massage, ultrasound, other modalities, and exercises to strengthen or improve range of motion for muscles and joints. Occupational therapists consult with the patient so that they may perform daily functions such as eating, bathing, and dressing as independently as possible. Consultation may include re-teaching skills, recommending assistive devices or environmental modifications, and orienting patients to devices or modifications. A speech therapist addresses communication issues that patients face, ultimately helping to restore speech function.

Home-based care is also available for terminally ill patients with a short life expectancy. A major goal of terminal care is to give the patients the opportunity to stay at home as long as they want, to support the

²⁰⁰ Weill Cornell Medical College. 2010. Department of Surgery. Types of Home Health Care Services.

Available at: http://www.cornellsurgery.org/patients/health/homehealth_hospice2.html. Accessed December 20, 2010.

²⁰¹ *Ibid.*

family, and keep health care costs as low as possible.²⁰² To some extent, care provided to terminally ill patients mimics hospice care. Under hospice care, medical measures generally focus on controlling pain and symptoms rather than curative measures and transition assistance is provided. Transition assistance may come in the form of medical social services where a social worker provides counseling, assessment of social, psychological and family problems related to the person's illness and treatment, and assistance in coordinating the use of community resources. National data from 2009 suggests that about 27.5 percent of hospice care is received in a private residence.²⁰³

Home care services are provided primarily by registered nurses and home health aides. According to the U.S. Bureau of Labor Statistics, there is a growing need for these providers as the population ages.²⁰⁴ In Connecticut, home health care services prescribed by physicians are provided through home health care agencies licensed by the state Department of Public Health. These agencies offer skilled nursing, home health aide services, physical therapy, occupational therapy, speech therapy, and hospice services.²⁰⁵ Although the majority of home-based hospital care is provided to the aging population, home-based hospital care is also sought among the under 65 population. Based on estimates from the Medical Expenditure Panel Survey (MEPS), 1 percent of the United States population under age 65 used home health care services in 2008. This estimate includes all care provided through home health agencies and home health providers.²⁰⁶ Specific to hospice care, 11.8 percent of hospice patients remained in care for longer than 180 days. Overall, the median length of care was 21.1 days and the mean length of care was 69 days.²⁰⁷

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 UpToDate, AccessMedicine, PubMed, and Cochrane Library. Search parameters included: home care services, home care agencies, home nursing, home care, intermediate care facilities, and skilled nursing facilities. Terms added to searches included: utilization, occupational therapy, physical therapy modalities, social support, socioeconomic factors, patient satisfaction, patient acceptance of health care, outcome assessment, insurance coverage, health status, health services accessibility, cost-benefit analysis.

CPHHP staff conducted independent literature searches using PubMed, Cochrane Database, Westlaw and Google Scholar. 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's School of Nursing on

²⁰² Ahlner-Elmqvist M, Jordhøy MS, Jannert M, *et al.* 2004. Place of death: hospital-based advanced home care versus conventional care: A prospective study in palliative cancer care. *Palliative Medicine* 18: 585.

²⁰³ National Hospice and Palliative Care Organization. 2010. Hospice Facts and Figures 2010 Edition. Available at: http://www.nhpco.org/files/public/Statistics_Research/Hospice_Facts_Figures_Oct-2010.pdf. Accessed December 20, 2010.

²⁰⁴ Bureau of Labor Statistics. Occupational Outlook Handbook, 2010-2011. Home health aides and personal and home care aides. Available at: <http://www.bls.gov/oco/ocos326.htm>. Accessed December 20, 2010.

²⁰⁵ State of Connecticut. Long term care and support services. Home Health Care. Available at: <http://www.ct.gov/longtermcare/cwp/view.asp?a=1398&q=306736#HomeHealthCare>. Accessed December 20, 2010.

²⁰⁶ Agency for Healthcare Research and Quality. Home Health Services-Mean and Median Expenses per Person With Expense and Distribution of Expenses by Source of Payment: United States, 2008. Medical Expenditure Panel Survey Household Component Data. Generated interactively. (January 05, 2011).

²⁰⁷ National Hospice and Palliative Care Organization. 2010. Hospice Facts and Figures 2010 Edition. Available at: http://www.nhpco.org/files/public/Statistics_Research/Hospice_Facts_Figures_Oct-2010.pdf. Accessed December 20, 2010.

matters pertaining to medical standards of care, traditional, current and emerging practices, and evidence-based medicine related to home health care. 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.

With the assistance of the Connecticut Insurance Department (CID), CPHHP and Ingenix Consulting requested and received 2007 and 2008 claims data from health plan carriers domiciled in Connecticut. Six carriers provided inpatient home health care claims data for their fully insured group plan participants and four provided claims data for their fully insured individual plan participants. However, the claims data for individual policies is considered less credible than the group plan data due to the lower response rate from carriers and fewer covered lives represented by the claims. Five carriers also provided information about home health care coverage in the self-funded plans they administer. It is anticipated that the self-funded plans managed by the sixth carrier offer coverage comparable to the other five carriers.

CPHHP and the CID contracted with Ingenix Consulting (IC) to provide actuarial and economic analyses of the mandated benefit. A description of the methods used for the actuarial analysis is available in the Ingenix Consulting report located in Appendix II.

IV. Social Impact

1. The extent to which home health care is utilized by a significant portion of the population.

Based on estimates from the Medical Expenditure Panel Survey (MEPS), 1 percent of the United States population under age 65 used home health care services in 2008, with 90 percent receiving the care from home health agencies.²⁰⁸ The use of home health care captured in the MEPS data further differs from what is covered by the Connecticut mandate since it also includes nonmedical home care such as cooking, cleaning, shopping and assistance with other activities of daily living.

2. The extent to which home health care 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.

Medicare²⁰⁹

Home health care is defined as “skilled nursing care and certain other health care services you receive in your home for the treatment of an illness or injury.”²¹⁰ Part A covers some home health care services. In order to qualify for home health care benefits, all of the following conditions must be met:

1. The individual must be under the care of a doctor, and must be getting services under a plan of care established and reviewed regularly by a doctor.
2. The individual must need, and a doctor must certify that he or she needs, one or more of the following:

²⁰⁸ Agency for Healthcare Research and Quality. Home Health Services-Mean and Median Expenses per Person With Expense and Distribution of Expenses by Source of Payment: United States, 2008. Medical Expenditure Panel Survey Household Component Data. Generated interactively. (January 05, 2011).

²⁰⁹ Centers for Medicare and Medicaid (CMS), Medicare and Home Health Care. Available at: <http://www.medicare.gov/publications/pubs/pdf/10969.pdf>. Accessed December 20, 2010.

²¹⁰ Medicare Coverage Guidelines for Home Health Care (Connecticut).

- a. Intermittent skilled nursing care,
 - b. Physical therapy,
 - c. Speech-language pathology services, or
 - d. Continued occupational therapy.
3. The home health agency caring for the individual must be approved by Medicare (Medicare-certified).
 4. The individual must be homebound, and a doctor must certify that he or she is home bound. To be home bound means the following:
 - a. Your condition keeps you from leaving home without help (such as using a wheelchair or walker, needing special transportation, or getting help from another person).
 - b. Leaving home takes a considerable and taxing effort.
 - c. A person may leave home for medical treatment or short, infrequent absences for non-medical reasons, such as attending religious services. You can still get home health care if you attend adult day care, but you would get the home care services in your home.²¹¹

Medicare covers the following services as long as they are reasonable and necessary for the treatment of one's illness or injury: skilled nursing care; physical therapy, occupational therapy, and speech-language pathology services; medical social services; and medical supplies.

Medicare does not cover the following:

1. 24-hour-a-day care at home,
2. meals delivered to one's home,
3. homemaker services like shopping, cleaning, and laundry when this is the only care you need, and when these services aren't related to your plan of care, and
4. personal care given by home health aides like bathing, dressing, and using the bathroom when this is the only care you need.

Medicare covers 100 percent of all covered home health services. However, enrollees may have to pay for "medical services and supplies that Medicare doesn't pay for when you agree to pay out of pocket for them," as well as "20 percent of the Medicare-approved amount for Medicare-covered medical equipment such as wheelchairs, walkers, and oxygen equipment."²¹² Medicare also provides a hospice benefit at nearly 100 percent of funding depending on certain criteria. This benefit has allowed most patients the option for dying at home.²¹³

Department of Social Services

Medicaid covers medically necessary services provided by licensed home health agencies that are delivered in the home.²¹⁴ Home health services must be ordered by a physician or nurse in order to be covered. The order is sent to a home health agency that assesses the client and works with the physician to complete an appropriate plan of care. The following home health care services are covered under Medicaid: nursing; home health aides; physical, occupational and speech therapy; and nursing for high risk pregnancies.

²¹¹ Centers for Medicare and Medicaid (CMS), Medicare and Home Health Care.

Available at: <http://www.medicare.gov/publications/pubs/pdf/10969.pdf>. Accessed December 20, 2010.

²¹² *Ibid.*

²¹³ Teno JM, Clarridge BR, Casey V, *et al.* 2004. Family perspectives on end-of-life care at the last place of care. *Journal of the American Medical Association* 291:88-93.

²¹⁴ Connecticut Department of Social Services, Connecticut Medicaid, Summary of Services. Available at: <http://www.ct.gov/dss/lib/dss/pdfs/medicaidservicesv3kk.pdf>. Accessed December 20, 2010.

Medicaid covers the services of home health aides only when the aide is assisting with activities of daily living, such as bathing, dressing, toileting, transferring and feeding. Medicaid does not cover other services the home health care aid provides such as housework or other chores.²¹⁵

Department of Public Health

The Department of Public Health requires that all nurses and Home Healthcare Agencies be registered with the department and maintains compliance of these guidelines. No information was found that would indicate the Department of Public Health provides home healthcare services.

Municipal health departments/health districts

Some municipalities provide limited home health care services for select populations. Most commonly, homemaker services, home repair, companion, social support service and benefits counseling are provided for the elderly population.²¹⁶ Other populations served include the disabled and pregnant women.

Other programs

Hospice care, regardless of ability to pay may be available through members of the National Hospice and Palliative Care Organization (NHPCO), the largest nonprofit membership organization representing hospice and palliative care programs.²¹⁷

Additional entities may provide or support funding health care in the home for terminally ill patients or patients that would otherwise require inpatient hospitalization. However, findings did not suggest that public schools provide home health care specific to these circumstances.

3. The extent to which insurance coverage is already available for home health care.

The state of Connecticut requires fully insured group and individual health policies delivered, renewed or amended in the state as of 1975 to cover home health care.²¹⁸ Approximately 46.6 percent of Connecticut residents are enrolled in fully insured plans subject to the mandate.²¹⁹ Information received from 5 carriers domiciled in Connecticut shows that 90.1 percent of the carriers self-funded members have coverage for home health services.

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.

Home health care, as covered by the mandate, refers to hospice care and hospital care provided in a home setting instead of a hospital setting. Persons needing such care could obtain the necessary treatment in a hospital setting rather than the home if home-based care were not covered. To the extent that the hospital care is stabilizing care, even uninsured populations would be able to obtain the care at a hospital under the federal Emergency Medical Treatment and Labor Act (EMTALA). The law requires all hospitals that participate in Medicare provide patients with screening, emergency care, “stabilizing care,” and appropriate transfers to other facilities regardless of their ability to pay.

²¹⁵ *Ibid.*

²¹⁶ City of Hartford. Human Services Division. Home care. Available at: http://www.hartford.gov/Human_services/html%20files_06/Elderly%20Services.htm#HOME%20CARE. Accessed November 23, 2010.

²¹⁷ National Hospice and Palliative Care Organization. 2010. Preamble and Philosophy. Available at: <http://www.nhpc.org/i4a/pages/index.cfm?pageid=5308>. Accessed January 4, 2011.

²¹⁸ CONNECTICUT GENERAL STATUTES. Revised January 1, 2010. CHAPTER 700, §38A-493.

²¹⁹ 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>. Accessed October 8, 2010.

Figure IV.6.1, illustrates the population using home health care services in 2008 by insurance type. Although far fewer uninsured individuals accessed home health care services than privately or publicly insured individuals, this data reflects that to some extent individuals without insurance are able to access care.²²⁰

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.

Insurance status, required cost sharing, coinsurance and deductibles, and personal financial resources determine whether a person will face unreasonable financial hardship when needing treatment. The home health care mandate introduces an alternative location for an eligible patient to receive medical care. This care is substituted for a longer inpatient hospital stay which generally is a more costly venue for receiving health care.

If a person elected to pay for home health care without insurance coverage, the result would likely be financial hardship. According to MEPS data (2008), the per person annual cost of home health care varies substantially with a median cost of \$2,266 and a mean cost of \$7,742.²²¹ For a family with an annual income of \$50,000, the proportion of income spent without available coverage would be 4.5 percent or 15.5 percent assuming the median and mean cost, respectively.

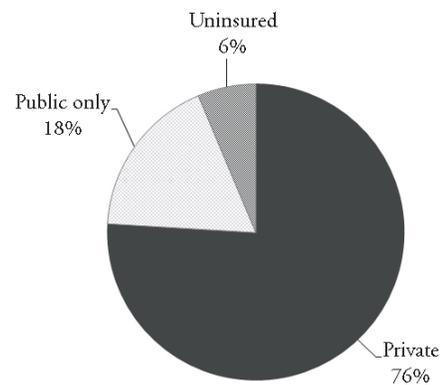
Further discussion of financial and socioeconomic effects of the mandated benefit may be found in Appendix II: Ingenix Consulting Actuarial Report, page 46-47.

6. The level of public demand and the level of demand from providers for home health care.

Public demand for home health care is expected to increase in coming years due to several factors including overall population growth in the United States, the aging of the population, increased preference for home health care, development of in-home medical technologies, and efforts to contain healthcare costs by moving patients out of hospitals and nursing facilities as quickly as possible.²²²

Furthermore, the total number of the public using home health care has grown recently. For example, Medicare beneficiaries using home health care grew from 2.8 million in 2004 to 3.4 million in 2007.²²³ The utilization of home health care by an increasing percentage of the population and the provision and referrals for such services by providers indicates a public and provider demand.²²⁴

Figure IV.6.1. Utilization of Home Health Care Services by Insurance Type (US Population <65 years old)^a



^aSource: Agency for Healthcare Research and Quality. Home Health Services-Mean and Median Expenses per Person With Expense and Distribution of Expenses by Source of Payment: United States, 2008. Medical Expenditure Panel Survey Household Component Data. Generated interactively. (January 05, 2011)

²²⁰ Agency for Healthcare Research and Quality. Home Health Services-Mean and Median Expenses per Person With Expense and Distribution of Expenses by Source of Payment: United States, 2008. Medical Expenditure Panel Survey Household Component Data. Generated interactively. (January 05, 2011).

²²¹ *Ibid.*

²²² United States Department of Labor, Career Guide to Industries, 2010-2011 Edition.

²²³ Medicare Payment Advisory Commission. Report to the Congress: Medicare Payments Policy, March 2009. Available at: http://www.medpac.gov/chapters/Mar09_Ch02E.pdf. Accessed January 4, 2011.

²²⁴ *Ibid.*

7. The level of public demand and the level of demand from providers for insurance coverage for home health care.

Some evidence of public demand for insurance coverage for home health care can be found in public hearing testimony. Several home health care providers and members of the public spoke in support of insurance coverage for home health care.

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

According to the National Association of Insurance Commissioners, as of May 2010, forty-eight states require coverage for home health care, with Alaska and New York as the exceptions.²²⁵ Most states mandates cover similar home health care services as Connecticut. Alabama, Arkansas, California, Delaware, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Nevada, New Hampshire, New Jersey, New Mexico, Minnesota, Missouri, Montana, Nebraska, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Kansas, South Dakota, Tennessee, Texas, Utah, Washington, and West Virginia provide that “[c]overage shall be a dollar amount equal to at least ½ of one year’s coverage available for nursing home benefits under the policy.” In Colorado, coverage must provide for at least 40 home health care visits.

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

Thirty states now require a fiscal note or an additional review process for any new required health insurance benefit prior to enactment.²²⁶ CPHHP staff conducted internet searches, database queries and telephone inquiries to locate reports generated by state agencies or appropriate public organizations on the mandate. States searched for which no evidence of a review was found include Alabama, Alaska, Arizona, Arkansas, Colorado, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Maryland, Maine, Virginia, Wisconsin, Louisiana, New Jersey, Washington and Texas. Reviews on bills related to home health care were conducted in California, Massachusetts, and Pennsylvania. The findings are described below.

California: In April 2010, the California Health Benefits Review Program (CHBRP) reviewed Senate Bill 890, Basic Health Care Services, which includes home health care. The report notes that there is clear and convincing evidence that home health services are associated with statistically significant reductions in days of hospitalization and nursing home use and with a non-significant decrease in mortality relative to usual care. Further, the report found there is clear and convincing evidence that home-based rehabilitation is associated with fewer days of hospitalization than inpatient rehabilitation. The report also found that there is insufficient evidence to determine whether home care improves physical or mental health outcomes for children with very low birth weight, genetic disorders, or chronic conditions. CHBRP estimates that as a result of the mandate, utilization would increase by 2,772 home health visits.²²⁷

Massachusetts: In July 2008, the Division of Health Care Finance and Policy provided a Comprehensive Review of Mandated Benefits in Massachusetts. The DHCFP found home health care to be cost-effective in a variety of scenarios.²²⁸

²²⁵ NAIC Compendium of State Laws on Insurance Topics. National Association of Insurance Commissioners. August 2008.

²²⁶ 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.

²²⁷ California Health Benefits Review Program, 2010. Analysis of Senate Bill 890, Basic Health Care Services. Available at: http://www.chbrp.org/docs/index.php?action=read&bill_id=91&doc_type=3. Accessed December 18, 2010.

²²⁸ Massachusetts Division of Health Care Finance and Policy, 2008. Comprehensive Review of Mandated Benefits in Massachusetts. Available

Pennsylvania: In January 2008, the Pennsylvania Health Care Cost Containment Council (PHC4) published a review of Senate Bill 499, which would require that optional home health benefits be offered to purchasers. However, the PHC4 review process involves interested parties submitting information on the mandate. The information submitted was not sufficient to complete a cost/benefit analysis and lacked the detail necessary to outline the need for, utilization of, and availability of home health care in the state. However, statements submitted from The Managed Care Association, Insurance Federation, and Highmark reported home health care to be a covered benefit under most commercial health insurance policies. Home health care was also reported to be generally included as part of the base health plan for health maintenance organizations and other managed care plans serving the commercial market. PCH4 did not recommend that Senate Bill 499 proceed to the mandated benefit review panel.²²⁹

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

Under the conditions specified in the mandate, the only alternative for hospice or home care is for such services to be performed in a hospital or medical center. Services that may be performed at home or in a medical center include rehabilitative services, birth, counseling, administration of special medications or intravenous medications, and various treatments for long-term conditions. However, not all inpatient or outpatient medical services can be provided in a home setting.

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.

Those eligible for home health care coverage would otherwise require similar treatment in a hospital on an inpatient basis. As mandated, the type of care provided in the home is geared towards meeting the medical needs of persons who would otherwise be in the hospital or who are terminally ill with a six-month prognosis to live. Although the services provided are medical, the requirement to cover the specified location of the “home” appears more social than medical.

Home health services may include the provision of physician-prescribed medical supplies, drugs, medicines and laboratory services; part-time or intermittent nursing care or home health aide services; physical, occupational or speech therapy; and medical social services. The majority of services that may be listed in the care plan would be considered medically necessary. To some extent medical social services, which are covered for terminally ill patients, may be considered as meeting a social need even though the resources provided are intended to address issues that may arise from the covered person’s illness or treatment.

The type of care provided under the mandate appears relatively consistent with health insurance and managed care. One of the roles of health insurance is to cover low utilization, high cost health services. Home health care qualifies as both low utilization and a high cost service. However, requiring coverage of these services in the home, the specification of thresholds for coinsurance, and limits on the number of payable visits and co-pays removes or restricts tools that may otherwise have been used by carriers in a different manner.

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

The home health care benefit was implemented in 1975 yet there is only one mandate out of the existing Connecticut health insurance mandates for which similarity could be suggested. The potentially

at: http://www.mass.gov/Eeohhs2/docs/dhcfp/r/pubs/mandates/comp_rev_mand_benefits.pdf. Accessed December 18, 2010.

²²⁹ Pennsylvania Health Care Cost Containment Council, 2008. Mandated benefits review, Senate Bill 499, Home Health Care. Available at: <http://www.phc4.org/reports/mandates/SB499/>. Accessed December 8, 2010.

comparable mandate is the requirement for group health plans to offer employers the option of coverage for comprehensive rehabilitation which includes physical, occupational, speech, social or psychological services and respiratory therapy. In addition to encompassing similar types of care as the home health care mandate, the rehabilitation mandate also dictates the location at which reimbursable services may be obtained (Comprehensive outpatient rehabilitation facilities or CORFs).

It is possible that subsequent mandate(s) could be passed requiring an extension of coverage for home health care in situations other than where “continued hospitalization would otherwise have been required” or the patient is terminally ill with less than six months left to live. Such a mandate might allow for rehabilitative services to be provided in the home rather than at provider offices or outpatient facilities.

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

Home health care accounts for an estimated 0.5 percent of the projected average health insurance premium for 2010. Since home health care is substituted for medical services that would otherwise be provided as inpatient hospital care, it is possible that the mandate is cost neutral or cost saving. One early study notes that from the standpoint of third-party underwriters, home health care is less expensive than extended hospitalization.²³⁰ Since the mandate is potentially cost neutral or cost saving, the mandate is not expected to reduce the availability of other benefits. However, to the extent that home health care is elected as a substitute, utilization of inpatient hospital stays may decrease.

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

Decisions about shifting to self-funded status are driven by a variety of factors: health insurance premiums increases, the contribution of a mandated benefit to premiums, and the proportion of the covered population likely to obtain the mandated service. Whether self-funded plans cover the benefit may also serve as a litmus test for whether employers would switch their status based on the mandate. For home health care, according to a survey of five carriers, 89 percent of the carriers’ self-funded groups included home health care coverage at least to the extent of Connecticut’s mandate. In addition to a high percentage of self-funded groups electing coverage, it is expected that home health care is either a cost neutral or cost saving benefit to include in health care plans. Therefore, it is not anticipated that employers shifted or will shift to self-funded plans as a result of this single mandate or in the absence of this mandate.

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

The state employee health insurance/benefit plans were subject to the home health care requirement from the mandate implementation date of 1975 up until July 1, 2010, when Connecticut transitioned from fully insured group plans to self-funded plans. As a self-funded group, the State of Connecticut is exempt from state health insurance mandates under the federal Employee Retirement Income Security Act (ERISA). Assuming Connecticut continues to cover the mandated benefits, 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 Medicare²³¹ 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 chapter. In terms of financial impact, if the state employee health insurance/benefit plans continue to provide coverage for the required benefit, the IC actuarial analysis estimates the medical cost to the state employee health insurance plan will

²³⁰ Hammond J. 1979. Home health care cost effectiveness: an overview of the literature. *Public Health Report* 94(4): 305–311.

²³¹ Personal communication. Scott Anderson, State of Connecticut Comptroller’s Office. September 14, 2010.

total \$2,898,852 in 2010.²³² This number does not account for any savings to the state plans that may occur as a result of substituting home health care for inpatient hospital stays.

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

As an alternative to inpatient and outpatient medical services performed in a hospital or other medical center, most home health care services are considered safe. Multiple systematic reviews on the use of home health care for a variety of conditions are available through the Cochrane Database of Systematic Reviews.

Condition specific reviews found home-based hospital care to be more effective than inpatient hospital care for preventing recurrence of deep vein thrombosis (DVT)²³³ and treating patients with peripheral vascular disease.²³⁴ Studies suggest that home management of children with newly diagnosed juvenile diabetes does not lead to any disadvantages in terms of blood glucose, acute diabetic complications and hospitalizations, psychological variables and behavior, or total costs.²³⁵ Other reviews noted conflicting findings or inconclusive evidence based on study limitations with regard to the effectiveness of home-based hospital care in patients with chronic obstructive pulmonary disease (COPD),²³⁶ mental health care for adolescents,²³⁷ and for reducing morbidity and mortality in people infected with HIV/AIDS.²³⁸

Overall, systematic reviews of the medical literature determined there was no evidence that hospital at home care leads to different outcomes for avoiding readmissions than inpatient hospital care.²³⁹ In addition, a recent review also concluded that home-based hospital care can be an effective way to manage patients compared with inpatient hospital care. Despite the latter findings, the authors concluded the review did not support the widespread adoption of hospital at home, nor the discontinuation of existing at home services based on insufficient data.²⁴⁰

National guidelines and clinical practice often incorporate home health care; however, not all research on the efficacy of home health care meets scientific evidence standards commonly used for systematic reviews. The National Guidelines Clearinghouse, available through the U.S. Agency for Healthcare Research and

²³² See Appendix II. Ingenix Consulting Actuarial Report. This estimate has been calculated by multiplying the 2010 PMPM medical cost in table 1.3A by 12 to get an annual cost per insured life, and then multiplying that product by 163,334 covered lives, as reported by the State Comptroller's office. This estimate is calculated using weighted averages for all claims paid by Connecticut-domiciled insurers and health maintenance organizations in the State. The actual cost of this 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 this mandated benefit would be in addition to the above amount.

²³³ Othieno R, Abu Affan M, Okpo E. Home versus inpatient treatment for deep vein thrombosis. *Cochrane Database of Systematic Reviews* 2007, Issue 3. Art. No.: CD003076.

²³⁴ Ashworth NL, Chad KE, Harrison EL, *et al.* Home versus center based physical activity programs in older adults. *Cochrane Database of Systematic Reviews* 2005, Issue 1. Art. No.: CD004017.

²³⁵ Clar C, Waugh N, Thomas S. Routine hospital admission versus outpatient or home care in children at diagnosis of type 1 diabetes mellitus. *Cochrane Database of Systematic Reviews* 2007, Issue 2. Art. No.: CD004099.

²³⁶ Ashworth NL, Chad KE, Harrison EL, *et al.* Home versus center based physical activity programs in older adults. *Cochrane Database of Systematic Reviews* 2005, Issue 1. Art. No.: CD004017.

²³⁷ Shepperd S, Doll H, Gowers S, *et al.* Alternatives to inpatient mental health care for children and young people. *Cochrane Database of Systematic Reviews* 2009, Issue 2. Art. No.: CD006410.

²³⁸ Young T, Busgeeth K. Home-based care for reducing morbidity and mortality in people infected with HIV/AIDS. *Cochrane Database of Systematic Reviews* 2010, Issue 1. Art. No.: CD005417.

²³⁹ Shepperd S, Doll H, Angus RM, *et al.* Admission avoidance hospital at home. *Cochrane Database of Systematic Reviews* 2008, Issue 4. Art. No.: CD007491.

²⁴⁰ Shepperd S, Iliffe S. 1998. The effectiveness of hospital at home compared with inpatient hospital care: a systematic review. *Journal of Public Health Medicine* 20(3):344-50.

Quality (AHRQ), archives dozens of medical conditions for which home health care is considered a location where treatment may be delivered. These conditions include COPD, DVT, ailments of bones and joints, depression, stroke rehabilitation, palliative care, mental ailments, and several others. In addition, the Visiting Nurse Association of America (VNAA) publishes an annual nursing procedure manual for practitioners with regard to home health care.²⁴¹

V. Financial Impact

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

The cost of the service is likely to increase (or decrease) at the same rate as any other medical service. The mandated benefit is a low-volume service and the presence of the insurance mandate is not expected to have any additional effect on its cost. In general, cost of a good increases if demand for the good is higher than what can be supplied. For a change in cost to be attributable to the mandate, the mandate must lead to an increase in utilization that exceeds what the health care system is ready to supply. Since this mandate has been in place since October 1, 1975, it is reasonable to assume that the market has adequately adjusted for any supply shortfalls (e.g., lack of qualified providers) that may have occurred as a result of increased demand from the mandate. Therefore, any observable changes in the cost of home health care over the next five years are expected to reflect medical inflation and the increase in services demanded from a growing elderly population.

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

Lack of longitudinal data on home health care utilization both before and after the implementation of the mandate limits the ability to attribute any change in utilization to the mandate. To attribute a change in use to the mandate, it is necessary to control for the extent to which the service was used in years prior to the mandate as well as other independent factors that may influence utilization of home health care. Projecting how the mandate may contribute to utilization over the next five years further requires controlling for time trends while holding demographic factors constant.

In addition, there is evidence to suggest that in the absence of a mandate for home health care coverage, such coverage may still be included in fully insured health plans. As suggested by a recent report from Pennsylvania, home health care services are generally part of the basic health plans available through commercial insurers. Furthermore, self-funded members in Connecticut are not enrolled in plans subject to the mandate, yet survey data suggests that about 9 out of 10 members have home health care coverage to an equal or greater extent than the mandate requires.

3. The extent to which the mandatory coverage for home health care may serve as an alternative for more expensive or less expensive service.

The cost effectiveness of home health care is traditionally measured in terms of the difference between the costs of home health services and the costs of alternative modes of patient care. Compared to inpatient and outpatient medical services, from the standpoint of third-party underwriters, home health care is less expensive than extended hospitalization.²⁴²

²⁴¹ Visiting Nurse Association of America. 2010-2011 Nursing Procedure Manual.

Available at: http://vnaa.org/vnaa/g?h=HTML/npm_2010-2011.html. Accessed December 14, 2010.

²⁴² Hammond J. 1979. Home health care cost effectiveness: an overview of the literature. *Public Health Report* 94(4): 305-311.

4. *The methods that will be implemented to manage the utilization and costs of the mandatory coverage for home health care.*

It is anticipated that carriers employ similar utilization management methods and cost controls that are used for other covered benefits. The legislation includes a significant amount of language related to strategies typically used to manage utilization and cost. Although statutory language permits the use of deductibles, coinsurance and limits on the number of visits, there are limits placed on the extent to which certain strategies may be employed. With the exception of high deductible health plans or health savings accounts, annual deductibles may not exceed \$50 and coinsurance paid by the member cannot exceed 25 percent of reasonable charges for home health care. Plans must also include at least 80 payable home health care visits per calendar year or twelve month period.

The statute also states that “such policy may also contain reasonable limitations and exclusions applicable to home health care coverage.”²⁴³

5. *The extent to which insurance coverage for home health care 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 carriers) or contribution to surplus (for not-for-profit carriers). Utilization of home health care accounts for on average, an estimated 0.5 percent or \$1.76 PMPM for group and 0.4 percent or \$0.97 PMPM for individual health plan premiums in 2010. For fully insured group policyholders, the average medical cost of insurance accounts for \$1.76 PMPM while retention accounts for \$0.29 PMPM. Under fully insured individual plans, the average total medical claims cost is \$0.75 PMPM and retention accounts for \$0.22 PMPM.

Since the mandate has been in place since October 1, 1975, the PMPM estimates presented do not capture the increase in cost attributable to the mandate but rather the average PMPM for home health care for the covered population projected for 2010. It is expected that the home health care benefit may result in medical claims that on average are either similar to or less than the claims that would be submitted for inpatient hospital care in the absence of a mandate.

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

The literature review did not identify any published evidence comparing the overall cost effectiveness of hospital care provided in the home to inpatient hospital stays. However, several studies examine cost effectiveness of home health care for specific health conditions or types of treatments. Findings suggest that home health care is cost effective compared to care offered on an inpatient hospital basis for uncomplicated vaginal deliveries,²⁴⁴ ultraviolet B phototherapy for the chronic skin condition psoriasis,²⁴⁵ intravenous steroid administration for patients with multiple sclerosis,²⁴⁶ medical services for the chronically ill with

²⁴³ CONNECTICUT GENERAL STATUTES. Revised January 1, 2010. CHAPTER 700, §38A-493.

²⁴⁴ Anderson RE, Anderson DA. The cost-effectiveness of home birth. *Journal of Nurse-Midwifery* 44(1): 30-5.

²⁴⁵ Koek MB, Sigurdsson V, van Weelden H, *et al.* 2010. Cost effectiveness of home ultraviolet B phototherapy for psoriasis: economic evaluation of a randomized controlled trial (PLUTO study). *British Medical Journal* 340:c1490.

²⁴⁶ Chataway J, Porter B, Riazi A, *et al.* 2006. Home versus outpatient administration of intravenous steroids for multiple-sclerosis relapses: a randomized controlled trial. *Lancet Neurology* 5(7):565-71.

tuberculosis,²⁴⁷ hospice care for the Medicare enrolled,²⁴⁸ and treatment of chronic obstructive pulmonary disorder among elderly patients.²⁴⁹ Researchers at Duke University found that hospice reduced Medicare costs by an average of \$2,309 per hospice patient.²⁵⁰

7. The impact of insurance coverage for home health care 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.

Among the fully insured population, insurance coverage for home health care is projected to contribute \$25,068,547 to the total cost of health care in Connecticut during 2010. Of this amount, approximately 6.6 percent reflects out-of-pocket payments. This number does not account for any savings to the system that may occur as a result of substituting home health care for inpatient hospital stays. Furthermore, a much smaller proportion of the total cost would be attributable to the passage of the Connecticut mandate since the total cost presented does not control for home health care utilization that would occur among the same population in the absence of the mandate.

Savings are not anticipated as a result of prevention or early detection of disease or illness. However, available research suggests that home-based care is either as cost effective or cost saving when compared to hospital-based care.

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.

On average, home health care accounts for approximately 0.5 percent of the cost of fully insured group health plans purchased by employers. Given the relatively small contribution of home health care to premium costs, it is expected that the impact of covering home health care is similar for both small employers and other employers. However, there is evidence to suggest that the substitution of home health care for inpatient hospital stays costs less than the amount that would be spent if home health care were not offered.

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

The overall cost of the health delivery system in the state is understood to include total insurance premiums (medical costs and retention) and cost sharing. Actuarial analysis of claims data received from health plan carriers in Connecticut shows an expected cost in 2010 of \$29,068,547 for home health care provided to Connecticut residents covered by fully insured group and individual health insurance plans.

Since services obtained in the home serve as an alternative to inpatient hospital care, cost-shifting between public and private payers is unlikely. It is expected that in the absence of the mandate, inpatient care would be obtained instead. With home health care expected to be cost-neutral or cost-saving, neither private nor public payers would be expected to assume additional cost.

²⁴⁷ Moalosi G, Floyd K, Phatshwane J, *et al.* 2003. Cost-effectiveness of home-based care versus hospital care for chronically ill tuberculosis patients, Francistown, Botswana. *International Journal of Tuberculosis and Lung Disease* 7(9 Suppl 1):S80-5.

²⁴⁸ Taylor DH Jr, Ostermann J, Van Houtven CH, *et al.* 2007. What length of hospice use maximizes reduction in medical expenditures near death in the US Medicare program? *Social Science Medicine* 65(7):1466-78.

²⁴⁹ Aimonino RN, Tibaldi V, Leff B, *et al.* 2008. Substitutive “hospital at home” versus inpatient care for elderly patients with exacerbations of chronic obstructive pulmonary disease: a prospective randomized, controlled trial. *Journal of the American Geriatric Society* 56(3):493-500.

²⁵⁰ Taylor DH Jr, Ostermann J, Van Houtven CH, *et al.* 2007. What length of hospice use maximizes reduction in medical expenditures near death in the US Medicare program? *Social Science Medicine* 65(7):1466-78.

Volume IV

Chapter 7

Ambulance Services

Review and Evaluation of Connecticut Statute

Chapter 700, §§ 38a-525 and 38a-498

Mandatory Coverage for Medically Necessary Ambulance Services. Direct Payment
to Ambulance Provider

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Chapter 7. Table of Contents

- I. Overview..... 103
- II. Background..... 104
- III. Methods..... 105
- IV. Social Impact..... 106
- V. Financial Impact..... 112

I. Overview

The Connecticut General Assembly directed the Connecticut Insurance Department to review the health benefits required by Connecticut law to be included in fully insured group and individual health insurance policies as of July 1, 2009. The review was conducted following the requirements stipulated under Public Act 09-179. Reviews of required health insurance benefits are a collaborative effort of Connecticut Insurance Department (CID) and the University of Connecticut Center for Public Health and Health Policy (CPHHP).

Connecticut General Statutes, Chapter 700, §§ 38a-525 and 38a-498 state that each group or individual health insurance policy,

...delivered, issued for delivery, renewed or amended in this state on or after October 1, 2002, shall provide coverage for medically necessary ambulance services for persons covered by the policy. The hospital policy shall be primary if a person is covered under more than one policy. The policy shall, as a minimum requirement, cover such services whenever any person covered by the contract is transported when medically necessary by ambulance to a hospital. Such benefits shall be subject to any policy provision which applies to other services covered by such policies. Notwithstanding any other provision of this section, such policies shall not be required to provide benefits in excess of the maximum allowable rate established by the Department of Public Health in accordance with section 19a-177.

In April 2010, CPHHP and Ingenix Consulting (IC) requested and received 2007 and 2008 claims data related to the mandated benefit from six 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 findings of this report are based on actuarial analysis of received claims data and reviews of pertinent literature and other information related to the mandated benefit.

Current coverage

The ambulance services mandate was enacted in March 1984 and amended in October 2002 (P.A. 02-124).

Premium impact

Group plans: On a 2010 basis, medical cost is estimated to be \$2.27 per member per month (PMPM). Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services in 2010 in group plans is \$2.73 PMPM, which is approximately 0.8 percent of estimated total costs in group plans. Estimated cost sharing in 2010 in group plans is \$0.09 PMPM.

Individual policies: Four of the six insurers/MCOs provided claims data for individual health insurance policies. On a 2010 basis, medical cost is estimated to be \$1.25 PMPM. Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services in 2010 in individual policies is \$1.62 PMPM, which is approximately 0.5 percent of estimated total costs in individual policies. Estimated cost sharing in 2010 in individual plans is \$0.23 PMPM.

Self-funded plans

Six insurers/MCOs provided information about self-funded plans showing that 94.3 percent of members in self-funded plans have coverage for this benefit.

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

II. Background

Ambulance services provide emergency medical care and stabilization for patients requiring transport to an emergency department (ED). Ambulance services are generally divided into two categories: Basic Life Support (BLS) and Advanced Life Support (ALS). BLS ambulances carry bag-mask ventilation devices, immobilization and splint devices, and dressings for wound care, but cannot transport patients requiring IVs or cardiac monitoring. ALS ambulances are equipped for advanced healthcare operations including IV supplies, intubation devices, and cardiac resuscitation.²⁵¹

Ambulance services must be certified or licensed to operate. Commercial services are licensed while nonprofit services are certified. Both are held to the same standards. In Connecticut, ambulance services are provided by various entities: volunteer organizations, local public safety providers, hospitals, private nonprofit agencies, or commercial ambulance companies. According to the Connecticut Department of Public Health, Office of Emergency Medical Services (OEMS), there are about 200 ambulance service providers in Connecticut that respond to approximately 400,000 service calls per year.²⁵² Not all ambulance service providers submit data electronically to the OEMS. Records show that in 2009, there were 335,390 service request calls for ambulances reported electronically that served 359,270 patients.²⁵³

Individuals call 911 to request an ambulance for a number of different reasons. The most common reason is trauma, followed by abdominal pain, altered level of consciousness, stroke, fainting, seizures, diabetic problems, cardiac arrest, and others.²⁵⁴ Any person feeling they need emergency medical care may call 911 and request transportation to the nearest hospital ED.

Use of ambulance services varies by age, insurance status, geography, time of day, and other factors.²⁵⁵ Studies have concluded that mental health and homelessness are important predictors of ambulance use.²⁵⁶ Lack of a primary care physician, insurance coverage, and access to nearby healthcare resources are contributing factors for whether someone requests ambulance services.

Several barriers to care exist including response time, distance to emergency departments, ED crowding, hospital closures, and inappropriate use. Access to EDs and specialized trauma centers and burn units vary by state and geographic location. Nearly 80 percent of the US population lives within two hours by ground or air transport of a burn center.²⁵⁷

Several measures are used for calculating ambulance response time, including time from dispatch to arrival on scene and time from dispatch to arrival on scene plus time from on-scene arrival until medical personnel meet the patient. A study of ambulance response rates in New York City concluded that on average an additional 2.1 minute increase in response time is observed when factoring the time it takes medical personnel on scene to reach a patient. Overall, the on-scene to patient interval accounted for 28 percent of

²⁵¹ Tintinalli JE, Stapczynski JS, Cline DM, *et al.* 2011. *Tintinalli's Emergency Medicine: A Comprehensive Study Guide*. 7th Edition. The American College of Emergency Physicians. The McGraw-Hill Companies, Inc: Columbus, Ohio.

²⁵² Personal communication. Connecticut Office of Emergency Medical Services.

²⁵³ Connecticut Department of Health. Division of Emergency Medical Services. Quarterly Provider Report for the 2009 Calendar Year. Available at: http://www.ct.gov/dph/cwp/view.asp?a=3127&q=387370&dphNav_GID=1827&dphNav=|. Accessed December 8, 2010.

²⁵⁴ Wisconsin EMS Association. Wisconsin EMS Statistics. Available at: http://www.wisconsinems.com/EMS_stats.htm. Accessed December 2010.

²⁵⁵ Larking GL, Claasen CA, Pelletier AJ, *et al.* 2006. National study of ambulance transports to United States emergency departments: importance of mental health problems. *Prehospital Disaster Medicine* 21(2):82-90.

²⁵⁶ Tangherlini N, Pletcher MJ, Covec MA, *et al.* 2010. Frequent use of emergency medical services by the elderly: a case-control study using paramedic records. *Prehospital Disaster Medicine* 25(3):258-64.

²⁵⁷ Klein MB, Kramer CB, Nelson J, *et al.* 2009. Geographic access to burn center hospitals. *Journal of the American Medical Association* 302(16):1774-81.

the actual response time.²⁵⁸

In areas where hospitals and EDs have closed, patients can experience an increase in travel time to EDs. Closures also contribute to overcrowding of remaining medical facilities. Crowding results in delays for paramedics waiting to transfer patients.²⁵⁹ Research shows that the ability of the healthcare system to absorb additional hospital closures is declining.²⁶⁰

Oversight of ambulance services occurs through legislative and regulatory mandates, regional councils within the state, sponsor hospitals, and coordination with the State Department of Public Health Office of Emergency Medical Services.²⁶¹

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
- PsycInfo
- SCOPUS
- UpToDate
- Cochrane Systematic Review
- Lyman Maynard Stowe Library Catalog (University of Connecticut Health Center Library)
- National Ambulance Center: www.airambulance.net; www.careambulance.net; <http://medicalassociationofbillers.yuku.com/topic/3511>
- Connecticut Department of Public Health, Office of Emergency Medical Services: http://www.ct.gov/dph/lib/dph/public_health_code/sections/19a-179-1_to_19a-179-21_office_of_ems.pdf
- Internet (FDA, NLM, CDC, CWLA, CTgov)

Search terms included: Ambulance(s), Emergency Mobile Unit(s), ambulance service(s), emergency medical services, EMS.

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

CPHHP may have consulted with clinical faculty and staff 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 if necessary. Additionally, staff may have consulted

²⁵⁸ Silverman RA, Galea S, Blaney S, *et al.* 2007. The “vertical response time”: Barriers to ambulance response in an urban area. *Academic Emergency Medicine* 14(9):772-8.

²⁵⁹ Eckstein M, Chan LS. 2004. The effect of emergency department crowding on paramedic ambulance availability. *Annals of Emergency Medicine* 43(1):100-5.

²⁶⁰ Sun BC, Mohanty SA, Weiss R, *et al.* 2006. Effects of hospital closures and hospital characteristics on emergency department ambulance diversion, Los Angeles County, 1998 to 2004. *Annals of Emergency Medicine* 47(4):309-16.

²⁶¹ Gelder CM, Frantz R, and Bogucki S. 2005. Emergency medical care in Connecticut. *Prehospital Emergency Care* 9(2):219-26.

practitioners in the community for additional and/or specialized information if necessary.

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 requested and received 2007 and 2008 claims data from insurance companies and MCOs domiciled in Connecticut. Six insurers/MCOs provided ambulance services claims data for their fully insured group and individual plan participants. The six insurers/MCOs also provided information about ambulance services coverage in the self-funded plans they administer.

CPHHP and the CID contracted with Ingenix Consulting (IC) to provide actuarial and economic analyses of the mandated benefit. Further details regarding the insurer/MCO claims data and actuarial methods used to estimate the cost of the benefit and economic methods used to estimate financial burden may be found in Appendix II.

IV. Social Impact

1. The extent to which ambulance services are utilized by a significant portion of the population.

There are approximately 400,000 service responses by ambulances in Connecticut each year.²⁶² Approximately two-thirds of ambulance call volume is accounted for by Medicare and Medicaid recipients. The remaining one-third is accounted for by privately insured and uninsured patients.²⁶³

Not all ambulance service providers submit data electronically to the OEMS. Records show that in 2009, there were 335,390 service request calls for ambulances reported electronically that served 359,270 patients.²⁶⁴ Of these, 23,880 were for children under age 18; 161,603 were for females; and 138,739 were for males.²⁶⁵

2. The extent to which ambulance services 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 Part B covers ambulance services to or from a hospital or skilled nursing facility only when other transportation could endanger a person's health. Payment is based on ambulance costs for transport to the closest appropriate facility.²⁶⁶ Medicare covers emergency and non-emergency ground transportation and emergency air transportation as the severity of medical need/health condition requires.

Medicare pays 80 percent of the Medicare approved amount after an individual meets the yearly Part B deductible. Individuals pay 20 percent. In most cases, the ambulance company cannot charge the individual more than 20 percent of the Medicare-approved amount.²⁶⁷ Medicare requires suppliers to retain

²⁶² Personal communication. Connecticut Department of Public Health.

²⁶³ Van Gelder CM, Frantz R, Bogucki S. 2005. Emergency medical services in Connecticut. *Prehospital Emergency Care* 9:219-26.

²⁶⁴ Connecticut Department of Health. Division of Emergency Medical Services. Quarterly Provider Report for the 2009 Calendar Year. Available at: http://www.ct.gov/dph/cwp/view.asp?a=3127&q=387370&dphNav_GID=1827&dphNav=. Accessed December 8, 2010.

²⁶⁵ *Ibid.*

²⁶⁶ Medicare Coverage Guidelines for Ambulatory Services (Connecticut).

²⁶⁷ *Ibid.*

appropriate documentation that contains information about the personnel involved in the transport and the patient's condition.

Public Programs Administered by Charities

No information was found that would indicate public programs administered by charities would be a source of funding for ambulance services. Much of the geographic area of the state relies on volunteer ambulance services for basic life support functions and some volunteer services do not bill patients for services provided.²⁶⁸ In addition, several towns are served by private non-profit or hospital-based ambulance service providers.

Public Programs Administered by Public Schools

No information was found that would indicate public schools would be a source of funding for ambulance services or provide ambulance services.

The Department of Public Health (DPH)

The Office of Emergency Medical Services in DPH licenses or certifies and provides oversight of the state's ambulance services providers but does not provide ambulance services. Many volunteer ambulance service providers rely on local mutual aid for advanced life support services.²⁶⁹

Municipal Health Departments

Approximately 10 towns in Connecticut provide basic life support ambulance services through their municipal health department.²⁷⁰ Advanced life support ambulance services in these communities may be provided through commercial, private non-profit, or hospital-based ambulance service providers.

The Department of Social Services (DSS)

Medicaid covers transportation when needed to obtain necessary medical services covered by Medicaid, and when it is not available from volunteer organizations, other agencies, personal resources, or is not included in the medical provider's Medicaid rate.²⁷¹ Medicaid only pays for trips to/from a medical provider for the purpose of obtaining services covered by Medicaid. DSS pays directly for emergency and non-emergency ambulance services. For all transportation, payments are made at the lower of:

- the usual and customary charged to the public if applicable,
- the Medicare rate, if one exists,
- the fee, as published by the Department in its fee schedule, or
- the amount requested or billed.²⁷²

3. The extent to which insurance coverage is already available for ambulance services.

State of Connecticut law requires coverage for medically necessary ambulance services in group and individual health insurance plans as of October 1, 2002.²⁷³ 2007 and 2008 claims data from six insurers/MCOs that cover 90 percent of the population in fully insured group and individual insurance plans in Connecticut showed evidence that claims are paid for the mandated services. Information received from the six insurers/MCOs domiciled in Connecticut shows that 94.3 percent of members in self-funded plans have

²⁶⁸ Van Gelder CM, Frantz R, Bogucki S. 2005. Emergency medical services in Connecticut. *Prehospital Emergency Care* 9: 219-26.

²⁶⁹ *Ibid.*

²⁷⁰ *Ibid.*

²⁷¹ DSS Provider Manual, Transportation, Available at: https://www.ctdssmap.com/CTPortal/Information/Get%20Download%20File/tabid/44/Default.aspx?Filename=ch7_iC_transportation_V1.0.pdf&URI=Manuals/ch7_iC_transportation_V1.0.pdf. Accessed January 3, 2011.

²⁷² U.S. Department of Health and Human Services. Health Resources and Services Administration. Connecticut Medicaid Covered Services. Available at: <http://www.hrsa.gov/reimbursement/states/Connecticut-Medicaid-Covered-Services.htm>. Accessed January 3, 2011.

²⁷³ CONNECTICUT GENERAL STATUTES ANNOTATED § 38A-493 (INDIVIDUAL INSURANCE POLICIES); § 38A-520 (GROUP INSURANCE POLICIES).

coverage for the benefit.

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 is required and generally available for persons enrolled in fully insured group and individual health insurance plans. Information received indicates that coverage is also generally available for persons covered by self-funded plans as well as for persons enrolled in Medicare and Medicaid. Due to the nature of the services provided, services are not withheld due to lack of insurance coverage at the point of delivery. Thus on the whole, health insurance coverage status is not a barrier to care.

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 ambulance services is required to be included in fully insured group and individual health insurance plans issued in Connecticut and is routinely included in self-funded plans, and is therefore generally available. Most ambulance services are a relatively low cost health service and the amount that can be charged by providers is regulated, thus even for uninsured or low-income individuals, unreasonable financial hardships specifically due to ambulance service costs alone are unlikely. For the uninsured, ambulance costs can add to the significant burden of health care costs associated with the health problem that precipitated the required ambulance service.

Further discussion of financial and socioeconomic effects of the mandated benefit for ambulance services may be found in Appendix II: Ingenix Consulting Actuarial and Economic Report, page 47-48.

6. The level of public demand and the level of demand from providers for ambulance services.

Medical librarians and CPHHP staff found no published literature regarding the level of public demand or level of demand from providers for medically necessary ambulance services. Because ambulance services are provided in emergency situations and allow for the delivery of emergency medical services on site and during transportation to hospitals, as well as rapid transportation to hospitals, public and provider demand is likely to be high.

7. The level of public demand and the level of demand from providers for insurance coverage for ambulance services.

Two persons associated with ambulance services testified in favor of insurance coverage for the mandated services during the time legislation for the mandated benefit was under consideration by the Connecticut General Assembly in March 2002.²⁷⁴

Evidence of the level of demand for insurance coverage of ambulance services is indicated by its wide availability in self-funded plans. According to the self-funded plan information received as part of this study, over 94 percent of persons enrolled in self-funded plans in Connecticut have coverage for ambulance services.

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

The Council for Affordable Health Insurance reports that eleven states including Connecticut have

²⁷⁴ Connecticut General Assembly. Report on Bills Favorably Reported By Committee. Insurance and Real Estate Committee. HB-5566. March 14, 2002.

coverage mandates for ambulance services.²⁷⁵ The states listed are Arizona, Connecticut, Florida, Louisiana, Michigan, Mississippi, Nevada, New York, Oklahoma, Pennsylvania, and Rhode Island. The National Association of Insurance Commissioners does not list states with coverage mandates for ambulance services.²⁷⁶

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

Thirty states now require a fiscal note or an additional review process for any new required health insurance benefit prior to enactment.²⁷⁷ States may also review existing health insurance mandates periodically. Internet searches and telephone inquiries found no studies from state agencies and public organizations related to the social impact of mandated insurance coverage for medically necessary ambulance services. Internet searches and/or telephone inquiries were conducted for 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 California, Colorado, Louisiana, Maine, Maryland, Massachusetts, New Jersey, Pennsylvania, Texas, Virginia, Washington, and Wisconsin.

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

Ambulance services provide emergency medical care on-site and in transit as well as ground and air transport to hospitals for persons in need of immediate health care. No alternatives to ambulance services are currently apparent.

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.

Ambulance services fulfill medical needs. Specifically, ambulances provide advanced or basic life support and transportation to hospitals for persons requiring immediate medical attention. Ambulances often respond to calls for persons involved in accidents, experiencing cardiovascular distress, or other serious medical problems. The ambulance services covered by the statute are required to be medically necessary, which provides further evidence that the mandated service is a medical need.

One role of health insurance is to cover unexpected health care costs. Because ambulances are used in emergency situations, the benefit is consistent with the role of health insurance. The statutes state that ambulance services benefits “shall be subject to any policy provision which applies to other services covered by such policies.”²⁷⁸ However, some aspects of managed care, for example, prior authorization, are not applicable. Health insurance plans generally do not require emergency services to be provided in-network or with prior authorization or a referral from a primary care provider.

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 enacted for other types of emergency or trauma-related services. If denials of insurance coverage for a medical service similar to ambulance services were viewed as withholding a medically necessary treatment, restricting access for a particular constituency or

²⁷⁵ Bunce VC, Wieske JP. 2009. Health insurance mandates in the states 2009. Council for Affordable Health Insurance. Available at: http://www.cahi.org/cahi_contents/resources/pdf/HealthInsuranceMandates2009.pdf. Accessed May 6, 2010.

²⁷⁶ NAIC Compendium of State Laws on Insurance Topics. National Association of Insurance Commissioners. August 2008.

²⁷⁷ 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.

²⁷⁸ CONNECTICUT GENERAL STATUTES ANNOTATED § 38A-498B (INDIVIDUAL INSURANCE POLICIES); § 38A-525B (GROUP INSURANCE POLICIES).

otherwise unfair in some way it is possible that mandated coverage could be proposed where currently, mandated coverage does not exist.

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-mandated benefits currently offered. However, the availability of any benefits 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. Near-universal coverage in self-funded plans suggests the mandated benefit for ambulance services has little impact on the availability of other benefits currently offered.

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

The extent to which required coverage for medically necessary ambulance services contributed to employer decisions to shift to a self-funded plan following passage of the ambulance services mandate is unknown. It is not anticipated that any more employers will shift to self-funded plans as a result of this single mandate. It is also not anticipated that repeal of this single mandate would lead to a shift from self-funded plans to fully insured plans among employers. Employers cognizant of the cumulative financial effects of mandated benefits and large enough to assume the risk of employee health care costs are more likely to consider shifting to self-funded 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 considering a shift to self-funded plans are likely to weigh these and other factors prior to reaching a decision. Employers also may shift to plans with higher coinsurance amounts to keep premiums at a more affordable level (“benefit buy down”). This can result in employees not taking up coverage and thus being uninsured, or not accessing care when it is needed because of high deductibles.

Six health insurers/MCOs domiciled in Connecticut provided information about self-funded plans for which they administer benefits. Over 94 percent of Connecticut residents in self-funded plans have coverage for the mandated services. Because coverage for ambulance services is typically included in health insurance plans not subject to state regulation, it is likely that the mandate has little to no 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.

The ambulance services mandate is a current benefit that has been included in the state employee health insurance and health benefits plans at least in part since 2002. Thus 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 Medicare²⁷⁹ 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.

State employee claims are included in the 2007 and 2008 claims data provided by insurers/MCOs for their fully insured group insurance enrollees. Because the state shifted to self-funded status on July 1, 2010 (during the time this report was being written), utilization under self-funded status is unknown. Self-funded plans, including those that provide coverage for state employees, are not regulated by the state insurance

²⁷⁹ Personal communication. Scott Anderson, State of Connecticut Comptroller’s Office. September 14, 2010.

department and are exempt from state health insurance required benefit statutes.

In terms of financial impact, if the state employee health insurance/benefit plans continue to provide coverage for the required benefit, the IC actuarial analysis estimates the medical cost to the state employee health insurance plan will total \$4,478,667 in 2010.²⁸⁰

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

Compared to the alternatives, ambulance services are generally safe and effective in providing prehospital care and transporting patients to hospitals and emergency departments. In most jurisdictions ambulance services are strictly regulated to ensure adequately trained personnel are available to respond, properly equipped vehicles are used, and effective coordination with the other emergency systems/personnel and health care providers/facilities occurs. Ground transportation is appropriate for the majority of patients and air transport is generally available for critically ill or injured patients when ground transport would be dangerously long or for patients in need of care and transport in remote or inaccessible areas. Studies document the effectiveness of the use of ambulance services for improved health outcomes for several diseases. For example, one study documents that an ambulance was used in 53.4 percent of patients with myocardial infarction (MI). Patients with MI transported to the hospital by ambulance had greater and significantly faster receipt of initial reperfusion therapies.²⁸¹ The authors concluded that wider use of ambulance services by patients with suspected MI may offer considerable opportunity for improvement in public health.

One of the major safety concerns is the rising number of ambulance crashes. Available data indicates increasing numbers of ambulance crashes each year.^{282,283} One study found that nearly nine percent of emergency medical technicians reported being involved in an ambulance crash within the past ten months.²⁸⁴ The odds of an ambulance crash were significantly higher for younger EMS professionals and those reporting sleep problems.²⁸⁵ For helicopter ambulance services, weather and pilot decision making are the main reasons for crashes.²⁸⁶

Several factors can negatively impact the effectiveness of ambulance services. Response time is an important factor for effectiveness, and it can be affected by distance, landscape features, urban and highway design, and type of building structure.²⁸⁷ Hospital and emergency department closures and access to appropriate trauma care also affect the effectiveness of ambulance services; however such barriers reflect the limitations of the

²⁸⁰ The estimate is calculated by multiplying the estimated 2010 weighted average PMPM medical cost in fully insured plans in Connecticut by 12 to get an annual cost per insured life, and then multiplying that product by 163,334 covered lives, as reported by the State Comptroller's office. The actual cost of this 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 this mandated benefit would be in addition to the above amount. See Appendix II, Ingenix Consulting Actuarial and Economic Report, for further discussion.

²⁸¹ Canto JG, Zalenski RJ, Ornato JP, *et al.* 2002. Use of emergency medical services in acute myocardial infarction and subsequent quality of care: observations from the National Registry of Myocardial Infarction 2. *Circulation* 106(24): 3018-23.

²⁸² McCallion T. 2007. Ambulance safety first: experts convene to discuss personal and patient safety issues. *JEMS* 32(6): 44-7.

²⁸³ Worth T, Elgin N. 2009. Medevac crashes on the rise. *American Journal of Nursing* 109(2): 27-8.

²⁸⁴ Studnek JR, Fernandez AR. 2008. Characteristics of emergency medical technicians involved in ambulance crashes. *Prehospital Disaster Medicine* 23(5): 432-7.

²⁸⁵ *Ibid.*

²⁸⁶ Dery M, Hustuit J, Boschert G, *et al.* 2007. Results and recommendations from the helicopter EMS pilot safety survey 2005. *Air Medical Journal* 26(1): 38-44.

²⁸⁷ Silverman RA, Galea S, Blaney S, *et al.* 2007. The "vertical response time": Barriers to ambulance response in urban areas. *Academic Emergency Medicine* 14(9): 772-8.

health care system at large rather than that of ambulance services specifically.^{288,289,290} Emergency department crowding can also negatively affect the ambulance services system because it causes delayed availability of ambulances while waiting to transfer patients to an open emergency department gurney²⁹¹ The authors conclude that the decrease in availability may have a significant effect on emergency medical services systems' abilities to provide timely response.²⁹² When training of ambulance services personnel is inadequate, mistakes regarding decisions about patients' need for ambulance services can occur. In one study, nine percent of patients who ambulance personnel determined did not need the ambulance were considered to be under-triaged.²⁹³ The same study noted that 46 percent of under-triaged patients had dementia or a psychiatric disorder as one of their presenting complaints.

IV. Financial Impact

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

The mandate is not expected to materially alter the availability or cost of medically necessary ambulance services over the next five years. The mandated benefit is included in most self-funded plans, thus the presence of the insurance mandate is not expected to have any additional effect on the cost of ambulance services. In addition, most patients accessing ambulance services are covered by public insurance programs and less than one-third of transported patients in Connecticut are covered by private insurance.²⁹⁴

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

For those persons whose insurance plans would not otherwise cover medically necessary ambulance services as defined in the statute, the mandated health benefit may increase appropriate use of the service. For those covered by self-funded plans, use out-of-pocket funds, or receive funding for ambulance services from other sources, a mandated benefit may not increase appropriate use. However, it is not uncommon for the mandated benefit to be included in self-funded plans that are not subject to state benefit mandates.

Inappropriate use is not expected to be a potential factor due to the nature of the service.

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.

Not applicable. Medically necessary ambulance services do not serve as an alternative for any other treatment, service or equipment, supplies or drugs.

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

²⁸⁸ Sun BC, Mohanty SA, Weiss R, *et al.* 2006. Effects of hospital closures and hospital characteristics on emergency department ambulance diversion, Los Angeles County, 1998 to 2004. *Annals of Emergency Medicine* 47(4): 309-16.

²⁸⁹ Nance ML, Carr BG, Branas CC. 2009. Access to pediatric trauma care in the United States. *Archives of Pediatric and Adolescent Medicine* 163(6): 512-8.

²⁹⁰ Klein MB, Kramer CB, Nelson J, *et al.* 2009. Geographic access to burn center hospitals. *Journal of the American Medical Association* 302(16): 1774-81.

²⁹¹ Eckstein M, Chan LS. 2004. The effect of emergency department crowding on paramedic ambulance availability. *Annals of Emergency Medicine* 43(1): 100-5.

²⁹² *Ibid.*

²⁹³ Schmidt TA, Atcheson R, Federiuk C. 2001. Hospital follow-up of patients categorized as not needing an ambulance using a set of emergency medical technician protocols. *Prehospital Emergency Care* 5(4): 366-70.

²⁹⁴ Van Gelder CM, Frantz R, Bogucki S. 2005.

It is anticipated that insurers and MCOs utilize the same utilization management methods and cost controls that are used for other covered benefits. The legislation allows insurers to subject the benefit to any policy provision which applies to other services covered by such policies. Additionally, ambulance services rates are regulated through the Department of Public Health.

5. The extent to which insurance coverage for ambulance services 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 II, Ingenix Consulting Actuarial and Economic Report, page 15.)

Group plans: When the medical cost of the mandate is spread to all insureds in group plans, medical costs are estimated to be \$2.27 PMPM and retention costs are estimated to be \$0.46 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$2.73 PMPM in 2010. Insurance coverage for the mandated benefit may be reasonably expected to increase group health insurance premiums accordingly, that is, \$32.76 per year per insured.

Individual plans: When the medical cost of the mandate is spread to all insureds in individual plans, medical costs are estimated to be \$1.25 PMPM and retention costs are estimated to be \$0.37 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$1.62 PMPM in 2010. Insurance coverage for the mandated benefit may be reasonably expected to increase individual health insurance premiums accordingly, that is, \$19.44 per year per insured.

For further information, please see Appendix II: Ingenix Consulting Actuarial and Economic Report.

6. The extent to which ambulance services 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.

Not applicable. At present, there seem to be no equally safe and effective alternatives. Medical librarians and CPHHP staff found no published literature documenting any equally safe and effective methods for transporting certain patients to hospitals.

7. The impact of insurance coverage for ambulance services 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 of claims data received from insurers/MCOs in Connecticut shows an expected cost in 2010 of \$37,624,143 for ambulance services for Connecticut residents covered by fully insured group and individual health insurance plans.

There may be potential savings or financial benefits resulting from stabilizing patients on the scene and immediate transport to a hospital for certain patients. Medically necessary ambulance services are provided in cases of emergency such as trauma-related injuries, heart attack, and other life-threatening circumstances. Basic and advanced life support provided by ambulance personnel may prevent death as well as adverse medical outcomes such as brain damage or other complications that may be more costly to treat both in the hospital setting and following discharge.

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.*

No published literature was found regarding the effect of mandated coverage of ambulance services on the cost of health care for small employers. Small employers may be more sensitive to premium increases than other employers and the estimated impact of the mandate on insurance premiums in fully insured group plans (\$2.73 PMPM) suggests potential differences in effects among different sized employers.

For further information regarding the differential effect of the mandates on small group versus large group insurance, please see Appendix II: Ingenix Consulting Actuarial and Economic Report, page 31.)

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 required benefit in its current form became effective January 1, 2002, it is unlikely that the mandate, taken individually, has any impact on cost-shifting between private and public payers of health care coverage at present.

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 of claims data received from insurers/MCOs in Connecticut shows an expected impact on the over cost of health care delivery in 2010 of \$45,063,255 for medically necessary ambulance services for Connecticut residents covered by fully insured group and individual health insurance plans.

For further information, please see Appendix II, Ingenix Consulting Actuarial and Economic Report.

Volume IV

Chapter 8

Prescription Drug Coverage. Mail Order Pharmacies.

Review and Evaluation of Connecticut Statute

Chapter 700, §§ 38a-544 and 38a-510

Prescription Drug Coverage. Mail Order Pharmacies.

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Chapter 8. Table of Contents

- I. Overview..... 117
- II. Background..... 118
- III. Methods..... 119
- IV. Social Impact..... 120
 - Table IV.8.1. Retail Prescription Drugs Utilization..... 120
- V. Financial Impact..... 126

I. Overview

In Public Act 09-179, An Act Concerning Reviews of Health Insurance Benefits Mandated in this State, the Connecticut General Assembly directed the Connecticut Insurance Department (CID) to review statutorily mandated health benefits existing on or effective on July 1, 2009. This report is part of that review and was conducted following the requirements stipulated under Public Act 09-179. This review was a collaborative effort of Connecticut Insurance Department and the University of Connecticut Center for Public Health and Health Policy (CPHHP).

Connecticut General Statutes, Chapter 700, Sections 38a-544 and 38a-510 mandate that group and individual health insurance policies issued, renewed or continued in this state provide coverage for prescription drugs that are obtained by methods other than a mail order pharmacy. That is, medical insurance cannot require an insured to obtain prescription drugs from a mail order pharmacy, and cannot limit access to said drug in this manner.

Specifically, CGSA sec 38a-544 provides that:

No medical benefits contract on a group basis, whether issued by an insurance company, a hospital service corporation, a medical service corporation or a health care center, which provides coverage for prescription drugs may require any person covered under such contract to obtain prescription drugs from a mail order pharmacy as a condition of obtaining benefits for such drugs.

(b) The provisions of this section shall apply to any such medical benefits contract delivered, issued for delivery or renewed in this state on or after July 1, 1989.

§ 38a-510 mandates the same coverage in individual health insurance policies delivered, issued for delivery, renewed or continued in Connecticut.

In May 2010, CPHHP and Ingenix Consulting (IC) requested 2007 and 2008 claims data related to the mandated benefit from six 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 a review of the legislative history, reviews of pertinent literature and the Ingenix Consulting report, this review found the following:

Current coverage

This mandate has been in effect since July 1, 1989 (P.A. 89-374.).

Premium impact

Group plans: There is no claims data on which to base an estimate of the cost of the mandate.

Individual policies: There is no claims data on which to base an estimate of the cost of the mandate.

Self-funded plans

Five health insurers/MCOs domiciled in Connecticut provided information about their self-funded plans, which represents an estimated 47 percent of the total population in self-funded plans in Connecticut. These five insurers/MCOs report that 65 percent of enrollees in their self-funded plans have coverage for the mandated services.

This report is intended to be read in conjunction with the General Introduction to this volume and the

Ingenix Consulting Actuarial and Economic Report which is included as Appendix II.

II. Background

Advances in medications in the last several decades have contributed greatly to the prevention, management and cure of many debilitating diseases. Frequently, medications can reduce or avert more costly health care services such as hospitalization and surgery. However, pharmaceutical costs are one of the fastest growing medical expenses increasing nearly six times from 1990 to present.²⁹⁵ The increase in prescription drug expenditures is due in part to greater pharmaceutical research budgets, increased spending on advertising, the aging population, the rise of chronic diseases, the introduction of “lifestyle medications” (e.g. medications for baldness, acne, wrinkles, etc.) and increased use of newer, higher priced brand name drugs.²⁹⁶ U.S. residents spent approximately \$234 billion on prescription drugs in 2008, which represents 10 percent of national health expenditures.²⁹⁷ Prescriptions drugs utilization increased 39 percent from 1999 to 2009 resulting in 3,679,671,222 prescriptions being filled at retail pharmacies in the United States and 46,489,823 prescriptions being filled at retail pharmacies in Connecticut.²⁹⁸ Per capita, Connecticut residents filled 13.2 prescriptions at retail pharmacies in 2009 with women and senior citizens accessing medications at higher rates than men and younger residents.

Increased coverage and rising expenditures for prescription drugs have led to the greater use of cost containment measures. One approach is pharmacy benefit managers (PBMs), which administer prescription benefit programs for employers and health plans.²⁹⁹ PBM services include drug formulary development, manufacturer rebate negotiation and collection, specialty pharmaceutical distribution, and mail-order prescription delivery options. In 2004, mail order pharmacies dispensed 214 million prescriptions, representing 6.5 percent of the outpatient prescriptions in the U.S. Converting the 90-day drug supply typical of mail order pharmacies to a 30-day drug supply used by community pharmacies, mail order pharmacies dispensed an estimated 642 million prescriptions in 2004, representing 17.3 percent of the outpatient market.³⁰⁰

Studies have found that drug utilization is higher in patients who access their medication via mail order pharmacy than those who obtain their medication at community pharmacies.³⁰¹ For example, patients prescribed diabetes medication who switched to mail order pharmacy showed increased medication adherence rates and reduced health care services resulting in lower medical costs.³⁰² The higher drug utilization in patients accessing their medication via mail order pharmacies may be due in part to the larger drug supply (90 day supply from mail order pharmacies rather than 30 day supply from community pharmacies), lower costs, and less burdensome travel requirements. However, few studies have controlled for

²⁹⁵ Valluri, S, Seoane-Vazquez, E, Rodriguez-Monguio, R, *et al.* 2007. Drug utilization and cost in a Medicaid population: a simulation study of community vs. mail order pharmacy. *BMC Health Services Research* 7: 122-131.

²⁹⁶ Kaiser Family Foundation. Prescription Drug Costs. Available at: <http://www.kaiseredu.org/Issue-Modules/Prescription-Drug-Costs/Background-Brief.aspx>. Accessed January 2, 2011.

²⁹⁷ Kaiser Family Foundation. 2010. Prescription Drug Trends. Available at: <http://www.kff.org/rxdrugs/upload/3057-08.pdf> Accessed January 2, 2011.

²⁹⁸ Kaiser Family Foundation. State Health Facts. Available at: <http://www.statehealthfacts.org/profileind.jsp?ind=265&cat=5&rgn=8>. Accessed January 2, 2011.

²⁹⁹ Johnsrud, M, Lawson, KA, Shepherd, MD. 2007. Comparison of mail-order with community pharmacy in plan sponsor cost and member cost in two large pharmacy benefit plans. *Journal of Managed Care Pharmacy* 13(2): 122-134.

³⁰⁰ Valluri, S, Seoane-Vazquez, E, Rodriguez-Monguio, R, *et al.* 2007. Drug utilization and cost in a Medicaid population: a simulation study of community vs. mail order pharmacy. *BMC Health Services Research* 7: 122-131.

³⁰¹ *Ibid.*

³⁰² Devine, S, Vlahiotis, A, Sundar, H. 2010. A comparison of diabetes medication adherence and healthcare costs in patients using mail order pharmacy and retail pharmacy. *Journal of Medical Economics*, 13(2): 203-211.

patient characteristics that may influence medication utilization. In other words, patients who have higher medication adherence may be more inclined to select mail order pharmacy.

Many, but not all, prescriptions are less expensive through mail order than community pharmacies due to a reduction in drug product cost, lower dispensing fees and higher rebates.³⁰³ However, the increased utilization of mail order prescriptions may result in higher overall prescription drug expenditures in spite of a lower cost per unit.³⁰⁴ All medications have a certain amount of waste because of discontinuation due to tolerability issues, medication changes, and ineffectiveness. However mail order prescriptions may be particularly vulnerable to waste due to the larger drug supply per prescription.³⁰⁵ Additional costs associated with mail order pharmacy that are not found in community pharmacy include packaging, handling mailing, and drugs lost in the mail.³⁰⁶ On occasion, patients may request that their insurance company pay for an additional fill at a retail pharmacy if the delivery of the mail order prescription has been delayed incurring greater costs for both patient and carrier.

With the larger drug supply per prescription, mail order pharmacies can be effective for patients who use a high volume of prescription drugs for chronic conditions or for patients who cannot access community pharmacy services.³⁰⁷ Many prescriptions such as antibiotics that need to be filled in a timely manner or for a single incidence may be more suitable for community based pharmacies.

Medications, whether they are dispensed by a community or mail order pharmacy are generally safe and effective when used appropriately. Safeguards such as treatment guidelines by governmental institutes and professional medical organizations are in place to reduce risks. For example, the FDA must review and approve drugs before they are introduced into the U.S. market to ensure their safety and efficacy. The FDA works with drug sponsors during product development, and reviews the safety and efficacy data, proposed label, and advertising.³⁰⁸ In addition, a medical provider must be licensed to prescribe medications and a pharmacist must be licensed to dispense medications. An additional safeguard potentially provided by a community pharmacy is the more patient-focused role of the pharmacist who may be available to provide services, information and limited forms of direct patient care.³⁰⁹ For example, a community pharmacist may be immediately accessible and able to answer questions from patients regarding changes to the name or appearance of a medication, which is often the case when switching from brand-name to generic drugs. In addition, community pharmacies typically dispense medications in a more timely manner which in certain cases is essential for medical effectiveness.

However, the use of medications poses possible serious side effects, toxicity, and drug interactions. Medications, particularly psychotropic drugs, have a potential for misuse and dependency. A recent report by the National Institute on Drug Abuse identified certain psychotropic drugs among the most commonly abused prescription medications in the United States.³¹⁰

³⁰³ Valluri, S, Seoane-Vazquez, E, Rodriguez-Monguio, R, *et al.* 2007.

³⁰⁴ *Ibid.*

³⁰⁵ *Ibid.*

³⁰⁶ *Ibid.*

³⁰⁷ *Ibid.*

³⁰⁸ Laughren, TP. 2010. What's next after 50 years of psychiatric drug development: An FDA perspective. *Journal of Clinical Psychiatry* 71(9): 1196-1204.

³⁰⁹ Shah, B, Chewning, B. 2006. Conceptualizing and measuring pharmacist-patient communication: a review of published studies. *Research in Social and Administrative Pharmacy* 2:153-185.

³¹⁰ National Institute of Drug Abuse. 2001. Prescription drugs: abuse and addiction. NIH publication no. 01-4881. Bethesda: NIDA, NIH, DHHS.

III. Methods

CPHHP staff conducted literature searches using the Cochrane Review, Pubmed, Google, PsycInfo, and Google Scholar using the following search terms: mail order pharmacies, mail order medications, mail order prevalence/utilization, pharmacy services, community pharmacy, pharmacist services and medication adherence. 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 faculty from the University of Connecticut School of Pharmacy on matters pertaining to medical standards of care, traditional, current and emerging practices, and evidence-based practices 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 requested 2007 and 2008 claims data from insurance companies and MCOs domiciled in Connecticut. No claims data was provided due to the nature of the mandate. Five insurers/MCOs provided information about mail order pharmacy utilization in the self-funded plans they administer.

CPHHP and the CID contracted with Ingenix Consulting to provide actuarial and economic analyses of the mandated benefit. Further details regarding the actuarial methods used to estimate the cost of the benefit and economic methods used to estimate financial burden may be found in Appendix II.

IV. Social Impact

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

U.S. residents spent approximately \$234 billion on prescription drugs in 2008, which represents 10 percent of national health expenditures.³¹¹ Prescription drugs utilization increased 39 percent from 1999 to 2009 resulting in 3,679,671,222 prescriptions being filled at retail pharmacies in the U.S and 46,489,823 prescriptions being filled at retail pharmacies in Connecticut.³¹² Per capita, Connecticut residents filled 13.2 prescriptions at retail pharmacies in 2009 with women and senior citizens accessing medications at higher rates than men and younger residents (see Table IV.8.1).

³¹¹ Kaiser Family Foundation. 2010. Prescription Drug Trends. Available at: <http://www.kff.org/rxdrugs/upload/3057-08.pdf> Accessed January 2, 2011.

³¹² Kaiser Family Foundation. State Health Facts. Available at: <http://www.statehealthfacts.org/profileind.jsp?ind=265&cat=5&rgn=8>. Accessed January 2, 2011.

Table IV.8.1. Retail Prescription Drugs Utilization		
	Connecticut	U.S.
Total Number of Retail Prescription Drugs Filled at Pharmacies	46,489,823.0	3,679,671,222.0
Retail Prescription Drugs Filled at Pharmacies (Annual per Capita)	13.2	12.0
Retail Prescription Drugs Filled at Pharmacies (Annual per Capita by Gender)		
Male	10.7	9.4
Female	15.3	14.4
Retail Prescription Drugs Fill at Pharmacies (Annual Per Capita by Age)		
0-18 years	4.2	3.9
19-64 years	12.4	11.3
65+ year	31.7	31.2

In 2004, mail order pharmacies dispensed 214 million prescriptions, representing 6.5 percent of the outpatient prescriptions in the U.S. Converting the 90-day drug supply typical of mail order pharmacies to a 30-day drug supply used by community pharmacies, mail order pharmacies dispensed an estimated 642 million prescriptions in 2004, representing 17.3 percent of the outpatient market.³¹³

2. The extent to which the service 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

In 2006, The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 became effective and established a voluntary Medicare outpatient prescription drug benefit (Part D). The 47 million Medicare beneficiaries are eligible to enroll in private drug plans. The plans vary in benefit design, covered drugs and utilization management strategies.

Medicare does not appear to require enrollees to obtain prescription drugs from a mail order pharmacy as a condition of obtaining benefits for such drugs. However, Medicare does encourage and offer a mail-order program where enrollees get up to a 90-day supply of covered prescription drugs sent directly to their home. Medicare describes the mail-order program as a cost-effective and convenient way to fill prescriptions.³¹⁴

Public Programs administered by Charities

No information was found that would indicate public programs administered by charities provide services for coverage of prescription drugs obtained through pharmacies other than mail order pharmacies. However, most major pharmaceutical manufacturers offer limited drug assistance programs that may provide free medications through physician offices and community health centers. Pharmaceutical manufacturers' websites advertise programs for the unemployed, uninsured, and underinsured who qualify, as well as for insured individuals during appeals processes if their plans deny coverage of the medications they need. Patients may confront barriers in accessing free medications through these programs. For example,

³¹³ Valluri, S, Seoane-Vazquez, E, Rodriguez-Monguio, R, et al. 2007. Drug utilization and cost in a Medicaid population: a simulation study of community vs. mail order pharmacy. *BMC Health Services Research* 7: 122-131.

³¹⁴ Centers for Medicare and Medicaid Services. How Medicare Drug Plans use Pharmacies, Formularies, and Common Coverage Rules. Available at: <http://www.medicare.gov/Publications/Pubs/pdf/11136.pdf>. Accessed January 5, 2011.

guidelines for qualifications can be onerous and time-consuming; individuals need a “medical home” and an established relationship with a provider; paperwork may be burdensome; patients may need to activate a coupon prior to going to the pharmacy and coupons may be only valid for a one month supply. Examples of pharmaceutical manufacturers with drug assistance programs include Pfizer, Bristol-Myers Squibb, Eli Lilly and Company, Wyeth-Ayerst Laboratories, SmithKline Pharmaceuticals, Inc., Ortho-McNeil Pharmaceutical, Abbott Laboratories, Roche Laboratories, Inc., Novartis Pharmaceuticals, and Glaxo Wellcome Inc.^{315, 316}

Public Programs administered by Public Schools

No information was found that would indicate public schools provide services for coverage of prescription drugs obtained through pharmacies other than mail order pharmacies

Department of Public Health (DPH)

No information was found that would indicate the Connecticut Department of Public Health provides services for coverage of prescription drugs obtained through pharmacies other than mail order pharmacies.

DPH distributes general fact sheets about Community Health Centers (CHCs) and include information about subsidized prescription drugs available to the public. Six Connecticut CHCs offer subsidized outpatient prescriptions through the 340B Pricing Plan for out-patient prescription drugs.

Municipal Health Departments

No information was found that would indicate municipal health departments provide services for coverage of prescription drugs obtained through pharmacies other than mail order pharmacies.

The Department of Social Services (DSS)

All state Medicaid programs cover prescription drugs for most beneficiary groups although policies vary in terms of co-payments, preferred drugs, and the number of prescriptions that can be filled. Since 2006, states have been required to reimburse Medicare for drug coverage for individuals who are dually eligible for Medicare and Medicaid.

Medicaid’s position on obtaining parallel drugs from a mail order pharmacy as a condition of obtaining benefits for such drugs appears to closely parallel Medicare’s position. Medicaid does not require enrollees to obtain drugs via mail order pharmacies, but encourages it.

3. The extent to which insurance coverage is already available for the service.

Connecticut law requires coverage for prescription drugs that can be obtained through pharmacies other than mail order pharmacies in fully insured group and individual health insurance plans that provide coverage for prescription drugs as of July 1, 1989.³¹⁷

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 is required and generally available for persons enrolled in fully insured group and individual health insurance plans that include coverage for prescription drugs. Persons enrolled in fully insured and self-funded group plans represent the vast majority of covered lives. Levels of patient cost-sharing vary

³¹⁵ Pfizer. 2010. Helpful Answers Program. Available at: <http://www.pfizerhelpfulanswers.com/pages/Programs/medicines.aspx?p=2>. Accessed: November 16, 2010.

³¹⁶ Pheil, P. 2010. Mental Health Today. Patient Assistance Programs Listed by Psychotropic Medication. Available at: <http://www.mental-health-today.com/medsassist.htm>. Accessed: November 16, 2010.

³¹⁷ CONNECTICUT GENERAL STATUTES ANNOTATED § 38A-530D (INDIVIDUAL INSURANCE POLICIES); § 38A-503D (GROUP INSURANCE POLICIES).

greatly depending on the prescription drug benefit plan and the cost of the drug prescribed. Medicare and Medicaid generally cover prescriptions.

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, Connecticut law requires coverage for prescription drugs that can be obtained through pharmacies other than mail order pharmacies in fully insured group and individual plans that include coverage for prescription drugs. Depending on the level of cost-sharing and personal financial resources available, that coverage may or may not be sufficient for the insured's family to avoid unreasonable financial hardship.

Further discussion of financial and socioeconomic effects of the mandated benefit may be found in Appendix II: Ingenix Consulting Actuarial and Economic Report, pages 48-49.

6 and 7. The level of public demand and the level of demand from providers for the service and level of public demand and the level of demand from providers for insurance coverage for the service.

There are some important considerations related to public and provider demand for the mandated benefit and for insurance coverage for the mandated benefit.

With rising expenditures for prescription drugs, offering medications via mail order pharmacies was introduced as a cost containment measure to benefit the consumer and insurance companies. In many cases, consumers benefit from mail order due to lower per unit cost, higher utilization, and reduction in travel time. However, mail order prescriptions may be particularly vulnerable to waste due to the larger drug supply per prescription and additional costs associated with shipping and handling.^{318, 319} Additionally, in a study comparing mail order and community pharmacy drug benefit costs for five employer-sponsored prescription drug benefit plans, mail order pharmacies were associated with higher costs to plan sponsors.³²⁰

Community pharmacies provide several services appealing to consumers and lacking in mail order pharmacies. For example, community pharmacist may be more patient-focused and available to offer information and limited forms of direct patient care.³²¹ Further, a community pharmacist may be immediately accessible and able to answer questions from patients regarding changes to the name or appearance of a medication, which is often the case when switching from brand-name to generic drugs. In addition, community pharmacies typically dispense medications in a more timely manner which in certain cases is essential for medical effectiveness.

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

According to the National Association of Insurance Commissioners, no states have a mandated insurance benefit similar to Connecticut's that require policies in fully insured plans to cover prescription drugs that can be obtained through pharmacies other than mail order pharmacies.³²²

9. The relevant findings of state agencies or other appropriate public organizations relating to the

³¹⁸ *Ibid.*

³¹⁹ *Ibid.*

³²⁰ Clark, BE, Siracuse, MV, Garis, RI. 2009. A comparison of mail-service and retail community pharmacy claims in 5 prescription benefit plans. *Research in Social Administrative Pharmacy* 5:133-142.

³²¹ Shah, B, Chewing, B. 2006. Conceptualizing and measuring pharmacist-patient communication: a review of published studies. *Research in Social and Administrative Pharmacy* 2:153-185.

³²² National Association of Insurance Commissioners. 2008. NAIC Compendium of State Laws on Insurance Topics.

social impact of the mandated health benefit.

Thirty states now require a fiscal note or an additional review process for any new required health insurance benefit prior to enactment.³²³ Internet searches and telephone inquiries found two studies from state agencies and public organizations related to the social impact of mandated insurance coverage for prescription drugs that can be obtained through pharmacies other than mail order pharmacies.

Pennsylvania: In January 2008, the Pennsylvania Health Care Cost Containment Council (PHC4) published a review of a proposed mandated health benefit for mail order prescriptions. PHC4 did not find sufficient information submitted to the Council to continue with a more formal review process. PHC4 noted that documentation lacked information that fully addressed the costs and financial benefits that might be associated with the mandate, and there was conflicting research on the costs of prescription drug benefits provided through mail-service pharmacies. The report also noted that opponents of the mandate raised concerns about the safety of mail-order dispensing, but not enough information was provide to determine the exact risk. Proponents stated that mail-service pharmacies have safety checks built into their system of fulfillment, and perform regular test mailings.³²⁴

Maryland: In December 2005, the Maryland Health Care Commission and the Maryland Insurance Administration reviewed SB 885, regarding mail-order purchase of maintenance drugs. Major findings include that the retail pharmacy protections have contributed to a lower use of mail order in the State. About 14 percent of prescription drug spending is spent at mail-order pharmacies, when nationally the share is over 18 percent. The report also notes that most insurance carriers and all PBMs can support mail-order programs, including mandatory mail order for 90-day supplies of maintenance drugs when permitted by law. Additionally, the report notes that the mandate would save consumers from \$7 million to \$16 million. However, the mandate would reduce revenue for retail pharmacies from \$88 million to \$210 million.³²⁵

States searched for which no evidence of a review was found include California, Colorado, Maine, Massachusetts, Virginia, Wisconsin, Louisiana, New Jersey, Washington and Texas.

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

Alternatives to obtaining prescription drugs through pharmacies other than mail order pharmacies include over the counter medicine, home remedies, complementary and alternative medicine (CAM), obtaining medications via foreign markets and forgoing treatment altogether.

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.

Obtaining prescription medications from sources other than mail order pharmacies fulfill a medical need. For example, prescriptions such as antibiotics that need to be filled in a timely manner or for a single incidence may be more suitable for community-based pharmacies. Furthermore, this mandate fulfills a social need by potentially decreasing overall medical costs. For example, the fewer doses typically dispensed by community-based pharmacies may reduce waste associated with medication tolerability issues, medication changes, and ineffectiveness. The statute also is consistent with the concept of managed care as it does not

³²³ 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.

³²⁴ Pennsylvania Health Care Cost Containment Council. 2008. Mandated benefits review, Senate Bill 260, Mail Order Prescription Drugs. Available at: <http://www.phc4.org/reports/mandates/SB260/docs/mandateSB260report.pdf>. Accessed December 8, 2010.

³²⁵ Maryland Health Care Commission. 2005. Mail-Order Purchases of Maintenance Drugs: Impact on Consumers, Payers, and Retail Pharmacies. Available at: <http://mhcc.maryland.gov/legislative/mailorderrpt.pdf>. Accessed December 8, 2010.

prohibit insurers/MCOs from using utilization review or other managed care tools at their disposal.

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

The mandate is narrow in scope. It is therefore difficult to anticipate any comparable benefit for other situations.

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-mandated benefits currently offered. However, the availability of any benefits 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. Due to the difficulty of isolating claims data related to this benefit, the impact of this specific mandate on the availability of other benefits is difficult to estimate.

For further information, see Appendix II: Ingenix Consulting Actuarial and Economic Report, page 22-23.

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

People enrolled in self-funded plans are expected to demand access to prescription drugs through their local community pharmacies in the same manner as persons covered in fully insured plans. Therefore, it is not anticipated that employers will shift to self-funded plans as a result of this single mandate. It is also not anticipated that repeal of this single mandate would lead to a shift from self-funded plans to fully insured plans among employers. Employers cognizant of the cumulative financial effects of mandated benefits and large enough to assume the risk of employee health care costs are the more likely to consider shifting to self-funded 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 considering a shift to self-funded plans are likely to weigh these and other factors prior to reaching a decision. Employers also may shift to plans with higher coinsurance amounts to keep premiums at a more affordable level (“benefit buy down”). This can result in employees not taking up coverage and thus being uninsured or not accessing care when it is needed because of high deductibles.

Five health insurers/MCOs domiciled in Connecticut provided information about their self-funded plans, which represents an estimated 47 percent of the total population in self-funded plans in Connecticut. These five insurers/MCOs report that 65 percent of enrollees in their self-funded plans have coverage for the mandated services.

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

This mandate is a current benefit that has been included in the state employee health insurance and health benefits plans since July 1, 1989. Thus 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 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.³²⁶

³²⁶ Personal communication. Scott Anderson, State of Connecticut Comptroller’s Office. September 14, 2010.

Because the state shifted to self-funded status on July 1, 2010 (during the time this report was being written), utilization under self-funded status is unknown. All self-funded plans, including those that provide coverage for state employees, are not regulated by the state insurance department and are exempt from state health insurance required benefit statutes. However, enrollees in self-funded plans, including state employees, are expected to demand access to prescription drugs through their local community pharmacies in the same manner as persons covered in fully insured plans.

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

Medications, whether they are dispensed by a community or mail order pharmacy are generally safe and effective when used appropriately. Safeguards such as treatment guidelines by governmental institutes and professional medical organizations are in place to reduce risks. For example, the FDA must review and approve drugs before they are introduced into the U.S. market to ensure their safety and efficacy. The FDA works with drug sponsors during product development, and reviews the safety and efficacy data, proposed label, and advertising.³²⁷ In addition, medical providers must be licensed to prescribe medications and a pharmacist must be licensed to dispense medications. However, the use of medications poses possible serious side effects, toxicity, and drug interactions. Medications, particularly psychotropic drugs, have a potential for misuse and dependency. A recent report by the National Institute on Drug Abuse identified certain psychotropic drugs among the most commonly abused prescription medications in the United States.³²⁸

One of the advantages of a community pharmacy is the more patient-focused role of the pharmacist who may be available to provide services, information and limited forms of direct patient care.³²⁹ For example, a community pharmacist may be immediately accessible and able to answer questions from patients regarding changes to the name or appearance of a medication, which is often the case when switching from brand-name to generic drugs. In addition, community pharmacies typically dispense medications in a more timely manner which in certain cases is essential for medical effectiveness.

IV. Financial Impact

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

The mandate is not expected to materially alter the availability or cost of prescription drugs over the next five years. Prescription drugs can be a high-volume, high-cost service and the presence of the insurance mandate is not expected to have any additional effect on its cost. Additionally, inclusion of mandated services in the majority of the self-funded plans further dilutes any effect the existence of a mandate may have on the cost of the service. The cost of the service is likely to increase (or decrease) at the same rate as any other medical service

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

Studies have found that drug utilization is higher in patients who access their medication via mail order

³²⁷ Laughren, TP. 2010. What's next after 50 years of psychiatric drug development: An FDA perspective. *Journal of Clinical Psychiatry* 71(9): 1196-1204.

³²⁸ National Institute of Drug Abuse. 2001. Prescription drugs: abuse and addiction. NIH publication no. 01-4881. Bethesda: NIDA, NIH, DHHS.

³²⁹ Shah, B, Chewning, B. 2006. Conceptualizing and measuring pharmacist-patient communication: a review of published studies. *Research in Social and Administrative Pharmacy* 2:153-185.

pharmacy than those who obtain their medication at community pharmacies.³³⁰ For example, patients prescribed diabetes medication who switched to mail order pharmacy showed increased medication adherence rates.³³¹ The higher drug utilization in patients accessing their medication via mail order pharmacies may be due in part to the larger drug supply (90 day supply from mail order pharmacies rather than 30 day supply from community pharmacies), lower costs, and less burdensome travel requirements. However, few studies have controlled for patient characteristics that may influence medication utilization. In other words, patients who have higher medication adherence may be more inclined to select mail order pharmacy.

3. The extent to which the mandated health benefit may serve as an alternative for more expensive or less expensive treatment, service or drug(s).

Both mail order and community pharmacies have cost advantages and disadvantages. The cost per unit can be lower in mail order than in community pharmacy due to a reduction in drug product cost, lower dispensing fees and higher rebates.³³² However, mail order pharmacy has costs that are not found in community pharmacy, including packaging, mailing, handling, and drugs lost in mail.³³³ Research findings suggest that patients accessing their medications via mail order pharmacy have increased utilization which may result in higher overall prescription drug expenditures in spite of a lower cost per unit.³³⁴ Furthermore, mail order prescriptions may lead to greater drug waste, due to tolerability issues, medication changes, and ineffectiveness.³³⁵ With larger drug supply in mail order (90 days), increased waste may be greater than drugs obtained from community pharmacies.

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 utilize the same utilization management methods and cost controls that are used for other covered benefits. The legislation does not prohibit insurers and MCOs from employing utilization management, prior authorization, pharmacy benefit managers (PBMs), or other utilization tools at their discretion.

5. The extent to which insurance coverage for the service 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).

Due to the difficulty of isolating claims data related to this benefit, an estimate of the increase or decrease in insurance premiums and administrative expenses for policyholders is not available. However, the provision of mandated services is not expected to significantly increase or decrease the insurance premiums or administrative expenses. When the cost of prescription drugs obtained through pharmacies other than mail order pharmacies is spread across the entire insured population the effect on premiums is likely to be extremely small.

³³⁰ Valluri, S, Seoane-Vazquez, E, Rodriguez-Monguio, R, *et al.* 2007. Drug utilization and cost in a Medicaid population: a simulation study of community vs. mail order pharmacy. *BMC Health Services Research* 7: 122-131.

³³¹ Devine, S., Vlahiotis, A, Sundar, H. 2010. A comparison of diabetes medication adherence and healthcare costs in patients using mail order pharmacy and retail pharmacy. *Journal of Medical Economics* 13(2): 203-211.

³³² Valluri, S, Seoane-Vazquez, E, Rodriguez-Monguio, R, *et al.* 2007.

³³³ *Ibid.*

³³⁴ *Ibid.*

³³⁵ *Ibid.*

For further information, please see the Appendix II: Ingenix Consulting Actuarial and Economic Report.

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

The cost per unit can be lower in mail order than in community pharmacy due to a reduction in drug product cost, lower dispensing fees and higher rebates.³³⁶ However, research findings suggest that patients accessing their medications via mail order pharmacy have increased utilization which may result in higher overall prescription drug expenditures in spite of a lower cost per unit.³³⁷ In a study comparing mail order and community pharmacy drug benefit costs for five employer-sponsored prescription drug benefit plans, co-payment incentives for mail order pharmacies were associated with higher utilization and higher costs to plan sponsors.³³⁸ Furthermore, discontinuation of medication is common and with larger drug supply (90 days) waste may be greater for mail order.³³⁹

Mail order may be more appropriate for patients with high adherence and who use a high volume of prescription drugs for chronic conditions. Prescriptions such as antibiotics that need to be filled in a timely manner may not be suitable for a mail order pharmacy.

7. *The impact of insurance coverage for the service 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.*

Due to the difficulty of isolating claims data related to this benefit, an estimate of the impact of the mandate on the total cost of health care is unknown. Studies have found that drug utilization is higher in patients who access their medication via mail order pharmacy than those who obtain their medication at community pharmacies.³⁴⁰ For example, patients prescribed diabetes medication who switched to mail order pharmacy showed increased medication adherence rates and reduced health care services resulting in lower medical costs.³⁴¹

To the extent that appropriate prescription drug utilization increases as a result of the mandate, the preventive effects of the use of such prescription drugs also increases.

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.*

No published literature was found regarding the effect of this mandate on the cost of health care for small employers. Although small employers may be more sensitive to premium increases than other employers, the lack of data from the carriers does not allow for estimated costs of the mandate among different types of employers.

For further information, please see the Appendix II: Ingenix Consulting Actuarial and Economic Report p.

³³⁶ Valluri, S, Seoane-Vazquez, E, Rodriguez-Monguio, R, *et al.* 2007. Drug utilization and cost in a Medicaid population: a simulation study of community vs. mail order pharmacy. *BMC Health Services Research* 7:122-131.

³³⁷ *Ibid.*

³³⁸ Clark, BE, Siracuse, MV, Garis, RI. 2009. A comparison of mail-service and retail community pharmacy claims in 5 prescription benefit plans. *Research in Social Administrative Pharmacy* 5:133-142.

³³⁹ *Ibid.*

³⁴⁰ *Ibid.*

³⁴¹ Devine, S, Vlahiotis, A, Sundar, H. 2010. A comparison of diabetes medication adherence and healthcare costs in patients using mail order pharmacy and retail pharmacy. *Journal of Medical Economics*, 13(2):203-211.

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. Due to the nature of this benefit, it is not expected to have an impact on cost-shifting between private and public payers either in the past or at present.

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. Due to the difficulty of isolating claims data related to this benefit no estimate of the financial impact of the mandated services on the overall cost of the health delivery system in the state is available.

For further information, please see Appendix II, Ingenix Consulting Actuarial and Economic Report.

Volume IV

Chapter 9

Co-payments Regarding In-network Imaging Services

Review and evaluation of CGSA §§ 38a-550 and 38a-511

Mandatory coverage of co-payments regarding in-network imaging services

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Chapter 9. Table of Contents

- I. Overview..... 133
- II. Background..... 134
- III. Methods..... 135
- IV. Social Impact..... 136
- V. Financial Impact..... 139

I. Overview

In Public Act 09-179, An Act Concerning Reviews of Health Insurance Benefits Mandated in this State, the Connecticut General Assembly directed the Connecticut Insurance Department to review statutorily mandated health benefits existing on or effective on July 1, 2009. 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.

CGSA §§ 38a-550 and 38a-511 mandate that group and individual health insurance policies issued, renewed, or continued in this state that provide coverage for MRIs, CT scans, or PET scans limit member co-pays or co-insurance to the amounts specified in the statutes.

Specifically, CGSA § 38a-550 provides that...

...Co-payments re in-network imaging services. (a) No health insurer, health care center, hospital service corporation, medical service corporation or fraternal benefit society that provides coverage under a group health insurance policy or contract for magnetic resonance imaging or computed axial tomography may (1) require total co-payments in excess of three hundred seventy-five dollars for all such in-network imaging services combined annually, or (2) require a co-payment in excess of seventy-five dollars for each in-network magnetic resonance imaging or computed axial tomography, provided the physician ordering the radiological services and the physician rendering such services are not the same person or are not participating in the same group practice.

(b) No health insurer, health care center, hospital service corporation, medical service corporation or fraternal benefit society that provides coverage under a group health insurance policy or contract for positron emission tomography may (1) require total co-payment in excess of four hundred dollars for all such in-network imaging services combined annually, or (2) require a co-payment in excess of one hundred dollars for each in-network positron emission tomography, provided the physician ordering the radiological service and the physician rendering such service are not the same person or are not participating in the same group practice.

(c) The provisions of subsections (a) and (b) of this section shall not apply to a high deductible health plan as that term is used in subsection (f) of section 38a-520.

(P.A. 06-180, S. 2)

§ 38a-511 mandates the same coverage in individual health insurance policies delivered, issued for delivery, renewed, or continued in Connecticut.

In March 2010, CPHHP and Ingenix Consulting (IC) requested and received 2007 and 2008 claims data related to the mandated benefit from six 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 that claims data, a review of the legislative history, reviews of pertinent literature and the Ingenix Consulting report, this review found the following:

Current coverage

This mandate has been in effect since 2006 (P.A.06-180).

*Premium impact*³⁴²

Group plans: When the cost of this mandate is spread to all insureds in group plans, the increase in medical cost is estimated to be \$1.00 PMPM and the retention cost is estimated to be \$0.20 PMPM in 2010.

Thus the total effect on insurance premiums is estimated at \$1.20 PMPM in 2010, which is 0.3 percent of premium. The member cost share is reduced by \$1.00 PMPM.

Individual plans: When the cost of this mandate is spread to all insureds in individual plans, the increase in medical costs is estimated to be \$0.69 PMPM and the retention cost is estimated to be \$0.21 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$0.90 PMPM in 2010, which is 0.3 percent of premium. The member cost share is reduced by \$0.69 PMPM. (Note: Individual data is less credible than group data primarily due to small sample size.)

Self-funded plans

Five health insurers/MCOs domiciled in Connecticut provided information about their self-funded plans, which represents an estimated 47 percent of the total population in self-funded plans in Connecticut. These five insurers/MCOs report that 94 percent of enrollees in their self-funded plans have coverage for these services. It is not known whether the self-funded plans limit co-pays and co-insurance to the amounts specified in the statutes.

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

II. Background

Magnetic Resonance Imaging (MRI)

Magnetic resonance imaging (MRI) was first introduced in the early 1980s. It is a diagnostic tool that uses a powerful magnetic field, radio frequency pulses, and a computer to produce detailed pictures of organs, soft tissues, bone, and virtually all other internal body structures. It is a noninvasive medical test that is used to diagnose and treat medical conditions. Unlike x-rays, CT scans and PET scans, MRIs do not use ionizing radiation.³⁴³

MRIs are used to examine the brain, spine, joints, abdomen and pelvis. They are also used to evaluate an abnormality seen on an x-ray, a sonogram, or a CT scan and can be used to diagnose soft tissue and organ abnormalities.³⁴⁴

Computed Axial Tomography Scanning (CT or CAT scanning)

CT or CAT scans were first introduced in 1974. They are noninvasive x-ray tests that produce cross-sectional images of the body using x-rays and a computer. These images allow a radiologist to look at the specific area of interest.

CT scans are frequently used to evaluate the brain, neck, spine, chest, abdomen, pelvis, and sinuses. They

³⁴² Ingenix Consulting report, Appendix II, p. 10.

³⁴³ RadiologyInfo.org. MRI of the Body (Chest, Abdomen, Pelvis). Available at: <http://www.radiologyinfo.org/en/info.cfm?pg=bodymr>. Accessed on January 4, 2011.

³⁴⁴ eMedicine. Magnetic Resonance Imaging (MRI). Available at: <http://www.imedicine.com/DisplayTopic.asp?bookid=99&topic=6622>. Accessed on January 4, 2011.

allow doctors to see diseases that, in the past, could often only be found at surgery or at autopsy.³⁴⁵

Positron Emission Tomography (PET scanning)

Positron emission tomography (PET) is a test that uses a special type of camera and a tracer (radioactive chemical) to look at organs in the body. The tracer usually is a substance (such as glucose) that can be used (metabolized) by cells in the body.

During the test, the tracer liquid is put into a vein in the arm. The tracer moves through the body, where much of it collects in the specific organ or tissue. The tracer gives off tiny positively charged particles (positrons). The camera records the positrons and turns the recording into pictures on a computer. PET scan pictures do not show as much detail as CT scans or MRIs.

A PET scan measures important body functions. It is often used to evaluate cancer, check blood flow, or see how organs are working. It is also used to evaluate the nervous system for conditions such as Alzheimer's disease, Parkinson's disease, multiple sclerosis, stroke, Huntington's disease, epilepsy, and schizophrenia.³⁴⁶

Today, most PET scans are performed on instruments that are combined PET and CT scanners. The combined PET/CT scans provide images that pinpoint the location of abnormal metabolic activity within the body. Use of the combined scans have been shown to provide more accurate diagnoses than the use of two scans performed separately.³⁴⁷

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, Cochrane Database, UpToDate, EMedicine and Web Search using Google.

General search terms used included: Magnetic Resonance Imaging, MRI, computed axial tomography, CT scan, Imaging technology, cost, cost-effectiveness, lack of access and safety.

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.

³⁴⁵ eMedicine. CT Scan. Available at: <http://www.imedicine.com/DisplayTopic.asp?bookid=99&topic=11618>. Accessed on January 4, 2011.

³⁴⁶ WebMD. 2009. Positron emission tomography. Available at: <http://www.webmd.com/a-to-z-guides/positron-emission-tomography>. Accessed on January 4, 2011.

³⁴⁷ RadiologyInfo.org. Positron emission tomography – Computed tomography (PET/CT). Available at: <http://www.radiologyinfo.org/en/info.cfm?pg=PET>. Accessed on January 5, 2011.

With the assistance of the Connecticut Insurance Department (CID), CPHHP and Ingenix Consulting requested and received 2007 and 2008 claims data from insurance companies and MCOs domiciled in Connecticut. Six insurers/MCOs provided claims data for their fully insured group and individual plan participants. Five insurers/MCOs also provided information about coverage in the self-funded plans they administer.

CPHHP and the CID contracted with Ingenix Consulting (IC) to provide actuarial and economic analyses of the mandated benefit. Further details regarding the insurer/MCO claims data and actuarial methods used to estimate the cost of the benefit and economic methods used to estimate financial burden may be found in Appendix II.

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.

A number of studies have found rapid increases in the use of medical imaging technology in the last ten years. A 2008 study found that the rate of CT scans in 2005 was 22 per 100 people.³⁴⁸ A CDC study found that the number of MRI, CT or PET scans that were ordered or delivered during physician office visits more than doubled from 1996 to 2006 to 3.9 per 100 visits. The number ordered or delivered during emergency department visits tripled, rising to 15.8 per 100 visits.³⁴⁹

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 Part A covers diagnostic tests like CT scans, magnetic resonance imaging (MRIs), EKGs, and X-rays. Medicare also covers clinical diagnostic tests performed in an inpatient hospital or nursing-facility. Part B covers an MRI performed on an outpatient basis, in any setting to diagnose an illness or injury.³⁵⁰

When an MRI diagnostic test is performed on an outpatient basis, the amount Medicare covers depends on the setting in which the MRI is provided. Medicare Part B pays for 80 percent of the Medicare-approved amount if the MRI is performed in a doctor's office, freestanding clinic, or independent testing facility. If the MRI is conducted in a hospital outpatient department, Part B pays the full Medicare-approved amount, except for a set co-payment.³⁵¹

Medicaid

Medicaid coverage of imaging services closely parallels the coverage provided by Medicare. Medicaid covers many different medically necessary imaging services including X-Rays, MRIs and CT scans.³⁵²

Connecticut Department of Public Health

³⁴⁸ Center for Studying Health System Change. 2008. Health Plans Target Advanced Imaging Services. Available at: <http://www.hschange.org/CONTENT/968/#ib3>. Accessed on January 5, 2011.

³⁴⁹ Freid V, Bernstein A. 2010. Health Care Utilization Among Adults Aged 55–64 Years: How Has It Changed Over the Past 10 Years? Available at: <http://www.cdc.gov/nchs/data/databriefs/db32.pdf>. Accessed on January 5, 2011.

³⁵⁰ Medicare Coverage Guidelines for X-Rays (Connecticut).

³⁵¹ *Ibid.*

³⁵² DSS Provider Fee Schedule: Independent Radiology.

The CT DPH licenses radiographers and physicians, but does not provide radiology or imaging services.

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

These co-pay limits have been mandated since 2006 in individual and group health insurance policies delivered, renewed, or amended in Connecticut.

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.*

Allowed medical costs for in-network complex medical imaging range from \$1200 to \$3200 for CT scans, \$1200 to \$4000 for MRIs and \$3000 to \$7000 for PET scans.³⁵³ Using the 20 percent co-insurance that is applied in Medicare B, the member cost-share could be substantial for those who require more than one such procedure in a year. This could result in some patients choosing not to undergo these tests.

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.*

For a person undergoing three MRIs in one year and assuming an average cost of \$3,000 per MRI, the actuarial report indicates that the cost of \$9,000 can cost up to 18 percent of a family's income for families earning \$50,000 annually, if there is no insurance for it.³⁵⁴ For these same three MRIs, if the patient has health insurance with 20 percent member cost-sharing, the \$1800 cost-sharing represents 3.6 percent of income for someone earning \$50,000. The mandate limits the cost-sharing to \$75.00 per MRI and reduces this burden to 0.45 percent of income if the MRI is performed by an in-network physician who is not affiliated with the prescribing physician.

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

A CDC study found that the number of MRI, CT or PET scans that were ordered or delivered during physician office visits more than doubled from 1996 to 2006 to 3.9 per 100 visits. The number ordered or delivered during emergency department visits tripled, rising to 15.8 per 100 visits.³⁵⁵

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 Radiological Society submitted testimony in favor of this legislation in 2006.

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

Research revealed no other states with this mandate.

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

In 2003, the Connecticut Department of Insurance issued a bulletin changing the restrictions on the amount of co-pay that could be imposed on insured members to no more than 50 percent.³⁵⁶ P.A. 06-180

³⁵³ Ingenix Consulting report, Appendix II, p. 27.

³⁵⁴ Ingenix Consulting report, Appendix II, p. 50.

³⁵⁵ Freid V, Bernstein A. 2010. Health Care Utilization Among Adults Aged 55–64 Years: How Has It Changed Over the Past 10 Years? Available at: <http://www.cdc.gov/nchs/data/databriefs/db32.pdf>. Accessed on January 5, 2011.

³⁵⁶ Connecticut Insurance Department. 2003. Bulletin PF-22. Available at: <http://www.ct.gov/cid/lib/cid/bullpf22.pdf>. Accessed on January 5,

was enacted in part as a response to this bulletin.³⁵⁷

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

Ultrasounds and conventional x-rays are alternatives to MRIs, CT scans and PET scans. However, they provide much less detail.³⁵⁸

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.*

MRIs, CT scans and PET scans are performed for the purpose of diagnosing, evaluating or screening for medical conditions. Health plan co-pays act to control over-utilization of a covered benefit and to lower premium cost, which is often shared between employer and employees.

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 benefits with co-pays or co-insurance associated with them.

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

Mandates generally increase the cost of insurance in conjunction with medical trends. Individuals and groups may respond at time of renewal by purchasing a lower level of coverage with increased member cost-sharing, rather than by dropping coverage altogether. High levels of member cost-sharing can act as a barrier to access, especially for low-income members.

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

Information received from the six insurers/MCOs domiciled in Connecticut representing an estimated 47 percent of the total self-funded population in Connecticut shows that 94 percent of members in self-funded plans have coverage for imaging services. It is not known whether the self-funded plans limit co-pays and co-insurance to the amounts specified in the statutes.

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

Because the State plans were fully insured in 2007 and 2008, the claims data from the carriers and the cost projections that are based on that data include the data from the State plans. Assuming that the State plans will continue to comply with this mandated health benefit, the total annual cost for this mandate in 2010 is estimated to be \$1,972,008. This has been calculated by multiplying the 2010 PMPM cost by 12 to get an annual cost per insured life, and then multiplying that product by 163,334 covered lives, which includes retired employees that are not eligible for Medicare, as reported by the State Comptroller's office.³⁵⁹

Caveat: This estimate is calculated using weighted averages for all claims paid by Connecticut-domiciled insurers and health maintenance organizations in the State. The actual cost of this mandate to the State

2011.

³⁵⁷ Associated Press. 2006. Reported by the Radiological Society of Connecticut. Democratic lawmakers rap state regulators over higher co-payments. Available at: <http://www.ctrad.org/PublishedArticles/pageView.asp?NewsletterID=31>. Accessed on January 5, 2011.

³⁵⁸ Brenner D, Hall E. Computed tomography – an increasing source of radiation exposure. 2007 *The New England Journal of Medicine* 2007; 357:2277-2284.

³⁵⁹ Personal communication with Scott Anderson, State Comptroller's office, September 14, 2010.

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.

Single CT scans are judged to be extremely safe and the benefits are deemed to far outweigh any risks. However, a number of studies have expressed concern over the cumulative effect of multiple CT scans because of the total exposure to radiation. The dose for single CT scans is generally low and safe, but it is many times higher than the dose for x-rays. CT studies often involve two or more scans and can result in dosages that pose an increased risk of cancer.³⁶⁰

The National Cancer Institute estimates that CT scans contribute 45 percent of the U.S. population's collective radiation dose from all medical x-ray examinations, although CT scans comprise only 12 percent of diagnostic radiologic procedures in large U.S. hospitals. CT is the largest contributor to medical exposure to the U.S. population.³⁶¹ The National Cancer Institute acknowledges CT scans as a crucial tool for diagnosis; however, it recommends that steps be taken by the medical community to limit its use to necessary procedures and to limit individual doses to the lowest amount possible, especially for children.

MRIs have a high level of safety, based on the large number of trouble-free studies that have been performed since the first use of them for clinical diagnosis.³⁶² However, MRIs expose the body to strong magnetic fields and they do pose a risk to patients with ferromagnetic foreign bodies in their bodies (such as pins, clips or shrapnel) or implanted electronic devices (such as pace-makers, infusion pumps, or neurostimulators). They can also pose a risk to patients and staff if ferromagnetic objects such as oxygen tanks or scissors are within the area of magnetic force.³⁶³

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

This mandate is limited to imaging services obtained from in-network providers who are not affiliated with the prescribing provider. Allowed costs are negotiated between the insurers/MCOs and the in-network providers, so the potential for this mandate to increase cost is limited to the shift of a portion of the co-pay from the member to the insurer/MCO.

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

³⁶⁰ Brenner D, Hall E. 2007. Computed tomography – an increasing source of radiation exposure. *The New England Journal of Medicine* 2007; 357:2277-2284.

³⁶¹ National Cancer Institute. Radiation Risks and Pediatric Computed Tomography (CT): A Guide for Health Care Providers. Available at: <http://www.cancer.gov/cancertopics/causes/radiation/radiation-risks-pediatric-CT>. Updated 12/08. Accessed on January 5, 2011.

³⁶² Schenck JF. 2000. Safety of strong, static magnetic fields. *J Magnetic Res Imag* 12:2-19.

³⁶³ Andersen E, Childre F. 2007. *AAOHN Journal* 55(4);137.

The IC report found that the reduced cost to individuals may have increased the use of these imaging services.³⁶⁴

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.*

MRIs, CT scans and PET scans are ordered instead of x-rays or sonography in many cases. The cost of x-rays and sonography are generally less than these more complex imaging procedures. They do not have the risks of exposure to radiation or magnetic fields associated with CT scans, MRIs and PET scans. They also do not pose problems for people who are claustrophobic.³⁶⁵ However, they generally do not give the same detail and clarity as the more complex imaging procedures.

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

This mandate is limited to imaging services obtained from in-network providers who are not affiliated with the prescribing provider. Insurers/MCOs can negotiate allowed costs with these providers. In addition, all other terms of the policy apply, so that utilization review can be exercised by the carriers to avoid inappropriate use of the imaging services.

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 II, Ingenix Consulting Actuarial and Economic Report, page 15.)

This mandate does not necessarily create new allowed costs, but it shifts a portion of the allowed cost from the member cost-share to the insurer/MCO's paid cost. It increases the insurer-paid medical cost, and the amount of that increase is the medical cost of this mandate. The retention cost of this mandate reflects 1) the greater cost of administering the co-pays on this benefit differently than the co-pays on other benefits under the same policy, and 2) the additional operational expenses associated with the mandate. These expenses include the cost of paying additional claims and producing marketing materials reflecting the plans and their benefits, etc.

Group plans: When the cost of this mandate is spread to all insureds in group plans, the increase in medical cost is estimated to be \$1.00 PMPM and the retention cost is estimated to be \$0.20 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$1.20 PMPM in 2010, which is 0.3 percent of premium. Member cost-share is reduced by \$1.00 PMPM.

Individual plans: When the cost of this mandate is spread to all insureds in individual plans, the increase in medical costs is estimated to be \$0.69 PMPM and the retention cost is estimated to be \$0.21 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$0.90 PMPM in 2010, which is 0.3 percent of premium. Member cost-share is reduced by \$0.69 PMPM. (Note: Individual data is less credible than group data primarily due to small sample size.)

³⁶⁴ Ingenix Consulting report, Appendix II, p. 51.

³⁶⁵ Nazarian L. 2008. The top 10 reasons musculoskeletal sonography is an important complementary or alternative technique to MRI. *AJR* 190;1621-1626.

For further information, please see Appendix II: Ingenix Consulting Actuarial and Economic Report.³⁶⁶

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.*

CT scans, MRIs, and PET scans are more expensive than x-ray or ultrasound.³⁶⁷ However, they are more effective than x-ray or ultrasound in many instances.

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. This mandate does not increase the total of medical costs plus cost sharing. It redistributes the total, shifting more of it to medical cost paid by the insurer/MCO and less of it to member cost share.

To the extent that the reduced cost share allows more members to comply with their treatment plan by obtaining the recommended complex imaging, this mandate is likely to increase utilization of these services. However, it may also result in reduced costs for treatment of conditions that are found and treated earlier as a result of the more detailed imaging provided by the covered services.

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.*

The actuarial report found that this mandate is expected to have roughly the same effect on the allowed cost of small group plans as it does on large group plans.³⁶⁸ 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.

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.*

This mandate does not result in cost-shifting between the public and private payers of health care coverage. It shifts some of the payment of negotiated allowed costs from the member cost-share to the insurer/MCO paid medical cost, thereby reducing member cost-share and increasing medical cost for the insurers/MCOs.

The only direct impact on the overall cost of the health care delivery system is the additional administrative costs necessitated by this mandate. The Ingenix Consulting report estimates this amounts to \$3,364,365.³⁶⁹

It may increase the utilization of these complex imaging services, thereby adding cost.

³⁶⁶ Ingenix Consulting report, Appendix II, p. 10.

³⁶⁷ Ingenix Consulting report, Appendix II, p. 27.

³⁶⁸ Ingenix Consulting report, Appendix II, p. 29.

³⁶⁹ Ingenix Consulting Summary Report.

Volume IV
Chapter 10
Comprehensive Rehabilitation Services

Review and Evaluation of Connecticut Statute

Chapter 700, § 38a-523

Group Hospital or Medical Insurance Coverage for Comprehensive Rehabilitation
Services

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Chapter 8. Table of Contents

- I. Overview..... 145
- II. Background..... 146
 - Table IV.10.1: Common clinical conditions in patients in need of comprehensive rehabilitation services 147
- III. Methods..... 148
- IV. Social Impact..... 149
- V. Financial Impact..... 156

I. Overview

The Connecticut General Assembly directed the Connecticut Insurance Department (CID) to review the health benefits required by Connecticut law to be included in fully insured group and individual health insurance policies as of July 1, 2009. Reviews are conducted following the requirements stipulated under Public Act 09-179 and are collaborative efforts of Connecticut Insurance Department and the University of Connecticut Center for Public Health and Health Policy (CPHHP).

Connecticut General Statutes, Chapter 700, § 38a-523 state that,

(1) Comprehensive rehabilitation services» shall consist of the following when provided in a comprehensive rehabilitation facility pursuant to a plan of care approved in writing by a physician licensed in accordance with the provisions of chapter 370 and reviewed by such physician at least every thirty days to determine that continuation of such services are medically necessary for the rehabilitation of the patient: (A) Physician services, physical and occupational therapy, nursing care, psychological and audiological services and speech therapy provided by health care professionals who are licensed by the appropriate state licensing authority to perform such services; (B) social services by a social worker holding a master's degree from an accredited school of social work; (C) respiratory therapy by a certified respiratory therapist; (D) prescription drugs and medicines which cannot be self-administered; (E) prosthetic and orthotic devices, including the testing, fitting or instruction in the use of such devices; (F) other supplies or services prescribed by a physician for the rehabilitation of a patient and ordinarily furnished by a comprehensive rehabilitation facility.

(2) Comprehensive rehabilitation facility» means a facility which is: (A) Primarily engaged in providing diagnostic, therapeutic and restorative services through such licensed health care professionals to injured, ill or disabled individuals solely on an outpatient basis and (B) accredited for the provision of such services by the Commission on Accreditation for Rehabilitation Facilities or the Professional Services Board of the American Speech-Language Hearing Association.

(3) Any insurance company, hospital or medical service corporation or health care center authorized to do the business of health insurance in this state shall offer to any individual, partnership, corporation or unincorporated association providing group health insurance coverage of the type specified in subdivisions (1), (2), (4), (6), (11) and (12) of section 38a-469 for its employees or members, a group hospital or medical service plan or contract providing coverage for expenses incurred for comprehensive rehabilitation services under such terms and conditions as are agreed to by the policyholder and the insurer.

In April 2010, CPHHP and Ingenix Consulting (IC) requested and received comprehensive rehabilitation claims data from six 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 shows that claims are being paid for comprehensive rehabilitation by health insurers and MCOs. The findings of this report are based on actuarial analysis of received claims data and reviews of pertinent literature and other information related to the mandated benefit.

Current coverage

Comprehensive rehabilitation is a mandatory offer mandate for group plans in Connecticut. Individual policies marketed in Connecticut are not required to include or offer comprehensive rehabilitation. This mandate originally went into effect in 1982 and was amended in 1990 (P.A. 82-20, S. 1, 2; P.A. 90-243, S. 107).

Premium Impact

Group plans: On a 2010 basis, medical cost is estimated to be \$2.42 per member per month (PMPM). Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services in 2010 in group plans is \$2.90 PMPM, which is approximately 0.8 percent of estimated total costs in group plans. Estimated cost sharing in 2010 in group plans is \$1.52 PMPM.

Individual policies: Not applicable.

Self-funded plans

Five health insurers/MCOs domiciled in Connecticut provided information about their self-funded plans, which represents an estimated 47 percent of the total population in self-funded plans in Connecticut. These five insurers/MCOs report that 78.8 percent of enrollees in their self-funded plans have coverage for the mandated services.

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

II. Background

As defined in the statute and for the purposes of this report, comprehensive outpatient rehabilitation services include physical therapy, occupational therapy, speech therapy, physician services, psychological services, social services performed by a social worker, respiratory therapy, drugs and medication, prosthetics and orthotics, and other supplies and services prescribed by a physician for the rehabilitation of the patient. These services must be provided in an accredited outpatient facility. Unlike most health insurance mandates in Connecticut, comprehensive outpatient rehabilitation is a mandatory offer mandate, which means the insurer is required to offer a policy that covers it, but the group buyer can choose whether it wants a policy with such coverage.

Segments of the research literature refer to post-acute rehabilitation, and some of this research is included in describing the background, safety, and effectiveness of comprehensive rehabilitation services. Additionally, because much of the geriatric population is covered by Medicare, efforts were made to include data and research based on the non-geriatric population when available; however, comprehensive rehabilitation services are frequently provided for geriatric populations and a significant portion of available research is based on this population. Similarly, many veterans injured during wars and conflicts often require rehabilitation services upon returning from active duty. Comprehensive rehabilitation services research based on these populations, while not summarily excluded, was carefully reviewed if included, because most care for the elderly and injured veterans is not funded through private health insurance policies.

Patients with many different illnesses, diseases, and conditions benefit from comprehensive outpatient rehabilitation. For details, see Table IV.10.1.³⁷⁰

³⁷⁰ Stucki G, Stier-Jarmer M, Grill E. 2005. Rationale and principles of early rehabilitation care after an acute injury or illness. *Disability and Rehabilitation* 27(7-8): 353-9.

Table IV.10.1: Common clinical conditions in patients in need of comprehensive rehabilitation services

<p>Patients with cardiopulmonary conditions:</p> <ul style="list-style-type: none"> • Coronary artery disease • Acute myocardial infarction, heart failure • Stable or instable angina pectoris • Coronary artery bypass grafting • Heart valve replacement • Heart or lung transplantation • Chronic obstructive pulmonary disease (COPD) • Asthma • ARDS (Acute respiratory distress syndrome) • Pneumonia • Lung cancer 	<p>Patients with neurological conditions:</p> <ul style="list-style-type: none"> • Diseases of the nervous system • Cerebrovascular diseases including stroke • Head injuries • Polytraumata • Spinal cord injuries • Tumor of the brain or other parts of the CNS • Patients after resuscitation
<p>Patients with musculoskeletal conditions:</p> <ul style="list-style-type: none"> • Musculoskeletal polytraumata • Singular musculoskeletal injuries • Arthropathies • Complex post knee and hip total arthroplasties • Spine disorders • Amputations 	<p>Geriatric patients:</p> <ul style="list-style-type: none"> • Cerebrovascular diseases including stroke • Musculoskeletal conditions including fractures • Injuries • Osteoarthritis or joint replacement • Cardiopulmonary disease including coronary heart disease and myocardial infarction • COPD

The services included for any one patient are organized through a plan of care developed by the patient’s treatment and rehabilitation providers and are dependent upon the unique physical and social rehabilitation needs resulting from the patient’s illness, disease, injury, or as part of the recovery process. Patients hospitalized for an acute illness or injury are at risk of experiencing a significant loss of functioning.³⁷¹ Rehabilitation aims to enable people experiencing or likely to experience disability to achieve and maintain optimal functioning.³⁷² Achieving and maintaining optimal functioning requires knowledge and skills from several different professionals collaborating as a team. For example, in cases of acquired brain injury (which can result from traumatic brain injury, stroke, brain tumors, or neurological disease), a very high proportion of patients require comprehensive rehabilitation services because complications of acquired brain injury are

³⁷¹ Stucki G, Stier-Jarmer M, Grill E. 2005.

³⁷² Rauch A, Cieza A, Stucki G. 2008. How to apply the International Classification of Functioning, Disability and Health (ICF) for rehabilitation management in clinical practice. *European Journal of Physical and Rehabilitation Medicine* 44(3): 329-42.

multifaceted.³⁷³

One of the most common tools used to measure functioning in rehabilitation is the International Classification of Functioning, Disability, and Health. Some studies also use quality of life measures in assessing the effectiveness of comprehensive rehabilitation, such as the World Health Organization Quality of Life-BREF (WHOQOL-BREF). Participation in outpatient rehabilitation has been shown to increase quality of life.³⁷⁴

Some disparities in access to comprehensive rehabilitation services are apparent in the research, including under-utilization by women,³⁷⁵ African American women,³⁷⁶ and minorities.^{377,378} Barriers to access to comprehensive rehabilitation services have been categorized as financial, structural, personal/sociodemographic, and attitudinal.³⁷⁹ These barriers have been described as essentially non-clinical in nature, yet they significantly affect use.³⁸⁰

There are some special or high risk populations that often require comprehensive rehabilitation services, including combat-wounded veterans and terror victims with multiple traumas and children with acquired brain injury. Such patients can present with multiple physical and psychological rehabilitation needs, including traumatic brain injury, amputations, and post-traumatic stress disorder.^{381,382,383} Speech-language therapy and audiology services are other important needs often addressed as part of the comprehensive rehabilitation services plan for these patients.³⁸⁴

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 and Scopus, and a web search using Google. Some of the search keywords used

³⁷³ Joint Committee on Interprofessional Relations Between the American Speech-Language-Hearing Association and Division 40 (Clinical Neuropsychology) of the American Psychological Association. 2007. Structure and function of an interdisciplinary team for persons with acquired brain injury. Available at www.asha.org/policy. Accessed January 10, 2011.

³⁷⁴ Ackerly SJ, Gordon HJ, Elston AF, *et al.* 2009. Assessment of quality of life and participation within an outpatient rehabilitation setting. *Disability and Rehabilitation* 31(11): 906-13.

³⁷⁵ Parkosewich JA. Cardiac rehabilitation barriers and opportunities among women with cardiovascular disease. *Cardiology in Review* 16(1): 36-52.

³⁷⁶ Allen JK, Scott LB, Stewart KJ, *et al.* 2004. Disparities in women's referral to and enrollment in outpatient cardiac rehabilitation. *Journal of General Internal Medicine* 19(7): 747-53.

³⁷⁷ Nguyen-Oghalai TU, Ottenbacher KJ, Kuo YF, *et al.* 2009. Disparities in utilization of outpatient rehabilitative care following hip fracture hospitalization with respect to race and ethnicity. *Archives of Physical Medicine and Rehabilitation* 90(4): 560-3.

³⁷⁸ Ottenbacher KJ, Campbell J, Kuo YF, *et al.* 2008. Racial and ethnic differences in post-acute rehabilitation outcomes after stroke in the United States. *Stroke* 39(5): 1514-9.

³⁷⁹ Ottenbacher KJ and Graham JE. 2007. The state-of-the-science: access to postacute care rehabilitation services. A review. *Archives of Physical Medicine and Rehabilitation* 88: 1513-21.

³⁸⁰ Buntin MB. 2007. Access to postacute rehabilitation. *Archives of Physical Medicine and Rehabilitation* 88: 1488-93.

³⁸¹ Sayer NA, Chiros CE, Sigford B. Characteristics and rehabilitation outcomes among patients with blast and other injuries sustained during the Global War on Terror. *Archives of Physical Medicine and Rehabilitation* 89(1): 163-70.

³⁸² Schwartz I, Tsenter J, Shochina M. 2007. Rehabilitation outcomes of terror victims with multiple traumas. *Archives of Physical Medicine and Rehabilitation* 88(4): 440-8.

³⁸³ Chevignard M, Toure H, Brugel DG, *et al.* 2010. A comprehensive model of care for rehabilitation of children with acquired brain injuries. *Child Care Health and Development* 36(1): 31-43.

³⁸⁴ Cherney LR, Gardner P, Logmann JA. 2010. The role of speech-language pathology and audiology in the optimal management of the service member returning from Iraq or Afghanistan with a blast-related head injury: position of the Communication Sciences and Disorders Clinical Trials Research Group. *Journal of Head Trauma and Rehabilitation* 25(3): 219-24.

include rehabilitation, comprehensive rehabilitation facility, patient care management, delivery of health care integrated, patient care team, rehabilitation nursing.

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 may have consulted with clinical faculty and staff 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. Additionally, staff may have consulted practitioners in the community for additional and/or specialized information.

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 and received 2007 and 2008 claims data from insurance companies and MCOs domiciled in Connecticut. Six insurers/MCOs provided claims data for their fully insured group plan participants. Five insurers/MCOs also provided information about comprehensive rehabilitation coverage in the self-funded plans they administer.

CPHHP and the CID contracted with Ingenix Consulting (IC) to provide actuarial and economic analyses of the mandated benefit. Further details regarding the insurer/MCO claims data and actuarial methods used to estimate the cost of the benefit and economic methods used to estimate financial burden may be found in Appendix II.

IV. Social Impact

1. The extent to which comprehensive rehabilitation services are utilized by a significant portion of the population.

Connecticut's estimated population covered by fully insured group health insurance plans is 1,220,577, or 40.8 percent of the total population.³⁸⁵ Although it is a "must offer" mandate, Connecticut insurers/MCOs appear to routinely include the benefit in fully insured plans. Therefore in general, it would seem that the benefit is available to approximately 40 percent of the total Connecticut population. Due to difficulties in isolating claims data for comprehensive rehabilitation services under the definitions listed in the statute, precise estimates of utilization of mandated services are not available.

CPHHP researchers found limited utilization data for stroke and heart attack survivors. For stroke and heart attack survivors, the Centers for Disease Control has published reports that document the percentage of survivors who receive outpatient rehabilitation for 21 states (including Connecticut) and the District of Columbia. For survivors of stroke age 18-64, 30.3 percent reported receiving outpatient rehabilitation;³⁸⁶ for

³⁸⁵ 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.

³⁸⁶ Centers for Disease Control and Prevention. 2007. Outpatient rehabilitation among stroke survivors—21 states and the District of Columbia, 2005. MMWR Weekly 56(20): 504-7.

heart attack survivors age 18-49, 25.3 percent received outpatient rehabilitation; and for survivors age 50-64, 35.5 percent received outpatient rehabilitation.³⁸⁷ In Connecticut for all ages, 46.5 percent received cardiac outpatient rehabilitation, which was over ten percent higher than the overall average (34.7 percent).

For further information please see Appendix II: Ingenix Consulting Actuarial and Economic Report, pages 11 and 27-28.)

2. The extent to which comprehensive rehabilitation services 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 Part B covers speech-language pathology, occupational therapy, and outpatient physical therapy. Medicare provides coverage for these services when a physician or therapist oversees a treatment plan, and the plan is periodically reviewed.³⁸⁸

Medicare limits coverage to \$1,860 for physical therapy and speech language pathology combined and to \$1,860 for occupational therapy.³⁸⁹ Medicare covers 80 percent and patients pay 20 percent of the therapy cost until the limit is reached, after which the patient pays 100 percent. Therapy limits apply when outpatient therapy is provided by physicians, speech-language pathologists, physical therapists, or nurse practitioners, and when provided at medical offices, skilled nursing facilities, or at the patient's home.³⁹⁰

Medicare limits do not apply to therapy services received in hospital outpatient departments or hospital emergency rooms.³⁹¹

Public Programs Administered by Charities

Hospitals and clinics may provide some comprehensive rehabilitation services for persons who are uninsured and do not qualify for public assistance. Some charitable organizations may also provide the services. For example, Easters Seals of Connecticut provides comprehensive rehabilitative services at facilities around the state. The organization does bill Medicare, Medicaid, and private insurance companies for their services. However, rehabilitative services may be provided at no cost for those without insurance. Staff members make efforts to help individuals who qualify for entitlement programs receive benefits.^{392, 393}

Public Programs Administered by Public Schools

No information was found that would indicate public schools would be a source of comprehensive rehabilitation services as defined in the statute or provide funding for comprehensive rehabilitation services as defined in the statute. Public schools may provide some of the services listed in the mandate to their students who require such services; however, schools are not recognized as comprehensive outpatient facilities

³⁸⁷ Centers for Disease Control and Prevention. 2008. Receipt of outpatient cardiac rehabilitation among heart attack survivors—United States, 2005. *MMWR Weekly* 57(04): 89-94.

³⁸⁸ Medicare.gov. 2010. Connecticut Coverage Under Medicare. Available at: <http://www.medicare.gov/Coverage/Search/Results.asp?State=CT%7CConnecticut&Coverage=50%7CPhysical%2C+Occupational%2C+and+Speech+Therapy&submitState=View+Results+%3E>. Accessed January 11, 2011.

³⁸⁹ Centers for Medicare and Medicaid Services. 2010. Medicare Limits on Therapy. Available at: <http://www.medicare.gov/Publications/Pubs/pdf/10988.pdf>. Accessed January 11, 2011.

³⁹⁰ *Ibid.*

³⁹¹ *Ibid.*

³⁹² Personal Communication. Janice, Billing Supervisor. Easter Seals Capital Region and Eastern Connecticut. January 6, 2011.

³⁹³ Easter Seals. Capital Region and Eastern Connecticut. Services.

Available at: http://hartford.easterseals.com/site/PageServer?pagename=CTHA_services. Accessed January 6, 2011.

as defined in the statute.

The Department of Public Health (DPH)

CPHHP researchers found no information on the provision of comprehensive rehabilitation services through the Connecticut Department of Public Health. Searches on the DPH website indicate a goal of covering rehabilitation services and therapies for Children with Special Health Care Needs.

Municipal Health Departments

No information was found that would indicate municipal health departments would be a source of comprehensive rehabilitation services or provide funding for comprehensive rehabilitation services as defined in the statute. Municipal health departments may assist residents in locating health-related information and resources in the community, including comprehensive rehabilitation services, and may provide referrals to providers.

The Department of Social Services (DSS)

Medicaid covers certain comprehensive rehabilitation services including physical therapy, occupational therapy, speech therapy, audiology, limited mental health services, functional therapy, day treatment programs for clients with acquired brain injury, and neuropsychological testing.³⁹⁴

In certain cases, the provider must receive prior authorization for specific services, including three or more visits per week for physical therapy, speech therapy or audiology; and two or more visits per week for occupational therapy.³⁹⁵

Medicaid does not cover services related solely to employment, work skills, or academic skills (reading, writing, and math), and services provided in a skilled nursing facility, intermediate care facility or intermediate facility for the mentally retarded.³⁹⁶

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

Connecticut law requires health insurers/MCOs to offer coverage for comprehensive rehabilitation services in fully insured group plans marketed in Connecticut.³⁹⁷ 2007 and 2008 claims data from six insurers/MCOs that cover 90 percent of the population in fully insured group and individual insurance plans in Connecticut showed evidence that claims are paid for the mandated services. Information received from five insurers/MCOs domiciled in Connecticut shows that 71.9 percent of members in their self-funded plans have coverage for the benefit. Ingenix Consulting actuarial analysis asserts that as a general practice most fully insured group plans in Connecticut include coverage for comprehensive rehabilitation services.

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 is generally available for persons enrolled in fully insured group health insurance plans. Coverage is also available to 71.9 percent of persons enrolled in self-funded plans. Persons enrolled in fully insured group and self-funded plans represent the majority of the insured population under age 65 in Connecticut. Coverage in individual health insurance plans is unknown and the mandate does not apply to individual

³⁹⁴ Connecticut Department of Social Services, Medical Care Administration, Connecticut Medicaid Summary of Services. Available at: <http://www.ct.gov/dss/lib/dss/pdfs/medicaidservicesv3kk.pdf>. Accessed January 11, 2011.

³⁹⁵ *Ibid.*

³⁹⁶ *Ibid.*

³⁹⁷ CONNECTICUT GENERAL STATUTES ANNOTATED § 38A-523.

health insurance policies.

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 comprehensive rehabilitation services as defined in the statute is generally included in fully insured group health insurance plans issued in Connecticut. Depending on the level of cost sharing and personal financial resources available, that coverage may or may not be sufficient for the insured's family to avoid unreasonable financial hardship.

Comprehensive rehabilitation services are generally required following treatment for a serious medical condition. For such patients and their families, significant health and economic costs may accrue, even for those with comprehensive health benefits. Additionally, lost work time and income are common for persons requiring comprehensive rehabilitation services, as well as other costs associated with illness and disease (e.g., travel) that are not covered by health insurance. 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 comprehensive rehabilitation services may be found in Appendix II: Ingenix Consulting Actuarial and Economic Report, page 51-52.

6. The level of public demand and the level of demand from providers for comprehensive rehabilitation services.

Medical librarians and CPHHP staff found no published literature regarding the level of public demand or level of demand from providers for comprehensive rehabilitation services as defined in the statute. Because comprehensive rehabilitation services are critical for restoration of functioning and independent living, public and provider demand is likely to be high.

7. The level of public demand and the level of demand from providers for insurance coverage for comprehensive rehabilitation services.

Medical librarians and CPHHP staff found no published literature regarding the level of demand from the public or from providers for insurance coverage for comprehensive rehabilitation services as defined in the statute.

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

According to the National Association of Insurance Commissioners, 15 states including Connecticut have an insurance mandate for at least one of the services/settings/policies included in the Connecticut mandate for comprehensive rehabilitation services.³⁹⁸ Most of the other 14 states mandate coverage for physical therapy, occupational therapy, and/or speech/language therapy. Texas is the only state that requires group and individual health insurance policies to include coverage for “outpatient rehabilitation therapy.”³⁹⁹ According to the Council for Affordable Health Insurance (CAHI), Connecticut is one of seven states with a mandate for “rehabilitation services.”⁴⁰⁰ The states with mandates listed by CAHI include Connecticut, Illinois, Louisiana, Massachusetts, Maine, Texas, and West Virginia.⁴⁰¹

³⁹⁸ National Association of Insurance Commissioners. 2008. NAIC Compendium of State Laws on Insurance Topics.

³⁹⁹ *Ibid.*

⁴⁰⁰ Bunce VC, Wieske JP. 2009. Health insurance mandates in the states 2009. Council for Affordable Health Insurance. Available at: http://www.cahi.org/cahi_contents/resources/pdf/HealthInsuranceMandates2009.pdf. Accessed May 6, 2010.

⁴⁰¹ *Ibid.*

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

Thirty states now require a fiscal note or an additional review process for any new required health insurance benefit prior to enactment.⁴⁰² 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 comprehensive rehabilitation services 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.

A number of states have issued benefit reviews for some of the individual components of the Connecticut mandate or a medical condition that precipitates the need for comprehensive rehabilitation services (e.g., prosthetic/orthotic devices, autism spectrum disorders). The reports focus on the impact of these services and conditions specifically, rather than the social impact of comprehensive rehabilitation on the whole.

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

Comprehensive rehabilitation services as defined in the statute provide a range of services tailored for individual needs of patients as directed through a physician-approved plan of care. Alternatives to comprehensive rehabilitation services may include provision of the services independent of a physician-approved plan of care or in a different setting (e.g., inpatient rehabilitation or home health care). Such alternatives may not be able to take full advantage of the efficiencies of care coordination and the high degree of communication among disparate providers that is present in comprehensive rehabilitation facilities, as defined in the statute, which may affect the effectiveness and cost-effectiveness of such alternatives.

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 comprehensive rehabilitation services fulfills medical needs as well as social needs. In terms of medical needs, comprehensive rehabilitation services as defined in the statute help patients in recovery efforts from serious disease or injury. In terms of social needs, comprehensive rehabilitation services as defined in the statute facilitate a return to levels of functioning that allow a higher level of independent living than would otherwise be achieved. Research also shows a strong relationship between quality of life and participation in outpatient rehabilitation.⁴⁰³

In summary, comprehensive rehabilitation services are frequently necessary as part of the process of recovery from injury or disease and required for independent living and functioning. One of the roles of health insurance is to cover unexpected health care costs. Comprehensive rehabilitation services as defined in the statute are required following serious and unexpected illness or injury. As such, the mandated 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 mandate could be replicated for other types of rehabilitation services. Because the current mandate only applies to group plans, a mandate that applies to individual

⁴⁰² 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.

⁴⁰³ Ackerley S, Gordon HJ, Elston AF, et al. 2009. Assessment of quality of life and participation within an outpatient rehabilitation setting. *Disability and Rehabilitation* 31(11): 906-13.

policies could possibly be enacted. Potential social implications of a comparable mandated benefit are limited because insurers/MCOs are only required to offer the coverage; purchasers are not required by law to include the coverage in plans offered to employees.

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

The impact of the benefit on the availability of other benefits currently offered is expected to be minimal due to the fact that it is a “mandated offer” benefit. Through the mandated offer process, employers may become aware of the benefit to employees of including coverage for comprehensive rehabilitation. In such cases, employers may place a higher value on comprehensive rehabilitation services than other non-mandated benefits and select plans that include comprehensive rehabilitation services; however, the implications of such decisions are not fully attributable to the presence of the mandate to offer comprehensive rehabilitation services.

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

Five health insurers/MCOs domiciled in Connecticut provided information about their self-funded plans, which represents an estimated 47 percent of the total population in self-funded plans in Connecticut. These five insurers/MCOs report that 78.8 percent of enrollees in their self-funded plans have coverage for the mandated services. Because the comprehensive rehabilitation services is a “mandatory offer” mandate and benefits are typically included in self-funded plans not subject to state health insurance mandates, it is expected that the mandate has little to no effect on employer decisions to shift to self-funded 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.

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

The comprehensive rehabilitation services mandate may be included in prior and current state employee health insurance and health benefits plans. Thus 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 Medicare⁴⁰⁴ 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.

State employee claims are included in the 2007 and 2008 claims data provided by insurers/MCOs for their fully insured group insurance enrollees. Because the state shifted to self-funded status on July 1, 2010 (during the time this report was being written), utilization under self-funded status is unknown. All self-funded plans, including those that provide coverage for state employees, are not regulated by the state insurance department and are exempt from state health insurance required benefit statutes.

In terms of financial impact, if the state employee health insurance/benefit plans continue to provide coverage for the required benefit, the IC actuarial analysis estimates the medical cost to the state employee

⁴⁰⁴ Personal communication. Scott Anderson, State of Connecticut Comptroller’s Office. September 14, 2010.

health insurance plan will total \$4,764,617 in 2010.⁴⁰⁵

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

The safety and effectiveness of comprehensive rehabilitation services has not been systematically reviewed for many of the diagnostic conditions treated in rehabilitation.^{406,407} Several studies have shown comprehensive rehabilitation services to be safe and effective tools for rehabilitation and improved functioning following particular illnesses/conditions such as multiple sclerosis, traumatic brain injury, stroke and knee arthroplasty.^{408,409,410,411} Additional research suggests that effectiveness of comprehensive rehabilitation is improved with timely access to services.^{412,413} One study, based at a Comprehensive Outpatient Rehabilitation Facility (CORF), with subjects of an average age of 78 years, found significant improvement in levels of functioning for all patients.⁴¹⁴

Due to the wide-ranging set of services included in comprehensive rehabilitation services as defined in the statute, a review of the safety and effectiveness of these individual components is not attempted in this review. In general, the individual components of comprehensive rehabilitation services, as defined in the statute, are understood to be as safe and as effective when provided as part of a comprehensive rehabilitation plan as they are when provided as stand-alone care, for example, speech and language therapy following stroke.⁴¹⁵ Because comprehensive rehabilitation services are provided for a wide range of injuries and illness, the effectiveness of comprehensive rehabilitation services may be more or less effective for certain rehabilitation efforts for certain patients and varies among types of illness and injury for which rehabilitation is attempted. Overall, comprehensive rehabilitation services are safe and effective to varying degrees depending on individual patient characteristics and capacity for improving functioning.

⁴⁰⁵ The estimate is calculated by multiplying the estimated 2010 weighted average PMPM medical cost in fully insured plans in Connecticut by 12 to get an annual cost per insured life, and then multiplying that product by 163,334 covered lives, as reported by the State Comptroller's office. The actual cost of this 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 this mandated benefit would be in addition to the above amount. See Appendix II, Ingenix Consulting Actuarial and Economic Report, for further discussion.

⁴⁰⁶ Arvu Bettger JA, Stineman MG. 2007. Effectiveness of multidisciplinary rehabilitation services in post-acute care: state-of-the-science. A review. *Archives of Physical Medicine and Rehabilitation* 88(11): 1526-34.

⁴⁰⁷ Aziz NA, Leonardi-Bee J, Phillips M, et al. 2008. Therapy-based rehabilitation services for patients living at home more than one year after stroke. *Cochrane Database of Systematic Reviews* April 16(2): CD005952.

⁴⁰⁸ Patti F, Ciancio MR, Cacopardo M, et al. 2003. Effects of short outpatient rehabilitation treatment on disability of multiple sclerosis patients—a randomized controlled trial. *Journal of Neurology* 250(7): 861-6.

⁴⁰⁹ Cicerone K, Azulay J, Trott C. 2009. Methodological quality of research on cognitive rehabilitation after traumatic brain injury. *Archives of Physical Medicine and Rehabilitation* 90(11 Suppl): S52-9.

⁴¹⁰ Legg L, Langhorne P. Rehabilitation therapy services for stroke patients living at home: systematic review of randomised trials. *The Lancet* 2004;363(9406):352-6.

⁴¹¹ Moffet H, Collet JP, Shapiro SH, Paradis G, Marquis F, Roy L. Effectiveness of intensive rehabilitation on functional ability and quality of life after first total knee arthroplasty: a single blind randomized controlled trial. *Archives of Physical Medicine and Rehabilitation* 2004;85(4):546-56.

⁴¹² Kunik CL, Flowers L, Kazanjian T. 2006. Time to rehabilitation admission and associated outcomes for patients with traumatic brain injury. *Archives of Physical Medicine and Rehabilitation* 87(12): 1590-6.

⁴¹³ Salter K, Jutai J, Hartley M, et al. 2006. Impact of early vs delayed admission to rehabilitation on functional outcomes in persons with stroke. *Journal of Rehabilitation Medicine* 38(2): 113-7.

⁴¹⁴ Yu F, Evans LK, Sullivan-Marx EM. 2005. Functional outcomes for older adults with cognitive impairment in a comprehensive outpatient rehabilitation facility. *Journal of the American Geriatric Society* 53: 1599-1606.

⁴¹⁵ Kelly H, Brady MC, Enderby P. 2010. Speech and language therapy for aphasia following stroke. *Cochrane Database of Systematic Review*, May 12(5): CD000425.

IV. 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 mandate is not expected to materially alter the availability or cost of comprehensive rehabilitation services over the next five years. The presence of “mandatory offer” insurance mandates is not expected to have any additional effect on cost. Additionally, inclusion of comprehensive rehabilitation services in nearly 80 percent of self-funded plans further dilutes any effect the existence of a mandate may have on the cost of the services. 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 mandated health benefit may increase the appropriate or inappropriate use of comprehensive rehabilitation services over the next five years.

Because the comprehensive rehabilitation services benefit is a mandatory offer mandate, the extent to which it may increase appropriate or inappropriate use over the next five years is limited. If employers or other purchasers of group health plans were unaware of the benefit and became aware due to the mandatory offer nature of the mandate, and subsequently purchased the coverage that was then accessed by an employee in need of comprehensive rehabilitation services as defined in the statute, it could be argued that the mandate increased appropriate use. Inappropriate use is not expected to occur due to the nature of the services included.

3. The extent to which comprehensive rehabilitation services may serve as an alternative for more expensive or less expensive treatment, service or equipment, supplies or drugs, as applicable.

Comprehensive rehabilitation services as defined in the statute provide a range of services tailored for individual needs of patients as directed through a physician-approved plan of care. Alternatives to comprehensive rehabilitation services may include provision of the services independent of a physician-approved plan of care or in a different setting (e.g., inpatient rehabilitation or home health care). Such alternatives may not be able to take full advantage of the efficiencies of care coordination and the high degree of communication among disparate providers that is present in comprehensive rehabilitation facilities, as defined in the statute, which may affect the effectiveness and cost-effectiveness of such alternatives.

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 utilize the same utilization management methods and cost controls that are used for 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 comprehensive rehabilitation services 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 II, Ingenix Consulting Actuarial and Economic Report, page 15.

Group plans: When the medical cost of the mandate is spread to all insureds in group plans, medical costs are estimated to be \$2.42 PMPM and retention costs are estimated to be \$0.48 PMPM in 2010. Thus,

the total effect on insurance premiums is estimated at \$2.90 PMPM in 2010. Insurance coverage for the mandated benefit may be reasonably expected to increase group health insurance premiums accordingly, that is, \$34.80 per year per insured.

Individual policies: Not applicable.

For further information, please see the Appendix II: Ingenix Consulting Actuarial and Economic Report.

6. The extent to which comprehensive rehabilitation services 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.

Comprehensive rehabilitation services as defined in the statute provide a range of services tailored for individual needs of patients as directed through a physician-approved plan of care. Alternatives to comprehensive rehabilitation services may include provision of the services independent of a physician-approved plan of care or in a different setting (e.g., inpatient rehabilitation or home health care). Such alternatives may not be able to take full advantage of the efficiencies of care coordination and the high degree of communication among disparate providers that is present in comprehensive rehabilitation facilities, as defined in the statute, which may affect the effectiveness and cost-effectiveness of such alternatives.

7. The impact of insurance coverage for comprehensive rehabilitation services 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 of claims data received from insurers/MCOs in Connecticut shows an expected impact on the total cost of health care in 2010 of \$57,593,213 for comprehensive rehabilitation services as defined in the statute for Connecticut residents covered by fully insured group health insurance plans.

Due to the nature of comprehensive rehabilitation services and the health status of patients who receive them, no prevention and early detection of disease or illness effects are anticipated.

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 impact of mandated offers of coverage for comprehensive rehabilitation services as defined in the statute on the cost of health care for small employers. Small employers may be more sensitive to premium increases than other employers; however, the statute does not require employers to include comprehensive rehabilitation services in health plans offered to employees. Because the comprehensive rehabilitation services mandate is for an optional coverage (a mandatory “offer”), small and large employers are not required to pay for health insurance plans that include such services.

For further information regarding the differential effect of the mandates on small group versus large group insurance, please see Appendix II: Ingenix Consulting Actuarial and Economic Report, page 31.

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 mandate became effective in 1982 and is a mandatory offer benefit, it is unlikely that the mandate, taken individually, has any impact on cost-shifting between private and public payers of health care coverage at present.

The overall cost of the health care delivery system in the state is understood to include total insurance premiums (medical costs and retention) and cost sharing. Actuarial analysis of claims data received from insurers/MCOs in Connecticut shows an expected impact on the overall cost of health care in 2010 of \$64,685,155 for comprehensive rehabilitation services for Connecticut residents covered by fully insured group health insurance plans.

For further information, please see Appendix II, Ingenix Consulting Actuarial and Economic Report.

Volume IV

Chapter 11

Mobile Field Hospital

Review and Evaluation of Connecticut Statute Chapter 700,

§§ 38a-525b and 38a-498b

Mandatory Coverage for Mobile Field Hospital.

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Chapter 11. Table of Contents

- I. Overview..... 161
- II. Background..... 161
- III. Methods..... 162
- IV. Social Impact..... 163
 - Table IV.11.1: States with Medical Field Hospital Capabilities 165
- V. Financial Impact..... 169

I. Overview

The Connecticut General Assembly directed the Connecticut Insurance Department to review the health benefits required by Connecticut law to be included in fully insured group and individual health insurance policies as of July 1, 2009. The review was conducted following the requirements stipulated under Public Act 09-179. Reviews of required health insurance benefits are a collaborative effort of Connecticut Insurance Department (CID) and the University of Connecticut Center for Public Health and Health Policy (CPHHP).

Connecticut General Statutes, Chapter 700, §§ 38a-525b and 38a-498b state that each group or individual health insurance policy,

...delivered, issued for delivery, renewed, amended or continued in this state on or after July 1, 2005, shall provide benefits for isolation care and emergency services provided by the state's mobile field hospital. Such benefits shall be subject to any policy provisions that apply to other services covered by such policy. The rates paid by group health insurance policies pursuant to this section shall be equal to the rates paid under the Medicaid program, as determined by the Department of Social Services.

Current coverage

This mandate went into effect on July 1, 2005 (P.A. 05-280). The purpose of the mobile field hospital is to provide medical services to state residents in the case of a natural disaster, terrorist attack or other emergency situation when Connecticut's acute care hospitals are over capacity, damaged, too distant or otherwise unable to provide medical care.

Premium impact

The state's mobile field hospital has not been activated or called into service to date; thus, no claims data exists on which to base an estimate of the cost of the mandate.

Self-funded plans

Coverage of the benefit in self-funded plans is unknown.

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

II. Background

Connecticut's mobile field hospital, the Otilie W. Lundgren Memorial Field Hospital (MFH), provides medical services to state residents in the case of a natural disaster, terrorist attack or emergency situation when Connecticut's acute care hospitals are over capacity, damaged, too distant or otherwise unable to provide medical care. The MFH is a mobile facility managed by the Connecticut Department of Public Health. It is designed for deployment in either 25-bed increments or in its full complement of 100 beds to any location in the state. It is not intended to supplant local first responders or healthcare institutions, but supports their operations.

The September 11 terror attacks and gulf coast hurricanes brought attention to the fact that governments and medical institutions were insufficiently prepared to address the increased demands for medical intervention during and following a terrorist attack or natural disaster. In response to this gap, several states, including Connecticut, developed capacity for a mobile field hospital for deployment under such

circumstances. Additional gaps in medical services availability for which the MFH may be deployed is the threat of hospital closure due to contagion or contamination due to infectious disease pandemics or resulting from chemical or nuclear attacks or accidents

As of December 2010, the MFH has not been deployed in Connecticut. No medical services have been provided and no insurance claims have been made or paid. While the MFH has not been activated as a state-sponsored patient care facility, one or more components have been deployed to support various other missions of the Connecticut Department of Public Health. Some examples include:

- Heating units from the MFH were deployed to a skilled nursing facility to provide necessary heat to residents while facility environmental controls were being repaired.
- Environmental control units from the MFH were deployed to provide a cooling station for a mass gathering event during a summer heat wave.
- A command trailer was deployed, together with a shelter boot from the MFH to support military/civilian communications drills and exercises.
- MFH shelters have provided an environment for set-up of first aid, vaccination, and family assistance stations.
- MFH shelters have provided an environment for set-up of an incident command post during local emergencies.
- None of these partial deployments have involved the provision of billable patient care.⁴¹⁶

III. Methods

CPHHP staff conducted literature searches using the Cochrane Review, Pubmed, and a web search using Google. Search terms included “mobile field hospital”, “field hospital”, “portable hospital”, “inflatable hospital”, “disaster medical facility”, “transportable emergency surge assistance unit”, “mobile response trailer systems”, and “mobile health care facility”. Where available, articles published in peer-reviewed journals and books authored or edited by experts in the applicable field of medicine are cited to support the analysis. Other sources of information may also be cited in the absence of peer-reviewed journal articles and books. Content from such sources may or may not be based on scientific evidence.

CPHHP 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, and non-profit and community-based organization websites.

CPHHP and the CID contracted with Ingenix Consulting to provide actuarial and economic analyses of the mandated benefit. Further details regarding the actuarial methods used to estimate the cost of the benefit and economic methods used to estimate financial burden may be found in Appendix II.

⁴¹⁶ Personal communication. Elise Goulin-Kremer, PhD, Public Health Administrator, Connecticut Department of Public Health. March 4, 2010.

IV. Social Impact

1. The extent to which isolation care and emergency services provided by the mobile field hospital is utilized by a significant portion of the population.

As of December 2010, the state's MFH has not been activated or mobilized in Connecticut for provision of isolation care and emergency services, therefore no state residents have utilized these services. It is difficult to estimate the extent to which the MFH would be utilized, because circumstances surrounding any event that might require deployment of the mobile field hospital are unknown. However, the physical characteristics, logistical limitations, and stated purpose of the MFH suggest that it would not have the capacity for delivery of vast amounts of medical care over long durations and would not be an appropriate venue for delivery of such care. Additionally, the health insurance mandate limits coverage to isolation care and emergency medical services, further limiting overall utilization.

2. The extent to which isolation care and emergency services through the mobile field hospital 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 provides coverage for emergency services and isolation care. No information was found that indicates such services would not be covered if provided at a mobile field hospital.

Public Programs Administered by Charities

No information was found that indicates any charities are sources of funding for isolation care and emergency services provided by the state's mobile field hospital.

Public Programs Administered by Public Schools

No information was found that indicates public schools are sources of funding for isolation care and emergency services provided by the state's mobile field hospital. Public schools are frequently designated as emergency shelters. While there may be some capacity for emergency medical care at public schools, the schools are neither portable nor equipped for isolation care and other services the MFH is specifically designed to provide.

The Department of Public Health (DPH)

No information was found regarding the availability of funding for mobile field hospital isolation care and emergency services through the Connecticut Department of Public Health. DPH manages the state's mobile field hospital, and there is information about the mobile field hospital and the services provided on the DPH website.

Municipal Health Departments

No information was found that indicates municipal health departments are sources of funding for isolation care and emergency services provided by the state's mobile field hospital. Like public schools, some municipal buildings may be designated emergency shelters and during a large-scale emergency situation may serve as locations for delivery of on-site emergency medical care.

The Department of Social Services (DSS)

Medicaid programs in Connecticut are required to cover services provided at the MFH. Connecticut Statutes, Chapter 319v, Section 17b-261e states, "The Commissioner of Social Services shall provide

coverage for isolation care and emergency services provided by the state’s mobile field hospital to persons participating in the HUSKY Plan Part A and Part B and fee for services Medicaid programs” under chapter 319v of the general statutes.

3. The extent to which insurance coverage is already available for isolation care and emergency services provided by the mobile field hospital.

State of Connecticut law requires coverage for isolation care and emergency services provided by the mobile field hospital for persons covered by fully insured group and individual health insurance plans as of July 1, 2005.⁴¹⁷

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 is required and generally available for persons enrolled in fully insured group and individual health insurance plans. Due to the nature of the circumstances surrounding deployment of the state’s mobile field hospital, it is unlikely that persons presenting at the facility needing necessary health care treatment would be unable to obtain it, regardless of 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.

Coverage is generally available for isolation care and emergency services provided by the state’s mobile field hospital, therefore unreasonable financial hardships due to a lack of coverage are not likely to occur. However, depending on the level of cost sharing and personal financial resources available, that coverage may or may not be sufficient for the insured’s family to avoid unreasonable financial hardship. Additionally, given that the mobile field hospital is only deployed under limited and emergency situations and has a public health mission, unreasonable financial hardships resulting from isolation care and emergency services provided are not expected to occur.

Further discussion of financial and socioeconomic effects of the mandated benefit may be found in Appendix II: Ingenix Consulting Actuarial and Economic Report, page 52.

6. The level of public demand and the level of demand from providers for isolation care and emergency services provided by the mobile field hospital.

Medical librarians and CPHHP staff found no published literature regarding the level of public demand or level of demand from providers for isolation care and emergency services provided by mobile field hospitals. Following the September 11th terror attacks, the anthrax threat and the gulf coast hurricanes, the public and providers have likely become more attuned to the potential for man-made and natural disasters, accidents, and spread of infectious disease and the potential need for a mobile facility for isolation care and emergency services.

7. The level of public demand and the level of demand from providers for insurance coverage for isolation care and emergency services provided by the mobile field hospital.

Medical librarians and CPHHP staff found no published literature regarding the level of public demand or level of demand from providers for insurance coverage for isolation care and emergency services provided by mobile field hospitals.

⁴¹⁷ CONNECTICUT GENERAL STATUTES ANNOTATED § 38A-498B (INDIVIDUAL INSURANCE POLICIES); § 38A-525B (GROUP INSURANCE POLICIES).

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

Currently, 14 states in addition to Connecticut have MFHs or equivalent capabilities. Seven state governments including Connecticut operate mobile field hospitals or similar units procured from the same vendor.⁴¹⁸ Similar units may be county or municipality owned/operated, or operated by health centers or hospitals. Please see Table IV.11.1 for further details.

No other state has a separate insurance mandate for MFH services, but emergency care coverage mandates would likely cover treatment delivered in MFHs. Several states pay for MFH services through funds allocated for a gubernatorial declaration of emergency. It is not clear whether health insurance coverage for emergency services would be the primary payer in these cases or if state-allocated emergency services funds would render insurance coverage moot.

State	Mobile Field Hospital Capacity	Deployment and Circumstances	Insurance Coverage and Rate
CA	600 beds: Three 200-bed mobile field hospitals. ⁴¹⁹	No.	Emergency care mandate. ^{420, 421}
FL	194 beds. Florida Department of Health: three 50-bed field hospitals. ⁴²² Broward County Health Department: 44-bed.	No.	No specific mandate on mobile field hospital. ⁴²³
GA	Approximately 400 beds. Eight 50-bed units. ⁴²⁴	Yes. One unit used in Albany, Georgia after a hospital was struck by a tornado. ⁴²⁵	Emergency care mandate. ⁴²⁶
IA	50-60 beds. ⁴²⁷ Can function as a mobile hospital or special shelter. ⁴²⁸	No. ⁴²⁹	Emergency care mandate. ⁴³⁰

⁴¹⁸ Personal communication. Chris Murphy, DHS Systems. July 2010.

⁴¹⁹ California Emergency Medical Services Authority. Disaster Medical Services Division Major Program Activities. Available at: http://www.emsa.ca.gov/meetings/files/2008/12-03-08/5B_DMS.doc. Last accessed November 29, 2010.

⁴²⁰ California Health Care. Emergency and Urgent Care. Available at: http://www.calhealth.net/california_health_emergency_urgent_care.htm. Last accessed November 29, 2010.

⁴²¹ California State Assembly. Assembly Budget Subcommittee No. 1 on Health and Human Services. Available at: <http://www.assembly.ca.gov/acs/committee/c1/hearing/april%2012%20-am.doc>. Last accessed November 29, 2010.

⁴²² Western Shelter Systems. 2009. Mobile Response Trailer Systems. Available at: <http://www.westernshelter.com/files/collections/Public%20Health%20Brochure.1232574901.pdf>. Last accessed November 29, 2010.

⁴²³ Florida Statutes. 2010. Title XXXVII. Chapter 627. Section 6056. Coverage for ambulatory surgical center service.

⁴²⁴ Thomas BA. Gainesvilletimes.com. May 2010. Portable hospital drill prepares health officials for emergencies. Available at: <http://www.gainesvilletimes.com/news/archive/33276/>. Last accessed November 29, 2010.

⁴²⁵ *Ibid.*

⁴²⁶ Georgia Code. 2010. Title 33, Insurance. Chapter 20A, Managed Health Care Plans. Article 1, Patient Protection.

⁴²⁷ Western Shelter Systems. 2009. Mobile Response Trailer Systems. Available at: <http://www.westernshelter.com/files/collections/Public%20Health%20Brochure.1232574901.pdf>. Last accessed November 29, 2010.

⁴²⁸ Iowa Department of Public Health. News. Mobile field hospital. Available at: <http://www.idph.state.ia.us/IdphNews/Reader.aspx?id=BB209780-159B-45CC-AC12-7663929DE846>. Last accessed November 29, 2010.

⁴²⁹ *Ibid.*

⁴³⁰ Iowa Insurance Division. Patient Protection and Affordable Care Act of 2009: Health Insurance Exchanges. Available at: <http://www.iid.state.ia.us/hcr/Exchanges.pdf>. Last accessed November 29, 2010.

Table IV.11.1: States with Medical Field Hospital Capabilities			
State	Mobile Field Hospital Capacity	Deployment and Circumstances	Insurance Coverage and Rate
KY	20 beds. ⁴³¹	Yes, non-emergency. Set up at the Ironman Games in 2007.	Emergency care mandate.
MI	140 beds. Two medical units—one 40-bed; one 100-bed. ⁴³²	No. ⁴³³	Emergency care mandate. ⁴³⁴
MS	100 beds. ⁴³⁵	No.	Use is limited to only those events at the level of a gubernatorial or presidential declaration of emergency. As such, the costs associated with deployment are covered under the declaration and patients treated are not charged for services, thus not a component of the health insurance process. ⁴³⁶
OH	210 beds. 24 modules. County operated. ⁴³⁷	No. ⁴³⁸	Emergency care mandate. ⁴³⁹
OK	Mobile response trailer system. ⁴⁴⁰ Two large trailers (capable of assisting 200 patients), 12 medium trailers (50-100 patients each), 14 small trailers (25 patients). ⁴⁴¹	No record of deployment.	Unknown.
NV	Yes. Capacity unknown. ⁴⁴²	Yes: Gulfport, Mississippi following Hurricane Katrina. ⁴⁴³	Unknown.
NC	400 beds. Eight 50-bed units owned by the state's trauma centers. ⁴⁴⁴	Yes: One unit deployed following a tornado. Used for triage only. ⁴⁴⁵ Also employed in Mississippi following Hurricane Katrina in 2005. ⁴⁴⁶	No specific mandate regarding MFHs. State disaster funds can finance medical expenses in a state of disaster. ⁴⁴⁷
PA	400 beds. Eight 50-bed portable hospitals. ^{448, 449}	No.	Emergency care mandate. ⁴⁵⁰
SC	300 beds. Six 50-bed mobile medical facilities. ⁴⁵¹	No. ⁴⁵²	Emergency care mandate. ⁴⁵³
TX	88 beds. ^{454, 455}	No. ⁴⁵⁶	Unknown.

⁴³¹ Nataloni R. 2009. American College of Physicians. ACPHospitalist. Treatment on the fly: mobile units help hospitals boost surge capacity Available at: <http://www.acphospitalist.org/archives/2009/09/disaster.htm>. Last accessed November 29, 2010.

⁴³² Pitts A. Michigan Department of Community Health. Office of Public Health Preparedness. Available at: http://www.michigan.gov/documents/mdch/bhs_Public_Health_Preparedness_4-09_278285_7.pdf. Last accessed November 29, 2010.

⁴³³ Chapman, SN. Michigan Department of Community Health. Office of Public Health Preparedness. Michigan healthcare program preparedness update. Available at: <http://www.region2north.com/Documents/R2N%202009%20Conf%20Files/SNC.MI%20Healthcare%20Preparedness%20Update.R2N.6.4.09.pdf>. Last accessed November 29, 2010.

⁴³⁴ State of Michigan. Insurance Code of 1956. Chapter 500. Section 3406k. Emergency health services; medical services coverage; “stabilization” defined.

⁴³⁵ Elliott D. 2009. WLOX 13. High tech portable hospital in Mississippi. Available at: <http://www.wlox.com/Global/story.asp?S=10281013>. Last accessed November 29, 2010.

⁴³⁶ Personal Communication. Jonathon Wilson, Clinical Director of Emergency Services. University of Mississippi Medical Center. June 30, 2010.

⁴³⁷ Western Shelter Systems. 2009. Mobile Response Trailer Systems. Available at: <http://www.westernshelter.com/files/collections/Public%20Health%20Brochure.1232574901.pdf>. Last accessed November 29, 2010

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

Literature searches, internet searches and telephone inquiries found no relevant findings from state agencies and public organizations related to the social impact of mandated insurance coverage for mobile field hospital services. 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.

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

The mobile field hospital is designed to be deployed when other medical care facilities are not available due to natural disasters, terror attacks, and similar large-scale and unexpected events. When the mobile field hospital is deployed, it is expected that other alternatives have been ruled out due to reasons for deployment such as physical damage to traditional hospitals, numerous injuries sustained at a remote location best treated on location, or a situation requiring isolation care (e.g., a chemical or biological factor).

⁴³⁸ Domestic Preparedness. 2005. Hamilton County, Ohio to Field 210-Bed Portable Patient Care Center to Provide Mass Casualty Hospital Surge Capacity. Available at: <http://www.domesticpreparedness.com/index.lasso?pgID=3&arID=162>. Last accessed November 29, 2010.

⁴³⁹ Ohio Revised Code. Title XXXIX, Insurance. Chapter 3923, Sickness and Accident Insurance. Section 65, Coverage for emergency services.

⁴⁴⁰ Western Shelter Systems. 2009. Mobile Response Trailer Systems. Available at: <http://www.westernshelter.com/files/collections/Public%20Health%20Brochure.1232574901.pdf>. Last accessed November 29, 2010.

⁴⁴¹ Oklahoma Office of Homeland Security. Regional Emergency Medical Services System. Available at: http://www.ok.gov/homeland/Regional_Response_System/Regional_Emergency_Medical_Services_System/index.html. Last accessed November 29, 2010.

⁴⁴² Lake CK. 2010. Case study: how to select a portable emergency medical facility solution. Available at: http://www.disaster-resource.com/articles/05p_140.shtml. Last accessed November 29, 2010.

⁴⁴³ Nataloni R. 2009. American College of Physicians. ACPHospitalist. Treatment on the fly: mobile units help hospitals boost surge capacity. Available at: <http://www.acphospitalist.org/archives/2009/09/disaster.htm>. Last accessed November 29, 2010.

⁴⁴⁴ *Ibid.*

⁴⁴⁵ *Ibid.*

⁴⁴⁶ Blackwell T. and Bosse M. 2007. Use of an Innovative Design Mobile Hospital in the Medical Response to Hurricane Katrina. *Annals of Emergency Medicine* 49(5):580-8.

⁴⁴⁷ North Carolina Statutes. 2010. §166A-6.0: State disaster assistance funds; programs.

⁴⁴⁸ Sullivan TM. 2009. Montgomery County Department of Public Safety 2009 Annual Report.

⁴⁴⁹ The Health Care Improvement Foundation. February 9 Demonstration of Deployable Medical Equipment. Available at: http://www.hcifonline.org/section/programs/regional_disaster_preparedness_project/february_9_demonstration_of_deployable_medical_equipment. Last accessed November 29, 2010.

⁴⁵⁰ Pennsylvania Code. § 154.14. Emergency services.

⁴⁵¹ Nataloni R. 2009. American College of Physicians. ACPHospitalist. Treatment on the fly: mobile units help hospitals boost surge capacity. Available at: <http://www.acphospitalist.org/archives/2009/09/disaster.htm>. Last accessed November 29, 2010.

⁴⁵² *Ibid.*

⁴⁵³ South Carolina Code of Laws. 2009. Title 38, Insurance. Chapter 71, Accident and Health Insurance. Article 15, Access to Emergency Medical Care.

⁴⁵⁴ Moore S. 2009. Beaumont Enterprise. Portable inflatable hospital ready to go at first sign of trouble. Available at: http://www.beaumontenterprise.com/news/local/portable_inflatable_hospital_ready_to_go_at_first_sign_of_trouble_01-13-2009.html?c=y&page=1#storytop. Last accessed November 29, 2010.

⁴⁵⁵ Texas Health Resources. 2006. Harris Methodist Hospitals and Texas Health Resources Unveil the First Portable Inflatable Surge Capacity Unit in the Nation. Available at: <http://www.texashealth.org/blank.cfm?print=yes&cid=1629&action=detail&ref=250>. Last accessed November 29, 2010.

⁴⁵⁶ Moore S. 2009. Beaumont Enterprise. Portable inflatable hospital ready to go at first sign of trouble. Available at: http://www.beaumontenterprise.com/news/local/portable_inflatable_hospital_ready_to_go_at_first_sign_of_trouble_01-13-2009.html?c=y&page=1#storytop. Last accessed November 29, 2010.

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.*

Isolation care and emergency services, including those provided at the mobile field hospital, are medical needs.

One of the roles of health insurance is to cover unexpected health care costs. Because the facility is deployed in emergency situations, the benefit is consistent with the role of health insurance. It would seem that isolation care and emergency services are generally outside the purview of managed care due to the nature of such services; in any event the statutes do not prohibit insurers/MCOs from using any appropriate managed care tools at their disposal. The statute states that mobile field hospital benefits “shall be subject to any policy provisions that apply to other services covered by such policy.”⁴⁵⁷ Health insurance plans generally do not require emergency services to be provided in-network or with prior authorization or a referral from a primary care provider.

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

The mobile field hospital benefit can be viewed as a “provider” mandate. The “provider” in this case is a highly specialized facility designed for deployment under extremely limited and unusual circumstances. Thus, it is unlikely that the mobile field hospital mandate could be used as a model for any other service or provider mandate.

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

The benefit is unlikely to have any effect on the availability of other benefits currently offered. The mobile field hospital is designed for deployment under limited circumstances for short periods. Additionally, financial exposure in fully insured group and individual insurance plans is limited because coverage is provided at Medicaid rates which are historically lower than non-government-sponsored coverage. Thus for persons in fully insured group and individual health insurance plans, medical services provided at the mobile field hospital may be reimbursed at rates lower than rates for the same medical services provided at other facilities.

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

The benefit is not expected to have or have had any effect on employers shifting to self-funded plans due to the limited scope of the services provided and temporary nature of the facility, which is expected to result in relatively low claims costs should the mobile field hospital be deployed.

Because the MFH has not been deployed, no claims history exists for fully insured or self-funded plans in Connecticut. No information about the extent to which the benefit is currently being offered by employers with self-funded plans is available.

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

The MFH mandate is a current benefit that has been included in the state employee health insurance and health benefits plans at least in part since 2005. Thus 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 Medicare⁴⁵⁸ is

⁴⁵⁷ CONNECTICUT GENERAL STATUTES ANNOTATED § 38A-498B (INDIVIDUAL INSURANCE POLICIES); § 38A-525B (GROUP INSURANCE POLICIES).

⁴⁵⁸ Personal communication. Scott Anderson, State of Connecticut Comptroller's Office. September 14, 2010.

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.

Because the mobile field hospital has not been deployed there is no claims history on which to base any estimate of the financial impact of the benefit on the state employee health insurance or health benefits plan.

The state shifted its employee plans to self-funded status on July 1, 2010. All self-funded plans, including those that provide coverage for state employees, are not regulated by the state insurance department and are exempt from state health insurance required benefit statutes.

16. The extent to which credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community determines isolation care and emergency services provided at the state's mobile field hospital to be safe and effective.

Despite numerous catastrophic disasters in recent years throughout the world and the medical relief efforts that followed, there is a dearth of published reports specifically related to the safety and effectiveness of delivery of isolation care and emergency services in a civilian mobile field hospital setting. Much of the existing research published in the years following the September 11th terror attacks and gulf coast hurricanes regarding services of the type provided by the MFH is focused on planning and preparation for catastrophic events or is related to military field hospital operations.

The effectiveness of any mobile field hospital or health care facility may be limited depending on the scale of the event precipitating deployment. A large-scale chemical or biological attack or natural disaster could result in the presentation of large numbers of injured or contaminated individuals that could quickly overwhelm treatment or isolation capacities. Not all potential contingencies related to isolation care and emergency services can be foreseen and patients requiring these services present many challenges to health care providers, including the safety and effectiveness of services provided.

IV. Financial Impact

1. The extent to which the mandated health benefit may increase or decrease the cost of isolation care and emergency services provided by the mobile field hospital over the next five years.

The mandate is not expected to significantly increase or decrease the cost of isolation care and emergency services provided by the mobile field hospital over the next five years. If the MFH is deployed in Connecticut, financial exposure in fully insured group and individual insurance plans is limited because services are provided at Medicaid rates which are historically lower than non-government-sponsored coverage. Thus for persons in fully insured group and individual health insurance plans, medical services provided at the mobile field hospital may be reimbursed at rates lower than rates for the same medical services provided at other facilities.

2. The extent to which the mandated health benefit may increase the appropriate or inappropriate use of isolation care and emergency services provided by the mobile field hospital over the next five years.

For those persons whose insurance plans would not otherwise cover medically necessary isolation care and emergency services, the mandated health benefit may increase appropriate use of the service. For those covered by self-funded plans and persons who lack health insurance, a mandated benefit may not increase appropriate use. Inappropriate use is not expected to be a potential factor due to the nature of the service.

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

The mobile field hospital is designed to be deployed when other medical care facilities are not available due to natural disasters, terror attacks, and similar large-scale and unexpected events. When the mobile field hospital is deployed, it is expected that other alternatives have been ruled out due to reasons for deployment such as physical damage to traditional hospitals, numerous injuries sustained at a remote location best treated on location, or a situation requiring isolation care (e.g., a chemical or biological factor).

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

Management of the utilization and costs of isolation care and emergency services provided by the MFH is not expected to be a concern due to the circumstances under which deployment would occur. The MFH also provides a limited set of services and has limited capacity. Nonetheless, the statute allows the mandated benefit to be subject to any policy provisions that apply to other services covered in the policy.

5. The extent to which insurance coverage for isolation care and emergency services provided by the mobile field hospital 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 II, Ingenix Consulting Actuarial and Economic Report, page 15.)

Because the MFH has not been deployed in Connecticut for provision of isolation care or emergency services, no claims history exists and an estimate of the increase or decrease in insurance premiums and administrative expenses for policyholders is not available. However, the provision of mandated services is not expected to significantly increase or decrease the insurance premiums or administrative expenses. Provision of services at the MFH is expected to be a rare event. When associated isolation care and emergency services costs are spread across the entire insured population the effect on premiums is likely to be extremely small.

6. The extent to which isolation care and emergency services provided by the mobile field hospital 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.

Not applicable. The mobile field hospital is designed to be deployed when other medical care facilities are not available due to natural disasters, terror attacks, and similar large-scale and unexpected events. When the mobile field hospital is deployed, it is expected that other alternatives have been ruled out due to reasons for deployment such as physical damage to traditional hospitals, numerous injuries sustained at a remote location best treated on location, or a situation requiring isolation care (e.g., a chemical or biological factor).

7. The impact of insurance coverage for isolation care and emergency services provided by the mobile field hospital 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. Because the MFH has not been deployed, no claims data is available on which to base an actuarial estimate of costs for the mandated services for Connecticut residents covered by fully insured group and individual health insurance plans.

There are important potential benefits or savings to insurers and employers resulting from prevention or early detection of disease or illness related to services provided by the MFH. In particular, isolation care prevents the spread of infectious disease and limits additional exposure to toxic substances.

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.

No published literature was found regarding the effect of mandated coverage for MFH services on the cost of health care for small employers. Although small employers may be more sensitive to premium increases than other employers, the expected small financial impact in the event of deployment of the MFH suggests little difference in effects among different types of employers.

For further information about the differential effect of health insurance mandates on small and large employers, please see Appendix II, Ingenix Consulting Actuarial and Economic Report, page 31.

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. Due to the nature of the MFH benefit, it is not expected to have an impact on cost-shifting between private and public payers either in the past or at present.

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 of claims data is not available because the MFH has not been deployed; therefore no estimate of the financial impact of the mandated services on the overall cost of the health delivery system in the state is available.

For further information, please see Appendix II, Ingenix Consulting Actuarial and Economic Report.

Volume IV

Chapter 12

Pain Management

Review and evaluation of CGSA §§ 38a-518i and 38a-492i

Mandatory coverage for pain management

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Chapter 12. Table of Contents

- I. Overview..... 175
- II. Background..... 176
- III. Methods..... 178
- IV. Social Impact..... 179
- V. Financial Impact..... 183

I. Overview

In Public Act 09-179, An Act Concerning Reviews of Health Insurance Benefits Mandated in this State, the Connecticut General Assembly directed the Connecticut Insurance Department to review statutorily mandated health benefits existing on or effective on July 1, 2009. 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.

CGSA. §§ 38A-518i and 38A-492i mandate that group and individual health insurance policies issued, renewed or continued in this state provide coverage for pain treatment by a pain management specialist.

Specifically, CGSA . 38a-518i provides that:

Mandatory coverage for pain management. Each group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (10), (11) and (12) of section 38a-469 delivered, issued for delivery, renewed, amended or continued in this state on or after January 1, 2001, shall provide access to a pain management specialist and coverage for pain treatment ordered by such specialist which may include all means medically necessary to make a diagnosis and develop a treatment plan including the use of necessary medications and procedures. As used in this section, “pain” means a sensation in which a person experiences severe discomfort, distress or suffering due to provocation of sensory nerves, and “pain management specialist” means a physician who is credentialed by the American Academy of Pain Management or who is a board-certified anesthesiologist, neurologist, oncologist or radiation oncologist with additional training in pain management (P.A. 00-216, S. 19, 28.)

§38A-492i mandates the same coverage in individual health insurance policies delivered, issued for delivery, renewed or continued in Connecticut.

In March 2010, CPHHP and Ingenix Consulting (IC) requested and received 2007 and 2008 claims data related to the mandated benefit from six 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 that claims data, a review of the legislative history, reviews of pertinent literature and the Ingenix Consulting report, this review found the following:

Current coverage

This mandate has been in effect since 2001 (P.A. 00-216).

Premium impact

The IC actuarial report estimated no cost for this mandate.⁴⁵⁹

Self-funded plans

No data was reported by the Connecticut insurers/MCOs for this mandate.

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

⁴⁵⁹ Ingenix Consulting report, Appendix II, p. 11.

II. Background

Pain

Pain is defined in CGSA §§ 38a-518i and 38a-492i as “a sensation in which a person experiences severe discomfort, distress or suffering due to provocation of sensory nerves.” Pain can be acute, such as that which follows surgery or an injury, or it can be chronic, such as pain due to neuropathy or arthritis. Pain is a protective mechanism of the body, alerting it to potential or actual damage.⁴⁶⁰

Pain can have many causes, including injuries such as sprains or broken bones; illnesses such as influenza; diseases such as cancer, lupus or rheumatoid arthritis; or conditions such as osteoarthritis or diabetic neuropathy. Stress or depression can also cause or exacerbate pain. Sometimes pain is caused by medications for other conditions, such as chemotherapy-induced neuropathy.

As stated in the CDC’s Health, United States 2006, Chartbook on Trends in the Health of Americans⁴⁶¹:

Pain can be constant or episodic, last for a minute or most of a lifetime, and can be dull or sharp, throbbing or piercing, localized or widespread, severe or less severe, and ultimately, tolerable or intolerable. Pain can have an undetectable or a nonphysical cause, making it hard to treat... Pain is always subjective. Although it is a physical sensation, perceptions of pain are influenced by social, cultural, and psychological factors, producing different sensations in different people.

As the American Cancer Society states: “Pain can interfere with normal daily activities; diminish enjoyment of everyday pleasures; prevent relaxation and sleep; and increase anxiety, depression, stress and fatigue. It can also make people withdraw from others, decrease their social activities, and have less contact with friends or family.”⁴⁶² Pain is a major cause of disability and work-place absence.⁴⁶³

Pain treatment

Treatments for pain are almost as varied as the causes of pain. Treatments range from the application of heat or cold to opioid prescriptions to knee and hip replacement surgery. There is a spectrum of pharmaceutical treatments for pain,⁴⁶⁴ ranging from over-the-counter medications such as aspirin, acetaminophen, ibuprofen, or naproxene to prescriptions for Schedule II controlled substances, such as opioids. Pain management treatments can also include muscle relaxants, nerve blocks, anti-depressants, and anti-convulsive drugs. Pharmaceutical drugs can be ingested orally, injected into a joint or the spine, or administered through an implanted port or infusion pump. They can be administered in the physician’s office or clinic, or self-administered by the patient. Non-pharmaceutical treatments include physical therapy, bio-feedback, cognitive behavioral therapy, and surgery. Complementary and alternative medicine treatments, such as acupuncture⁴⁶⁵ and chiropractic, are also used to treat pain.

Goals of pain treatment may include eliminating the cause of the pain, enabling a patient to tolerate

⁴⁶⁰ MedlinePlus. 2010. Pain. Available at: <http://www.nlm.nih.gov/medlineplus/pain.html>. Accessed on January 13, 2011.

⁴⁶¹ Centers for Disease Control and Prevention, National Center for Health Statistics. 2006. Health, United States 2006. Chartbook on trends in the health of Americans, p. 68. Available at: <http://www.cdc.gov/nchs/data/abus/abus06.pdf>. Accessed on January 13, 2011.

⁴⁶² American Cancer Society. 2007. Cancer facts and figures, special section: cancer-related pain. P. 22. Available at: <http://www.cancer.org/acs/groups/content/@nho/documents/document/caff2007pwsecuredpdf.pdf>. Accessed on January 14, 2011.

⁴⁶³ Stewart W, Ricci J *et al.* 2003. Lost productive time and cost due to common pain conditions in the US workforce. *Journal of the American Medical Association* 290(18); 2443-2454.

⁴⁶⁴ Personal communication with Jill Fitzgerald, PharmD; Lisa Holle, PharmD; and Devra Dang, PharmD, University of Connecticut School of Pharmacy. December 10, 2010.

⁴⁶⁵ Brinkhaus B, Witt C *et al.* 2006. Acupuncture in Patients with Chronic Low Back Pain. *Arch Intern Med.* 2006(166):450-457.

persistent pain and continue to function, or providing palliative relief to a patient as a part of end-of-life care. There is a significant level of under-treatment of pain, as well as a significant potential for abuse of pain medication.⁴⁶⁶

Pain management

Pain management means the assessment and treatment of pain. The goal of chronic pain management is to improve function through the development of self-management skills that allow the patient to pursue a healthy lifestyle in the face of persistent pain.⁴⁶⁷

Management of Chronic Pain

The American Pain Society issued a position statement in 2000 on the management of chronic pain.⁴⁶⁸ It is widely acknowledged that chronic pain problems tend to be qualitatively different from acute pain, not only temporally but also in character and response to treatment. The care of chronic pain problems requires specialized expertise, because chronic pain problems do not respond reliably to many of the strategies used for the treatment of acute pain, and because inappropriate care for chronic pain conditions can often lead to clinical exacerbation and increased suffering and disability. Therefore, it is appropriate for plans to develop policies and strategies that can facilitate the following:

- Identification of members with chronic benign pain conditions or syndromes
- Appropriate referral of such members to specialized providers
- Education and assistance to PCPs in accomplishing these objectives
- Development of disease-state management programs for chronic pain, similar to those designed for other chronic diseases, that provide pathways and guidelines that encourage the appropriate utilization of pain management specialists and other resources, and result in the documented effectiveness of the chosen treatment strategies.

Pain management

A pain management specialist is defined in the above statutes as “a physician who is credentialed by the American Academy of Pain Management or who is a board-certified anesthesiologist, neurologist, oncologist or radiation oncologist with additional training in pain management.” (There are several other types of physicians, such as rheumatologists, and non-physicians, such as Nurse Practitioners and some alternative medicine practitioners, who also provide pain management services. These health care providers are not included in this mandate.)

The requirements for credentialing by the American Academy of Pain Management are:

- Practice in the field of pain management for at least two years;
- Commitment to on going education in the field of pain management (at least 50 hours of continuing medical education every four years in pain or pain management);
- Commitment to practice in an ethical manner; and
- Commitment to promoting continuous quality improvement for the relief of pain.⁴⁶⁹

⁴⁶⁶ Federation of State Medical Boards of the United States, Inc. 2004. Model policy for the use of controlled substances for the treatment of pain. Available at: <http://www.painpolicy.wisc.edu/domestic/model04.pdf>. Accessed on January 18, 2011.

⁴⁶⁷ Institute for Clinical Systems Improvement (ICSI). 2009. Assessment and management of chronic pain. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2009 Nov. 91 p. [187 references]

⁴⁶⁸ American Pain Society. 2000. Pain assessment and treatment in the managed care environment. Available at: http://www.ampainsoc.org/advocacy/downloads/assess_treat_mce.pdf. Accessed on January 14, 2011.

⁴⁶⁹ American Academy of Pain Management. 2011. Credentialing. Available at: <http://www.aapainmanage.org/members/Credentialing.php>. Accessed on January 14, 2011.

Board certification in the specified specialties requires up to five years additional training beyond that necessary for general medical practice. Training in a subspecialty such as pain medicine or hospice and palliative medicine can take an additional one to two years.

Anesthesiology

An anesthesiologist is trained to provide pain relief and maintenance or restoration of a stable condition during and immediately following an operation or an obstetric or diagnostic procedure.⁴⁷⁰ Board certification requires four years training. Subspecialty certification in hospice and palliative medicine or pain medicine requires additional training and examination.

Neurology

A neurologist specializes in the diagnosis and treatment of all types of disease or impaired function of the brain, spinal cord, peripheral nerves, muscles and autonomic nervous system, as well as the blood vessels that relate to these structures.⁴⁷¹ Board certification requires four to five years training. Subspecialty certification in pain medicine or hospice and palliative medicine requires additional training and examination.

Oncology

Oncology is listed as a subspecialty under internal medicine, obstetrics and gynecology, and pediatrics.⁴⁷² These specialties require three to four years training. Subspecialty certification in oncology requires additional training and examination.

Radiation oncology

A radiation oncologist uses special knowledge and skills to prevent and relieve the suffering experienced by patients with life-limiting illnesses.⁴⁷³ Board certification requires five years training, with additional training required for a subspecialty in hospice and palliative medicine.

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, UpToDate, Cochrane Systematic Review, DynaMed, Micromedex and Internet sources such as guidelines.gov, NIH and painfoundation.

General search terms used included: Analgesia, Pain/diet therapy, Pain/drug therapy, Pain/nursing, Pain/prevention and control, Pain/radiotherapy, Pain/rehabilitation, Pain/surgery, Pain/therapy, Health Services Accessibility, Utilization, Health Services Needs and Demand, Patient Acceptance of Health Care, Needs Assessment, Public Demand, Quality of Health Care, Patient Acceptance of Health Care, Barrier, Unmet Need, Treatment Outcome, Costs and Cost Analysis.

CPHHP staff conducted independent literature searches using similar search terms used by the UCHC

⁴⁷⁰ American Board of Medical Specialties. 2011. About physician specialties – anesthesiology. Available at: http://www.abms.org/Who_We_Help/Consumers/About_Physician_Specialties/anesthesiology.aspx. Accessed on January 14, 2011.

⁴⁷¹ American Board of Medical Specialties. 2011. About physician specialties – neurology. Available at: http://www.abms.org/Who_We_Help/Consumers/About_Physician_Specialties/neurology.aspx. Accessed on January 14, 2011.

⁴⁷² American Board of Medical Specialties. 2011. About physician specialties. Available at: http://www.abms.org/Who_We_Help/Consumers/specialties.aspx. Accessed on January 14, 2011.

⁴⁷³ American Board of Medical Specialties. 2011. About physician specialties – radiology, hospice and palliative medicine. Available at: http://www.abms.org/Who_We_Help/Consumers/About_Physician_Specialties/radiology.aspx. Accessed on January 14, 2011.

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 requested 2007 and 2008 claims data from insurance companies and MCOs domiciled in Connecticut. Due to the nature of the mandated benefit, the insurers/MCOs were unable to provide claims data for their fully insured group and individual plan participants or information about coverage in the self-funded plans they administer.

CPHHP and the CID contracted with Ingenix Consulting (IC) to provide actuarial and economic analyses of the mandated benefit. Further details regarding the insurer/MCO claims data and actuarial methods used to estimate the cost of the benefit and economic methods used to estimate financial burden may be found in Appendix II.

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.

A 2008 study reported that 75 million Americans have chronic or recurring pain and that pain accounted for 20 percent of all outpatient visits.⁴⁷⁴ Narcotic analgesic drugs, used primarily to relieve severe pain, account for 12 percent of all prescriptions⁴⁷⁵ and were prescribed in 23 percent of emergency department visits in 2003-2004.⁴⁷⁶ In 2006, the CDC issued a special report on pain as a part of its "*Health, United States 2006, Chartbook on Trends in the Health of Americans.*"⁴⁷⁷ It stated that 26 percent of people over 20 years of age in the United States had reported a problem with pain that persisted for more than 24 hours.

In 2007, the CT DPH reported that one in five Connecticut residents had some form of arthritis.⁴⁷⁸

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,

⁴⁷⁴ Alford D, Liebschutz J *et al.* 2008. *Journal of General Internal Medicine* 23(6): 841-845.

⁴⁷⁵ *Ibid.*

⁴⁷⁶ Centers for Disease Control and Prevention, National Center for Health Statistics. 2006. *Health, United States 2006. Chartbook on trends in the health of Americans*, p. 78. Available at: <http://www.cdc.gov/nchs/data/hus/hus06.pdf>. Accessed on January 13, 2011.

⁴⁷⁷ Centers for Disease Control and Prevention, National Center for Health Statistics. 2006. *Health, United States 2006. Chartbook on trends in the health of Americans*, p. 68. Available at: <http://www.cdc.gov/nchs/data/hus/hus06.pdf>. Accessed on January 13, 2011.

⁴⁷⁸ Connecticut Department of Public Health. 2007. *Arthritis*. Available at: <http://www.ct.gov/dph/cwp/view.asp?a=3135&q=393096>. Accessed on January 14, 2011.

municipal health departments or health districts or the Department of Social Services.

Medicare

Medicare Part B covers outpatient physicians' services and physical therapy services.⁴⁷⁹ It does not cover prescription drugs.

Medicare hospice benefits cover, among other things, drugs for symptom control or pain relief, short-term inpatient care for pain and symptom management, and any other Medicare-covered services needed to manage pain.⁴⁸⁰ Enrollees pay no more than \$5 for each prescription drug and other products for pain relief and 5 percent of the Medicare-approved amount for inpatient respite care.⁴⁸¹

Medicare Part D may cover pain medications, subject to the plan's formulary and pre-authorization rules.

Medicaid

Medicaid generally covers therapeutic services such as pain management. Medicaid covers "drugs which are used primarily for the relief of pain and symptom control related to terminal illness and that are included in the provider's formulary, subject to review and approval by the department."⁴⁸²

Connecticut Department of Public Health

The CT DPH licenses or certifies various health care practitioners who may provide pain management services, but it does not provide pain management services directly.

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

Connecticut General Statutes, §§ 38a-518i and 38a-492i require fully insured private insurance policies delivered, renewed or amended in Connecticut to provide access to a pain management specialist and coverage for pain treatment. This mandate has been in effect since January 1, 2001 for fully insured individual and group policies. Connecticut's public insurance programs also cover pain treatment.

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.

Although the statute mandates coverage for cover pain treatment ordered by a pain management specialist, it is essentially a provider mandate. Lack of access to a pain management specialist does not prevent patients from obtaining treatment for pain.⁴⁸³ Most types of pain treatment are covered under other provisions of health insurance policies, such as the prescription drug benefit. Treatment for pain associated with a particular condition would generally be covered as part of the coverage for that condition, e.g., cancer treatment.

In the absence of this mandate, patients may not be able to consult a specialist in pain management, thereby potentially limiting the quality of their pain management care.

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.

⁴⁷⁹ Centers for Medicaid and Medicare. 2010. Medicare Benefit Policy Manual, Ch. 15.

⁴⁸⁰ Centers for Medicare and Medicaid Services (CMS), Medicare Hospice Benefits, p.6. Available at: <http://www.medicare.gov/Publications/Pubs/pdf/02154.pdf>. Accessed on January 14, 2011.

⁴⁸¹ *Ibid.*

⁴⁸² DSS Provider Manual, Hospice, p. 9 (https://www.ctdssmap.com/CTPortal/Information/Get%20Download%20File/tabid/44/Default.aspx?Filename=ch7_iC_Hospice_V1.0.pdf&URI=Manuals/ch7_iC_Hospice_V1.0.pdf).

⁴⁸³ Ingenix Consulting report, Appendix II, p. 53.

Lack of access to a pain management specialist does not impose a financial hardship on a member who needs pain treatment. Such treatment would be covered under the general medical and pharmacy benefits of the insurance plan.

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

The American Pain Society issued a position statement in 2000 entitled Pain Assessment and Treatment in the Managed Care Environment,⁴⁸⁴ which recognizes that “the care of chronic pain problems requires specialized expertise, because chronic pain problems do not respond reliably to many of the strategies used for the treatment of acute pain, and because inappropriate care for chronic pain conditions can often lead to clinical exacerbation and increased suffering and disability.”

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 Society of Anesthesiologists and the Connecticut State Medical Society testified in favor of this bill at its public hearing.⁴⁸⁵

The American Pain Society, in the position statement cited above, states:

All patients benefit from timely and effective assessment and treatment of pain by their primary care providers (PCPs). When treatment is not effective, early access to appropriate specialists can result in improved outcomes (as defined in the section on quality and outcomes).

It is appropriate for MCOs to justify the referral of patients in pain and the utilization of appropriate treatment methods for such patients. Therefore, reasonable criteria for referral and utilization should be developed, distributed to providers, and used in this process.

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

According to the Council on Affordable Health Insurance, three states mandate access to pain management specialist in insurance policies: Connecticut, Colorado and Kansas.⁴⁸⁶

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

The Connecticut Board of Examiners for Nursing⁴⁸⁷ and the Connecticut Medical Examining Board⁴⁸⁸ both have policies recognizing the importance of access to appropriate and effective pain relief to the provision of quality nursing and medical practice. Physicians and nurses are encouraged to view the diagnosis and

⁴⁸⁴ American Pain Society. 2000. Pain assessment and treatment in the managed care environment. Available at: http://www.ampainsoc.org/advocacy/assess_treat_mce.htm. Accessed on January 14, 2011.

⁴⁸⁵ Connecticut General Assembly, Insurance and Real Estate Committee. 2000. Report on bills favorably reported by Committee, SB-406.

⁴⁸⁶ Council on Affordable Health Insurance. 2010. Mandates in the States 2010. Available at: http://www.cahi.org/cahi_contents/resources/pdf/MandatesintheStates2010.pdf. Accessed on January 12, 2011.

⁴⁸⁷ Connecticut Board of Examiners of Nursing. 2006. Statement of the Connecticut Board of Examiners for Nursing on the use of controlled substances for the treatment of pain. Available at: http://www.ct.gov/dph/lib/dph/phho/nursing_board/guidelines/statementontheuseofcontrolledsubstances12202006.pdf. Accessed on January 13, 2011.

⁴⁸⁸ Connecticut Board of Medical Examiners. 2005. Statement of the Connecticut Medical Examining Board on the Use of Controlled Substances for the Treatment of Pain. Available at: http://www.ct.gov/dph/lib/dph/phho/medical_board/guidelines/statementoftheconnecticutmedicalexaminingboardrevised62005.pdf. Accessed on January 13, 2011.

treatment of pain as integral to the practice of medicine and of nursing, and as part of quality medical and nursing practice.

Internet searches and telephone inquiries found one study from state agencies and public organizations related to the social impact of mandated insurance coverage for pain management:

California: In April 2010, the California Health Benefits Review Program (CHBRP) reviewed Assembly Bill 1826, Pain Prescriptions. The bill would prohibit the use of fail-first protocols as methods of utilization management for pain medications covered through an outpatient pharmacy benefit by a health care service plan. The report notes that pain is a prevalent condition in the U.S. population, with approximately 26 percent of adults experiencing chronic pain. However, the report notes that although there is some evidence that fail-first protocols can lead to lower levels of pain satisfaction, delays in receiving medications, and higher rates of unfulfilled prescriptions, this research cannot be generalized to populations outside of those studied. Therefore, CHBRP states that the public health impact of AB 1826 is unknown.⁴⁸⁹

States searched for which no evidence of a review was found include Alabama, Alaska, Arizona, Arkansas, Colorado, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, 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.

The alternative to allowing access to a pain management specialist for pain treatment is to have the member's treating physician provide the pain treatment. This is what typically happens for acute, short-term pain due to surgery or injury.

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.

Pain is a medical condition and pain treatment is a medical service. To the extent that access to pain management specialists can reduce the risk of overdose, abuse of pain medications, and opioid addiction, it could be said to meet a societal need as well as a medical need.

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 health plans that require a member to obtain a referral from a primary care provider before consulting a specialist.

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

Because there is little or no additional cost associated with this mandate, it is not expected to have any impact on the availability of other benefits currently offered.

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

No data was received from Connecticut insurers/MCOs as to the number of self-funded plans that provide coverage equaling or exceeding this mandate.

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

⁴⁸⁹ California Health Benefits Review Program, 2010. Analysis of Assembly Bill 1826, Pain Prescriptions. Available at: http://www.chbrp.org/docs/index.php?action=read&bill_id=70&doc_type=3. Accessed December 20, 2010.

benefits plan.

The IC actuarial report did not include any cost to the state employee health insurance or health benefit plans for this mandate because the mandate simply permits the patient to receive care from the best type of provider for their condition. To the extent that the mandate provides coverage for patient-controlled analgesics that were not covered before, it may add a *de minimis* cost.⁴⁹⁰

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.*

Pain treatments have significant side effects that must be weighed against the benefits for each patient on a case by case basis. Many of the pharmacological treatments for pain, when combined with other medications, herbal supplements or alcohol, can be dangerous. In addition, prescription opioid abuse, misuse and diversion are ever-present possibilities.⁴⁹¹ The need for aggressive treatment of chronic pain must be balanced against these side effects and risks.

Primary care physicians, mindful of these risks, evaluate patients with chronic pain and tailor therapy accordingly. Methods exist to assess the risk of opioid abuse or misuse and to monitor at-risk patients who nevertheless need opioid medications. For some patients, this may be beyond the skill of a primary care physician, and referral to a pain management specialist may be indicated.⁴⁹²

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 Ingenix Consulting report indicated no cost for this mandate over the next five years.

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

The presence of this benefit mandate is likely to increase the use of pain management specialists for management of chronic pain. This may actually reduce the cost and duration of pain treatment and pain management by providing more knowledgeable management at a lower cost over the long run for those with chronic pain and by limiting the potential for addiction to opioid pain drugs.⁴⁹³

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.*

Office visits to pain management specialists may be more expensive than office visits to primary care providers, and there may be a difference in the cost of pain treatments prescribed by the two types of providers. However, the overall difference in cost is deemed to be *de minimis*.⁴⁹⁴

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

⁴⁹⁰ Ingenix Consulting report, Appendix II, p. 11.

⁴⁹¹ Passik S. 2009. Issues in long-term opioid therapy: unmet needs, risks and solution. *Mayo Clin Proc* 84(7); 593-601.

⁴⁹² *Ibid.*

⁴⁹³ *Ibid.*

⁴⁹⁴ *Ibid.*

The mandate is limited to care and medications that are prescribed by a pain management specialist. “Pain management specialist” is defined as a physician who is credentialed by the American Academy of Pain Management or who is a board-certified anesthesiologist, neurologist, oncologist, or radiation oncologist with additional training in pain management.

The statute mandates coverage of all pain treatment ordered by a pain management specialist. It is unclear whether the terms “medically necessary” and “necessary medications and procedures” would allow for utilization management by an insurer/MCO.

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.

The IC actuarial report did not include any cost for this mandate because the mandate simply permits the patient to receive care from the most appropriate type of provider for their condition. To the extent that the mandate provides coverage for patient-controlled analgesics that were not covered before, it may add a *de minimis* cost.

For further information, please see Appendix II: Ingenix Consulting Actuarial and Economic Report.⁴⁹⁵

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.

Treatments for pain are almost as varied as its causes. Some are very inexpensive. Some are very costly.

Office visits to pain management specialists may be more expensive than office visits to primary care providers, and there may be a difference in the cost of pain treatments prescribed by the two types of providers. However, the overall difference in cost is deemed to be *de minimis*.⁴⁹⁶

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. This mandate is expected to have a *de minimis* impact on the total cost of health care in Connecticut.⁴⁹⁷

The cost of treatment by a pain management specialist may be at least partially offset by more effective pain management and reduced use of pain management drugs that are habit-forming or addictive.

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 actuarial report found that this mandate is expected to have roughly the same effect on the allowed cost

⁴⁹⁵ Ingenix Consulting report, Appendix II, p. 6.

⁴⁹⁶ *Ibid.*

⁴⁹⁷ Ingenix Consulting report, Appendix II, p. 11.

of small group plans as it does on large group plans, which is *de minimis*.⁴⁹⁸

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 mandate on the overall cost of health care delivery in the state is *de minimis*.⁴⁹⁹ 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.

⁴⁹⁸ Ingenix Consulting report, Appendix II, p. 29.

⁴⁹⁹ Ingenix Consulting report, Appendix II, p. 11.

Volume IV

Chapter 13

Continuation of Maternity Benefits

Review and evaluation of Connecticut General Statutes

Chapter 700, § 38a-547

Termination of policy or contract due to insurer ceasing to offer health insurance in this state; maternity benefits to continue for six weeks following termination of the pregnancy

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Chapter 13. Table of Contents

- I. Overview..... 189
- II. Background..... 190
- III. Methods..... 194
- IV. Social Impact..... 194
- Table IV.13.1. Average expenditures per pregnancy for uncomplicated pregnancies; mean/median (MEPS, 2004)..... 198
- V. Financial Impact.....202

I. Overview

The Chairs of the Insurance and Real Estate Committee of the Connecticut General Assembly directed the Connecticut Insurance Department to review statutorily mandated health benefits existing on or effective on July 1, 2009, pursuant to section (b) of Public Act 09-179, An Act Concerning Reviews of Health Insurance Benefits Mandated in this State. Each review was conducted following the requirements stipulated under Public Act 09-179 as a collaborative effort of Connecticut Insurance Department (CID) and the University of Connecticut's Center for Public Health and Health Policy (CPHHP). The CID and CPHHP contracted with the actuarial firm Ingenix Consulting (IC) to conduct an actuarial and economic analysis for each mandate.

This chapter evaluates the financial and social impact of the requirement for maternity benefit continuation for pregnant women (MBC) as specified under Connecticut General Statutes, Chapter 700, Section 38a-547. This mandate applies only when a health carrier plans to stop offering health plans in the state and as a result discontinues a group health plan under which a pregnant woman or pregnant women are enrolled. The statute, which applies to fully insured group health plans, reads as follows:

As used in this section, the term “employer” means any individual, partnership, corporation or unincorporated association providing group hospital or medical insurance coverage for its employees. Whenever any insurance company, hospital service corporation or medical service corporation authorized to do the business of health insurance in this state declines to continue or renew a health insurance policy or contract issued to an employer because it is ceasing to offer health insurance within this state, the subsequent termination of coverage for such group shall be without prejudice to any claim for maternity benefits made by any employee or dependent covered under such policy or contract who is pregnant on the date of termination of such group coverage, provided such insurance company, hospital service corporation or medical service corporation is given written notice of any such pregnant employee or dependent within thirty days after the termination date. Maternity benefits and benefits for treatment of medical complications resulting from such pregnancy shall be payable for six weeks following the termination of pregnancy, subject to the terms and conditions of such policy or contract.

To evaluate this mandate, in March 2010, CPHHP and IC requested and received 2007 and 2008 claims data related to the mandated benefit from six insurers and managed care organizations (carriers) 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). Six carriers provided data for group plans.

Current coverage

Carriers of fully insured group health plans must continue maternity benefits for pregnant women even if the carrier is ceasing to offer plans in the state and discontinues the employer plan under which the pregnant women is insured. This benefit, enacted in 1990, is limited to the fully insured population enrolled in group plans, which accounts for approximately 40.8 percent of Connecticut residents.

Premium impact

Group plans: The MBC benefit only applies if a carrier ceases to offer health plans in the state and terminates fully insured group health plans under which a pregnant member or pregnant members are enrolled. As of January 1, 2011, these prerequisite circumstances have not occurred in Connecticut, thus there is no claims data on which to base an estimate of the cost of the mandate.

Individual policies: The MBC mandate is not applicable to individual policies.

Self-funded plans

No information was available regarding whether self-funded plans extend a guarantee of coverage for maternity benefits under the circumstances specified under 38a-547.

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 II.

II. Background

Pregnancy refers to the period from conception to birth during which time the mother is carrying a developing offspring, referred to as an embryo or fetus depending on its stage of development. Fetus refers to the unborn offspring from the end of the eight week following conception until birth. The time, conditions and medical care specific to pregnancy are classified with respect to when delivery or birth occurs. The period prior to birth is referred to as antenatal or more colloquially as prenatal. The period following birth, traditionally extending six weeks, is labeled postpartum or postnatal with the later generally referring to the infant and the former referring to the mother.

After delivery, conventionally the newborn is referred to as a neonate and the period as neonatal for twenty eight days.⁵⁰⁰ At birth, the baby is classified as premature (<27 weeks), full term (37-42 weeks) or post term (>42 weeks) depending on the number of weeks of gestation. (Gestational age, or weeks of gestation, is counted from the date of the mother's last menstrual cycle).

Premature neonates tend to have underdeveloped organs and/or anatomic or functional immaturity due to the shortened period of growth and often require intensive care. Resulting short-term health issues may include risk of death, chronic lung disease, hypothermia, respiratory abnormalities, severe intracranial hemorrhage, hypoglycemia, infection and retinopathy.⁵⁰¹ In the longer term, the potential for long-term neurodevelopment impairment and chronic health problems are also greater among those born preterm compared to full term, with risk decreasing with gestational age. (Examples of long-term issues include recurrent illnesses, gastroesophageal reflux, poor growth, impaired lung function, impaired cognitive skills, motor deficits, cerebral palsy, sensory impairment, and behavioral or psychological problems).⁵⁰² According to the Centers for Disease Control and Prevention (CDC) approximately 1 in 8 pregnancies in the United States result in preterm birth. The causes of preterm birth are uncertain, yet these infants are at greater risk for death and disability.⁵⁰³ The predominate goal of medical services rendered during pregnancy focus on delivery of a healthy newborn with minimal risk to the mother throughout the pregnancy and delivery.

Antepartum (Prenatal) Care

Major concerns addressed during the prenatal period include risk factors for pre-term or premature birth, low birth weight, infection and potential transmission of health conditions *in utero*. Ectopic pregnancy, preeclampsia, fetal malformations, and congenital malformations or anomalies are also among the concerns addressed during prenatal care.

Ectopic pregnancy is an unviable pregnancy where implantation of the embryo occurs outside of the uterus,

⁵⁰⁰ Stedman's Medical Dictionary. 2005. 28th Ed. Lippincott Williams and Wilkins.

⁵⁰¹ Mandy GT. 2010. Short-term complications of the premature infant. *UpToDate*. Available at: http://www.uptodate.com/online/content/topic.do?topicKey=neonatology/12639&selectedTitle=1%7E150&source=search_result. Accessed December 23, 2010.

⁵⁰² *Ibid.*

⁵⁰³ Centers for Disease Control and Prevention. 2010. Preterm Birth.

Available at: <http://www.cdc.gov/reproductivehealth/maternalinfanthealth/PretermBirth.htm>. Accessed December 23, 2010.

typically in the fallopian tube. These pregnancies, which have a risk of hemorrhage, are the most common cause of maternal death, accounting for 4 to 10 percent of all pregnancy related deaths. Surgical removal of the ectopic pregnancy is the only medical remedy.⁵⁰⁴

Preeclampsia refers to pregnancy-related onset of hypertension and proteinuria after 20 weeks of gestation. Symptoms may include a sudden increase in blood pressure, excessive protein in urine, swelling in the woman's face and hands, and headaches. This condition occurs in about 5 to 8 percent of U.S. pregnancies. It is a common cause of maternal and perinatal morbidity and mortality. Potential health impacts include a decrease in birth weight if onset is severe and early, separation of the placenta from the uterus (placental abruption), preterm delivery, eclamptic seizures and multiple organ failure. According to a recent review, no preventive interventions have been found and the only effective treatment involves early delivery, thus resulting in a preterm birth.^{505, 506}

Congenital malformation or abnormalities are permanent physical defects to organs such as the brain, heart, lungs, liver, bones and intestinal tract that are caused by genetic or prenatal events during early embryonic life. Present in one out of three infant deaths, congenital malformations are the leading cause of infant mortality in the U.S. Approximately 2-3 percent of babies are born with congenital malformations, many of whom have heart defects, a cleft lip or palate, spina bifida or limb defects.⁵⁰⁷

Outcomes of pregnancy are often measured in terms of fetal deaths, pre-term birth, gestational age at birth, infant birth weight, infant mortality and other morbidities. A number of factors are considered to elevate the risk of potential health conditions occurring during pregnancy. Maternal age (especially <16 or >35); multiple pregnancy (e.g., twins, triplets, etc.); the presence of diabetes, heart disease, hypertension, kidney disease, autoimmune disorders, cancer, HIV or certain infections; maternal overweight or underweight; problems in prior pregnancies; and substance use. These factors are associated with pre-term births, low birth weight, and increased mortality.⁵⁰⁸ A number of problems may also arise during a pregnancy which increase the risk of preterm labor.

Traditionally, early discovery of pregnancy and ongoing prenatal care has been encouraged as a means to minimize potential health risks. The publication "Guidelines for Perinatal Care" includes the standards set by the American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG) with regard to pregnancy-related care. Numerous recommendations or position statements also exist with regard to specific technologies, conditions and procedures related to pregnancy-care. In general terms, a comprehensive prenatal care program consists of routine office visits for ongoing risk assessments and evaluation of health status for both mother and fetus, a care plan adjusted to anticipate problems and their related interventions, patient education and communication, psychosocial support, and referrals to additional services as needed.⁵⁰⁹

The administration of prenatal care in terms of content and frequency varies substantially across practices.

⁵⁰⁴ Tulandi T. 2010. Incidence, risk factors, and pathology of ectopic pregnancy. UpToDate. Available at: <http://www.uptodate.com/patients/content/topic.do?topicKey=-QHCCGmhr7Xhm7H>. Accessed December 23, 2010.

⁵⁰⁵ Agusut P, Sibai B. 2010. Clinical features, diagnosis, and long-term prognosis of preeclampsia. Available at: http://www.uptodate.com/online/content/topic.do?topicKey=pregcomp/4788&selectedTitle=1%7E150&source=search_result. Accessed December 23, 2010.

⁵⁰⁶ Agusut P. 2010. Prevention of preeclampsia. UpToDate. Available at: http://www.uptodate.com/online/content/topic.do?topicKey=pregcomp/5540&selectedTitle=1%7E150&source=search_result. Accessed December 23, 2010.

⁵⁰⁷ MD Terms. 2002. Definition of congenital malformation. Available at: <http://www.medterms.com/script/main/art.asp?articlekey=2820>. Accessed December 23, 2010.

⁵⁰⁸ National Women's Health Information Center. 2010. Frequently asked Questions. Prenatal care. Available at: <http://www.womenshealth.gov/faq/prenatal-care.cfm>. Accessed December 23, 2010.

⁵⁰⁹ Lockwood CJ, Magriples U. 2010. The initial prenatal assessment and routine prenatal care. UpToDate. Available at: http://www.uptodate.com/online/content/topic.do?topicKey=antenatl/2937&selectedTitle=1%7E150&source=search_result. Accessed December 23, 2010.

Most experts recommend the following frequency of visits by week of gestation for normal pregnancies: 1 visit per month for weeks 4 through 28, 2 visits per month for weeks 28 through 36, and weekly visits for week 36 through birth. For mothers' with risk factors present, a more frequent visit schedule may be recommended.⁵¹⁰

Delivery of prenatal care is further described by trimesters where the first trimester includes week 1 through 12, the second trimester includes week 13 through 26, and the third trimester includes week 27 through the end of the pregnancy. In cases of high-risk pregnancies, personal or family health history, or ethnic background, additional tests are often recommended.⁵¹¹

At the initial visit in the first trimester, the guideline for care involves obtaining a thorough patient history (family history, surgeries or operations, diseases, past pregnancies, medical conditions, substance use, medication use), estimating the delivery date, conducting a physical exam to assess overall health (e.g., blood pressure, height, and weight), conducting a vaginal exam, blood and urine lab work, laboratory tests for potential threats to the pregnancy, and advising the mother with regard to appropriate seat belt use, vitamins, nutrition, weight gain and risks of substance abuse and infection precautions.^{512, 513}

Subsequent first trimester visits typically include measuring weight and blood pressure, discussing signs and symptoms, and routine lab tests without a pelvic exam. For the second trimester, additional assessment of fetal growth, heartbeat, and movement are added to the office visit and during the third trimester pelvic exams are resumed, the head position of the fetus is evaluated and cervical changes are assessed.^{514, 515} In the third trimester, a biophysical profile (BPP) is created to monitor the overall health of the baby and decide whether the baby should be delivered early. The BPP includes an ultrasound exam and non-stress test to assess the breathing, movement, muscle tone, heart rate and amount of amniotic fluid surrounding the fetus.⁵¹⁶

Prenatal Tests

A number of prenatal tests are administered as a component of prenatal care. Tests are used to screen for or diagnose conditions that can lead to adverse maternal, fetal or infant outcomes such as preterm delivery, miscarriage, and developmental disability. Certain procedures, such as Chorionic villus sampling, are also offered for detection of genetic or chromosomal disorders. Some of the potential conditions detected and some related health risks are summarized below.

Maternal-carried infection or diseases such as group B streptococcus, bacterial vaginosis, influenza, parvovirus B19, listeriosis, cytomegalovirus, and urinary tract infection are routinely assessed. Depending on the infection, risk of severe maternal anemia, preterm labor, miscarriage and sensory or intellectual disabilities in the newborn may occur.⁵¹⁷

⁵¹⁰ National Women's Health Information Center. 2010. Frequently asked Questions. Prenatal care. Available at: <http://www.womenshealth.gov/faq/prenatal-care.cfm>. Accessed December 23, 2010.

⁵¹¹ *Ibid.*

⁵¹² Lockwood CJ, Magriples U. 2010. The initial prenatal assessment and routine prenatal care. UpToDate. Available at: http://www.uptodate.com/online/content/topic.do?topicKey=antenatl/2937&selectedTitle=1%7E150&source=search_result. Accessed December 23, 2010.

⁵¹³ National Women's Health Information Center. Frequently asked Questions. 2010. Prenatal care. Available at: <http://www.womenshealth.gov/faq/prenatal-care.cfm>. Accessed December 23, 2010.

⁵¹⁴ Mayo Clinic Staff. 2010. Prenatal care: first-trimester visits. Mayo Clinic. Available at: <http://www.mayoclinic.com/print/prenatal-care/PR00008/METHOD=print>. Accessed December 23, 2010.

⁵¹⁵ National Women's Health Information Center. Frequently asked Questions. 2010. Prenatal care. Available at: <http://www.womenshealth.gov/faq/prenatal-care.cfm>. Accessed December 23, 2010.

⁵¹⁶ American Congress of Obstetricians and Gynecologists. 2010. Routine pregnancy tests. Available at: http://www.acog.org/publications/patient_education/bp133.cfm. Accessed December 23, 2010.

⁵¹⁷ National Women's Health Information Center. 2010. You are pregnant. Pregnancy complications. Available at: <http://www.womenshealth.gov/pregnancy/you-are-pregnant/pregnancy-complications.cfm>. Accessed December 23, 2010.

Blood or urine samples are used to test for gestation-related conditions such as anemia, hypertension, gestational diabetes, and preeclampsia.

Chromosomal abnormalities can cause neural tube defects, mental retardation, short stature, seizures, heart problems, death of the embryo or fetus before birth, heart problems, cleft palate, and Prader-Willi syndrome.⁵¹⁸

Gene mutations can result in conditions such as sickle cell anemia, cystic fibrosis, muscular dystrophy, congenital adrenal hyperplasia, hemophilia A, alpha- and beta- thalassemia, fragile X syndrome, polycystic kidney disease, Tay-Sachs disease.⁵¹⁹

Test results may lead to administering of antibiotics, immunizations or pharmaceuticals; medical management of conditions present in the mother; or in some cases termination of pregnancy.⁵²⁰ Additional guidance on activity level, timing of delivery, and nutrition may also be made to minimize health risks.

Delivery

As the delivery date approaches, prenatal care involves discussion between the medical care provider and the patient regarding the risks and benefits of the different routes of delivery, management of pain during labor (regional, local or general anesthesia), postpartum issues, breastfeeding, care of the newborn, and neonatal circumcision.⁵²¹ Delivery may be planned for the hospital, a birthing center, or the home. The use of anesthesia to address pain is also discussed. The procedure for delivery involves a vaginal examination to determine fetal position and cervix dilation. Delivery may be vaginal or by Cesarean section.

A number of complications may occur that require intervention. A clinician may detect a variety of potential issues before delivery, during delivery, or after delivery.⁵²² A few potential issues for each stage are listed below.

Before: multi-fetal pregnancy, post-term pregnancy, premature rupture of membranes, and abnormal fetal presentation

During: amniotic fluid embolism, shoulder dystocia, fetopelvic disproportion, preterm labor, protracted labor, and umbilical cord prolapse

After: Other maternal complications such as postpartum hemorrhage or an inverted uterus may occur after delivery and require treatment. In some cases resuscitation of the newborn is needed or other newborn complications requiring treatment are needed.

Postpartum Care

Following delivery, the newborn must be monitored as the body becomes responsible for circulation, breathing, body temperature, blood sugar regulation, and digestion. Concurrently, the transition for the

⁵¹⁸ Liptak G (reviewer). 2008. Introduction: chromosomal and genetic abnormalities. Merck Manuals. Available at: <http://www.merckmanuals.com/home/sec23/ch266/ch266a.html>. Accessed December 23, 2010.

⁵¹⁹ Dungan JS (reviewer). 2008. Prenatal diagnostic testing. Merck Manuals. Available at: <http://www.merckmanuals.com/home/sec22/ch256/ch256c.html>. Accessed December 23, 2010.

⁵²⁰ National Women's Health Information Center. 2010. You are pregnant. Pregnancy complications. Available at: <http://www.womenshealth.gov/pregnancy/you-are-pregnant/pregnancy-complications.cfm>. Accessed December 23, 2010.

⁵²¹ Connecticut Department of Public Health. Vital Statistics (Registration Reports). Table 1: Connecticut, 2008 Estimated population by age and sex. Table 2A: Connecticut, 2008 Population, births, deaths, fetal deaths, and infant deaths by place of occurrence and residence and marriages by place of occurrence. Available at: <http://www.ct.gov/dph/cwp/view.asp?a=3132&q=394598>. Accessed December 1, 2010.

⁵²² Moldenhauer JS (reviewer). 2008. Introduction: abnormalities and complications of delivery. Merck Manuals. Available at: <http://www.merckmanuals.com/professional/sec18/ch264/ch264a.html>. Accessed December 23, 2010.

mother includes physical and emotional changes, breastfeeding, and learning about general newborn care issues (e.g., bathing, umbilical cord care, and taking a temperature), safety concerns and signs of neonatal illness.⁵²³ The most common complications affecting the mother are postpartum bleeding, infections, breastfeeding issues, and depression.⁵²⁴ During the newborn's first 48 hours of life detection of congenital malformations, sepsis, and newborn breastfeeding issues such as initiation of breastfeeding, dehydration, or clinical jaundice are significant health concerns.⁵²⁵

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, UptoDate, DynaMed, Cochrane database, EMedicine, CINAHL, and a web search using Google. Search keywords included: maternity, prenatal, postpartum, postnatal, neonate, inpatient, outpatient, policy termination, social impact, insurance, insurance coverage, reimbursement, economics, and cost.

CPHHP staff conducted independent literature searches using the Cochrane Review, Scopus, Westlaw, and Google Scholar using similar search terms to those 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 maternity 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 requested and received 2007 and 2008 claims data from insurance companies and MCOs domiciled in Connecticut. Six carriers provided claims data for their fully insured group plan participants.

CPHHP and the CID contracted with Ingenix Consulting (IC) to provide actuarial and economic analyses of the mandated benefit. A description of the methods used for the actuarial analysis is available in the Ingenix Consulting report located in Appendix II.

IV. Social Impact

1. The extent to which coverage of continuation of maternity benefits is utilized by a significant portion of the population.

As of December 2010, no health carrier has discontinued offering health plans and therefore terminated a group plan under which MBC may be required. Therefore, the benefit has not been utilized. Assuming a carrier or carriers left the health plan market in Connecticut and discontinued offering employer based

⁵²³ Friedman MA, Spitzer AR. 2004. Discharge criteria for the term newborn. *Pediatric Clinics of North America* 51(3): 599-618.

⁵²⁴ Moldenhauer JS. 2008. Women's Health Issues. Post-delivery Period.

Available at: <http://www.merck.com/mmhe/sec22/ch262/ch262a.html>. Accessed November 5, 2010.

⁵²⁵ Friedman MA, Spitzer AR. 2004. Discharge criteria for the term newborn. *Pediatric Clinics of North America* 51(3): 599-618.

health plans, utilization of the benefit depends on the number of pregnant women enrolled in the employer-based health plans at that time. As a rough estimate using vital statistics from 2008, to the extent that the carrier covers women between the ages of 20 to 39, around 8 out of every 100 women (ages 20 to 39) covered may be pregnant. 88.3 percent of live births in Connecticut in 2008 occurred among women ages 20 to 39 and 53.8 percent of live births occurred among women ages 25 to 34. Although the prevalence is likely to differ somewhat for the fully insured population and across industries, these numbers may serve as an approximation of the size of the population that may utilize maternity care.

Among pregnant women in the U.S. during 2004, results from the nationally representative MEPS survey found more than 99 percent of pregnant women had delivery expenses and more than 9 out of 10 had prenatal care expenses, regardless of insurance status. In addition, around 22 percent of pregnant women had expenses for prescription medications.⁵²⁶

2. The extent to which continuation of maternity benefits 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.

Access to maternity care is available to some extent through public, not-for-profit or private entities. The existing options are often limited to families with low-incomes or families deemed at high-risk. With the exception of Medicaid, comprehensive coverage of prenatal, delivery and postpartum care is unlikely to be available through one payer.

Medicare

Medicare provides coverage for reasonable and necessary services associated with maternity for a limited number of individuals under the age of 65 who are disabled. Medicare requires that “[s]killed medical management is appropriate throughout the events of pregnancy, beginning with diagnosis of the condition, continuing through delivery, and ending after the necessary postnatal care.” Further, “in the event of termination of pregnancy, regardless of whether terminated spontaneously or for therapeutic reasons (i.e., where the life of the mother would be endangered if the fetus were brought to term), the need for skilled medical management and/or medical services is equally important as in those cases carried to full term.” Following delivery, the mother is covered for postnatal care but any treatment or services for the infant are not covered under Medicare.⁵²⁷

Department of Social Services

The Department of Social Services is the oversight agency for the Medicaid program, Healthy Start, and Nurturing Families. Many of these programs are delivered in local settings including hospitals, community health centers, social service agencies and local health departments.

The Medicaid program offers HUSKY A coverage from pre-pregnancy and up to 60 days after giving birth for eligible expecting mothers earning at or below 250 percent of the federal poverty level (\$45,775 for a family of three). The coverage is for free health care. Approximately one in five births are covered by Medicaid. “Medical necessity is the guideline used for coverage.”⁵²⁸

Emergency Medicaid allows coverage for labor and delivery of a child for undocumented immigrants but

⁵²⁶ Machlin SR, Rohde F. 2007. Health care expenses for uncomplicated pregnancies. Research Findings No.27. Agency for Healthcare Research and Quality. Available at: http://www.meps.ahrq.gov/mepsweb/data_files/publications/rt27/rt27.pdf. Accessed December 23, 2010.

⁵²⁷ Centers for Medicare and Medicaid Services. 2010. Medicare Benefit Policy Manual. Chapter 1, section 80. Revision 119. Available at: <http://www.cms.gov/manuals/Downloads/bp102c01.pdf>. Accessed August 30, 2010.

⁵²⁸ Personal communication. Nina Holmes, DSS Medical Policy Unit. May 21, 2010.

does not include prenatal or postnatal care. However, a baby born to an undocumented immigrant is considered a U.S. citizen and therefore, may be eligible for Medicaid at birth.

The *Healthy Start* program is geared towards income-eligible uninsured pregnant women as a source for free medical care, labor, delivery, nursing care, medications, counseling and related services. Eligible families with children under three years old can participate in counseling and parenting classes. This program is administered by DSS and DPH through grant-based contracts with hospitals, clinics, local departments of health and other local organizations.⁵²⁹

Municipal Health Departments

At the local level, some health departments provide maternity and newborn related services by delivering programs funded by federal, state or local initiatives. For example, the Maternal Infant and Outreach Program in Hartford conducts neighborhood outreach and supports pregnant women and families throughout the year following the birth of the child by providing health, nutritional, educational and emotional support during home visits.⁵³⁰ Municipalities may also offer low-cost prenatal programs and maternity services at a reduced fee.

Department of Public Health (DPH)

The DPH shares administrative duties for many of the programs discussed under the DSS section above. In addition, the WIC program offers breastfeeding and nutrition support through supplemental food assistance and counseling but not postpartum hospital stay support.

Other Public Agencies/Programs

In some cases, birthing centers may offer a sliding scale for maternity care that includes prenatal care, delivery, recovery time, and post-delivery monitoring and education.⁵³¹ Home-visits and parenting groups are offered through birthing hospitals and community agencies.⁵³²

Several entities offer parent-support services. The Connecticut Children's Trust Fund, an independent state agency, funds the Nurturing Families program to help high-risk families navigate the challenges of parenthood when the first child is born. Not-for-profits such as Catholic Charities offer parenting education and follow-up services for a year after the birth of a child and help expecting mothers obtain access to health care or other needed services.⁵³³ Hospitals may have lactation consultants, a Nurturing Families program, or similar programs.

Hospitals may also offer sliding scale fees or charity care funds to assist income-eligible families afford the cost of delivery. A large proportion of charity care is allocated to pregnant women and children.⁵³⁴ However, charity care funds are limited, vary widely across hospitals, and rely on financing from hospital

⁵²⁹ State of Connecticut Department of Social Services. Health Care.

Available at: <http://www.ct.gov/dss/cwp/view.asp?a=2353&q=305218#HS>. Accessed August 30, 2010.

⁵³⁰ Hartford Department of Health and Human Services. Maternal and Child Health Division.

Available at: http://www.hartford.gov/Human_services/html%20files_06/Maternal.htm. Accessed August 30, 2010.

⁵³¹ Connecticut Childbirth and Women's Center. Frequently Asked Questions. Available at: <http://www.ctbirthcenter.com/faq.htm>. Accessed August 31, 2010.

⁵³² State of Connecticut Children's Trust Fund. October 2005. Nurturing Families Network.

Available at: <http://www.ct.gov/ctf/cwp/view.asp?a=1786&q=296678>. Accessed August 31, 2010.

⁵³³ Catholic Charities and Diocese of Norwich. Pregnancy Services. Available at: <http://www.ccfns.org/pregnancy.htm>. Accessed August 31, 2010.

⁵³⁴ State of Connecticut Office of Health Care Access. 2006. Glossary of terms. Available at:

<http://www.ct.gov/ohca/cwp/view.asp?a=1738&q=277038>. Accessed August 31, 2010.

benefactors.⁵³⁵

3. *The extent to which insurance coverage is already available for continuation of maternity benefits.*

Connecticut law requires coverage for maternity benefits for pregnant women enrolled in fully insured group health plans that are discontinued as a result of a health plan carrier no longer offering plans in Connecticut. This mandate has been in place since 1990⁵³⁶ and applies to approximately 40.8 percent of Connecticut residents.⁵³⁷

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 is required and generally available for persons enrolled in fully insured group health insurance plans. It is possible that if MBC were not in place, prenatal care and postpartum care may not be accessed to the degree recommended by the medical community. To the extent that pregnancy-related medical complications are emergencies, it may be possible to access emergency medical care regardless of insurance status. Under the federal Emergency Medical Treatment and Active Labor Act (EMTALA), hospitals authorized for Medicare reimbursement must provide stabilizing care to patients experiencing a medical emergency, regardless of the patient's ability to pay. Similarly, pregnant women would be able to access emergency medical care under EMTALA for the delivery of a child.

Furthermore, if the prerequisite scenario unfolded under which the MBC mandate would become active, a pregnant woman enrolled in the discontinued employer plan would not be excluded from coverage under the new employer plan based on her pregnancy. Three years following the passage of the MBC mandate, Connecticut Public Act 93-345 prohibited excluding coverage for pregnancy based on a pre-existing condition clause.⁵³⁸ Similarly, in 1996 the federal government passed the federal Health Insurance Portability and Accountability Act, which prohibits excluding coverage for pregnancy based on a pre-existing condition clause.

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.*

The cost of pregnancy-related health care could result in unreasonable financial hardship on those persons needing treatment. A recent report using 2004 data from the nationally representative Medical Expenditures Panel Survey (MEPS) describes the average expenditures for uncomplicated pregnancies (Table X). The mean per pregnancy cost for combined prenatal care and delivery cost was \$7,564 for all pregnancies, \$8,366 for privately insured pregnancies and \$6,540 for Medicaid pregnancies.⁵³⁹ For a pregnancy without insurance coverage, the cost would likely be most comparable to the cost for privately insured pregnancies. A family with an annual income of \$50,000 would be paying around 13 percent of their income for delivery or 15.1 percent of their income for prenatal care and delivery combined. (Notably, mean expenses for pregnancy are higher than median costs, suggesting that a subset of the population with uncomplicated

⁵³⁵ State of Connecticut Office of Health Care Access. 2009. Annual report on the financial status of Connecticut's short term acute care hospitals for fiscal year 2008. Available at: www.ct.gov/ohca/lib/ohca/publications/2009/fsreport_2008.pdf. Accessed August 31, 2010.

⁵³⁶ CONNECTICUT GENERAL STATUTES. Revised January 1, 2010. § 38A-498B (INDIVIDUAL INSURANCE POLICIES); § 38A-525B (GROUP INSURANCE POLICIES).

⁵³⁷ 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>. Accessed October 8, 2010.

⁵³⁸ CONNECTICUT GENERAL STATUTES. Revised January 1, 2010. § 38A-476 (GROUP INSURANCE POLICIES).

⁵³⁹ Machlin SR, Rohde F. 2007. Health care expenses for uncomplicated pregnancies. Research Findings No.27. Agency for Healthcare Research and Quality. Available at: http://www.meps.ahrq.gov/mepsweb/data_files/publications/rf27/rf27.pdf. Accessed December 23, 2010.

pregnancies had much higher prenatal care expenses).

Table IV.13.1. Average expenditures per pregnancy for uncomplicated pregnancies; mean/median (MEPS, 2004)

Coverage	Prenatal Care and delivery			Types of Prenatal Care		
	Prenatal and Delivery	Prenatal Care	Delivery	Office-based	Prescription Drugs	Other expenses
All types	\$7,564/\$6,542	\$1,852/ \$1,159	\$5,850/ \$5,027	\$1,281/\$807	\$1,784/\$640	\$224/ \$59
Private plan	\$8,366/ \$7,625	\$1,962/ \$1,313	\$6,520/ \$5,872	\$1,474/ \$1,080	*	\$186/ \$66

*Cell size <30. Unreliable estimate.

Alternatively, a higher proportion of expenses for pregnancies are paid out of pocket when covered by private insurance (7.9 percent) compared to Medicaid (0.8 percent). If a pregnant individual was able to gain Medicaid coverage, the average amount paid out of pocket for the pregnancy would likely be closer to \$52 than \$660. For a family with \$50,000 in annual earnings, out of pocket expenses would account for 0.1 percent rather than 1.3 percent of the family income.

6. The level of public demand and the level of demand from providers for continuation of maternity benefits.

Evidence of public and provider support for maternity care is emphasized in national health goals (Healthy People);⁵⁴⁰ “Guidelines for Perinatal Care,” a joint publication of the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics; and utilization data for pregnancy related care.⁵⁴¹

7. The level of public demand and the level of demand from providers continuation of maternity benefits.

Connecticut public records provide weak evidence of demand for MBC. According to public hearing testimony, the mandate was created as a response to concerns that a pregnant woman with health insurance through an employer would not be covered by a new plan if a health carrier decided to no longer offer plans within the state. At the time, insurers typically regarded pregnancy as a pre-existing condition and would not provide benefits to those who became pregnant prior to enrollment in their insurance plan. The hearing transcripts suggest that a situation occurred in Connecticut where a pregnant woman lost coverage due to a carrier ceasing to offer health plans in the state.⁵⁴²

There is more evidence of demand for prohibiting the exclusion of insurance coverage for pregnancy as a pre-existing condition under group health plans. Three years following the passage of the MBC mandate, Connecticut Public Act 93-345 prohibited excluding coverage for pregnancy based on a pre-existing condition clause.⁵⁴³ Similarly, at the federal level the Health Information Portability and Accountability Act (HIPAA) was enacted in 1996, also prohibiting group plans from excluding pregnancy as a preexisting condition.

⁵⁴⁰ US Department of Health and Human Services. 2010. Health people 2020. Available at: <http://www.healthypeople.gov/2020/default.aspx>. Accessed December 23, 2010.

⁵⁴¹ Machlin SR, Rohde F. 2007.

⁵⁴² *Ibid.*

⁵⁴³ CONNECTICUT GENERAL STATUTES. Revised January 1, 2010. § 38A-476 (GROUP INSURANCE POLICIES).

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

Research conducted did not identify any other state health insurance mandates specific to carriers ceasing to offer health plans in the state nor related continuation of maternity care benefits for pregnant members. The “continuity of care” mandates identified typically addressed a carrier’s obligations to continue coverage for ongoing treatment or medical care for certain conditions even if participation of the health care provider in the network has been discontinued by the carrier. For example legislation in Wisconsin is as follows: “If an enrollee is undergoing a course of treatment with a participating provider who is not a primary care physician and whose participation with the plan terminates, the defined network plan shall provide the coverage ... for the remainder of the course of treatment or for 90 days after the provider’s participation with the plan terminates, whichever is shorter... If maternity care is the course of treatment and the enrollee is a woman who is in the second or third trimester of pregnancy when the provider’s participation with the plan terminates, [coverage continues] until the completion of postpartum care for the woman and infant.”⁵⁴⁴

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

Thirty states now require a fiscal note or an additional review process for any new required health insurance benefit prior to enactment.⁵⁴⁵ 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. No evidence of review for a similar mandate was found these states.

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

The MBC mandate becomes relevant if a carrier ceases to offer health plans in the state. The benefit required is for the carrier to continue providing maternity care for women who declared pregnancy within thirty days of the policy being terminated. Since maternity care is only required to be continued to the extent that the plan covered maternity care, the relevant debate of alternatives is what other stakeholder (e.g., carrier, employer, pregnant woman, or future carrier) might meet the need for continuation of maternity coverage. The issue underlying the need for continuation of coverage for a pregnant woman likely originated from carriers excluding coverage for pregnancy under preexisting condition clauses.

The preexisting condition issue has since been addressed by state and federal legislation. Three years following the passage of the MBC mandate, Connecticut Public Act 93-345 prohibited excluding coverage for pregnancy based on a pre-existing condition clause.⁵⁴⁶ Similarly, in 1996 the federal government passed the federal Health Information Portability and Accountability Act, which prohibits excluding coverage for pregnancy based on a pre-existing condition clause. Given that both federal and state law prohibits denying coverage for pregnancy based on pre-existing condition clauses, a pregnant woman whose fully insured employer-based health plan has been discontinued should not be subject to having her pregnancy excluded as a preexisting condition if the employer enrolls in a new health plan.

⁵⁴⁴ Wisconsin Code. 2010. Chapter 609. Defined network plans. 609.24 Continuity of care.

⁵⁴⁵ 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.

⁵⁴⁶ CONNECTICUT GENERAL STATUTES. Revised January 1, 2010. § 38A-476 (GROUP INSURANCE POLICIES).

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.

Pregnancy is a medical condition for which maternity care is provided. Prenatal care and delivery are considered the standard of care for pregnancy. Prenatal care plays a role in the continued monitoring of health for the mother and fetus, the detection of potential health conditions, and the provision of anticipatory guidance to the mother for both the pregnancy and the transition following the birth of the child. In some instances monitoring of the pregnancy results in detection of health issues that can be remedied or minimized. To the extent that prenatal care sometimes includes testing for conditions that lack medical interventions during the pregnancy period, such care may be considered meeting the social needs of the caregiver rather than a direct medical need.

Traditionally, insurance has provided a means to spread the cost of unexpected, high cost events across the population. Pregnancy, although high cost, is not necessarily unexpected. All insurance policies do not cover pregnancy; and, historically, pregnancy was often excluded from policies if it was a preexisting condition. Today, some insurance policies still do not include coverage for pregnancy-related health care. However, coverage of maternity care in general is consistent with the concept of managed care.

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

The MBC mandate has been in place since 1990. To date, no similar mandates addressing circumstances where a carrier ceases to offer health plans in the state have been enacted. Potentially continuation of benefits for other pre-existing diseases, illnesses or conditions requiring a time-limited scope of treatment could be initiated in a similar manner.

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

The MBC benefit is initiated only under unusual circumstances and the continuation of benefits is constrained to the timeframe necessary for maternity care and pregnancy-related complications, as dictated by state statute. The benefit is unlikely to have any effect on the availability of other benefits currently offered given the circumstances under which the mandate becomes active. It is expected that a carrier planning to discontinue offering health plans in Connecticut may consider the potential cost of MBC among its fully insured group plans during the decision making process.

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

The benefit is not expected to have or have had any effect on employers shifting to self-funded plans due to the relatively small size of the population eligible for benefits and the temporary nature of MBC. Given these aspects of the mandate, should MBC be required, it is expected to result in relatively low claims costs. No claims history exists for fully insured or self-funded health plans in Connecticut because the prerequisite circumstances for MBC has not occurred. No information is available on the extent to which MBC is currently being offered under self-funded plans.

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

The MBC mandate is a benefit that has been required under the state employee health insurance and health benefits plans from 1990 through July 1, 2010. As of July 1, 2010, the state shifted its employee plans to self-funded status. All self-funded plans, including those for state employees, are not regulated

by the state insurance department and are exempt from state health insurance required benefit statutes. It is expected that for the period in which state employee health plans were required to cover the benefit, the social impact of the benefit for the approximately 134,344 covered lives and 30,000 state retirees not enrolled in Medicare⁵⁴⁷ would 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. Because the prerequisite circumstances for MBC to be activated have not occurred, no claims history exists on which to base an estimate of the financial impact of the benefit on the state employee health insurance or health benefits plan.

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

Prenatal care is generally recognized by the medical community as safe and effective despite systematic reviews of the literature finding a lack of conclusive evidence that prenatal care improves birth outcomes. The author of one review suggests that it is possible that detection of potential benefits from prenatal care may be beyond the statistical power of current studies and that the variation in delivery of prenatal care in terms of quality and quantity complicates measurement.⁵⁴⁸ Another review suggested that the capacity of technology for prenatal care may be limited in preventing adverse fetal outcomes but is potentially helpful in reducing morbidity.⁵⁴⁹

In either case, the prevailing opinion is similar to a recent DPH report, which emphasized that the positive impact on prenatal birth outcomes is well known.⁵⁵⁰ Summarizing Connecticut data, the report stated that in 1998, mothers who received inadequate prenatal care had seven times more premature deliveries and three times more low birth weight deliveries than those who receive adequate prenatal care. The report also points out one conundrum of assessing prenatal care. For Connecticut mothers who received intensive prenatal care, there was a higher likelihood of prematurity or low birth weight than any other level of prenatal care (using APNCU levels of prenatal care). The report suggests that although intensive care may reduce risk of prematurity or low birth weight, it does not reduce risk to the same extent or level as prenatal care for others perhaps because the initial risk is higher among the intensive care group.⁵⁵¹

Reviews of specific procedures such as amniocentesis and percutaneous umbilical sampling suggest that there is some risk involved; especially when conducted to assess the potential for chromosomal or genetic malformations. According to the Merck Medical Manual, risks of amniocentesis include soreness, spotting of blood or leakage of amniotic fluid among 1 to 2 percent of women, and miscarriage in 1 in 500 or 1 in 1,000 procedures.⁵⁵² Loss of pregnancy is also a risk of percutaneous umbilical sampling with the rate of miscarriage expected to occur following 1 out of 100 procedures.⁵⁵³ In addition to the above risks, a potential adverse effect of positive results is anxiety related to knowledge of an abnormality.

⁵⁴⁷ Personal communication. Scott Anderson, State of Connecticut Comptroller's Office. September 14, 2010.

⁵⁴⁸ Fiscella K. 1995. Does prenatal care improve birth outcomes? A critical review. *Obstetrics and Gynecology* 85(3): 468-79.

⁵⁴⁹ McCormick MC, Siegel JE. 2001. Recent Evidence on the Effectiveness of Prenatal Care. *Ambulatory Pediatrics* 1(6): 321-5.

⁵⁵⁰ Connecticut Department of Public Health. 2002. One Hundred and Fifty-First Registration Report, 1998.

Available at: <http://www.ct.gov/dph/lib/dph/hisr/pdf/rr1998.pdf>. Accessed December 23, 2010.

⁵⁵¹ *Ibid.*

⁵⁵² Dungan JS (reviewer). 2008. Prenatal diagnostic testing. Merck Manuals.

Available at: <http://www.merckmanuals.com/home/sec22/ch256/ch256c.html>. Accessed December 23, 2010.

⁵⁵³ *Ibid.*

V. Financial Impact

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

The mandate is not expected to significantly increase or decrease the cost of maternity care over the next five years. If a carrier leaves the state or goes out of business and MBC is initiated, the pregnant women covered would likely consume the same amount of maternity care as they would if the carrier had not discontinued offering the health plan.

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

The mandated health benefit is expected to preserve the level of maternity care utilization among members of fully insured group health plans that would exist over the next five years if all carriers continue to offer health plans in the state. If a carrier ceases to offer health plans in the state during the next five years, the MBC mandate may increase appropriate use of maternity care compared to if the mandate did not exist and the pregnant women were unable to regain equivalent maternity coverage.

For those covered by self-funded plans, fully insured individual plans and persons who lack health insurance, the mandated benefit is not likely to impact utilization of maternity care. Inappropriate use is not expected to be a potential factor due to the nature of the service.

3. The extent to which continuation of maternity benefits may serve as an alternative for more expensive or less expensive treatment, service or equipment, supplies or drugs, as applicable.

The MBC mandate may serve as an alternative to a given employer (who has had their group health plan discontinued due to a carrier ceasing to offer health plans in the state) seeking coverage for pregnant individuals under a newly acquired, fully insured group health plan.

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

The state statute specifies that coverage requirements for “maternity benefits and benefits for treatment of medical complications resulting from such pregnancy shall be payable for six weeks following the termination of pregnancy, subject to the terms and conditions of such policy or contract.” In addition to the statutory limit of six weeks of coverage following the end of the pregnancy, a health plan may require cost-sharing, out-of-pocket expenses, co-pays, prior authorizations, or coverage exclusions to the extent articulated in a the discontinued plan. To the extent that utilization and cost management strategies existed in the discontinued health plan, such strategies would be employable under MBC.

5. The extent to which insurance coverage for continuation of maternity benefit may be reasonably expected to increase or decrease the insurance premiums and administrative expenses for policyholders.

Because the prerequisite conditions for MBC have not occurred in Connecticut since implementation of the mandate, no claims history exists and an estimate of the increase or decrease in insurance premiums and administrative expenses for policyholders is not available. However, the provision of mandated services is not expected to significantly increase or decrease the insurance premiums or administrative expenses. The use of MBC is expected to be a rare event for which a limited population is eligible for benefits. When

associated maternity care costs are spread across the entire insured population the effect on premiums is likely to be extremely small, especially since the carrier will no longer be offering health plans in the state and thus the costs may not be passed onto the fully insured group population in Connecticut.

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

The MBC mandate does not appear to serve as a more or less expensive avenue for addressing the prerequisite conditions described in the Connecticut statute when compared to the alternative that would exist under Connecticut Public Act 93-345 or the federal HIPPA law. Since these laws do not permit coverage for pregnancy to be excluded from coverage under preexisting condition clauses, it appears that if an employer replaces the fully insured group health plan with one from another carrier also offering maternity care, the pregnant individual would continue to have coverage for her pregnancy.

7. The impact of insurance coverage for continuation of maternity benefits 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. Because the prerequisite conditions for MBC have not occurred, no claims data is available on which to base an actuarial estimate of costs for the mandated services for Connecticut residents covered by fully insured group health insurance plans.

It is not expected that a carrier ceasing to offer health plans in the state would acquire any savings from offering MBC given that the potential positive health outcomes or reduction in adverse health effects would not be covered by the carrier in the future.

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.

No published literature was found regarding the effect of mandated coverage for MBC on the cost of health care for small employers. Although small employers may be more sensitive to premium increases than other employers, the low likelihood of the MBC benefit coming into play suggests little difference in effects among different types of employers. Also, since the employer previously covered maternity, it appears that there should not be any new cost to employers in the state.

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

The overall cost of the health delivery system in the state is understood to include total insurance premiums (medical costs and retention) and cost sharing. Actuarial analysis of claims data is not available because the prerequisite conditions for MBC have not occurred; therefore no estimate of the financial impact of the mandated services on the overall cost of the health delivery system in the state is available.

Due to the nature of the MBC benefit, employees may lose coverage because the carrier is no longer offering health plans in Connecticut. Without the mandate, the cost may continue to be paid by the employer through premiums and the employee through cost sharing under a health plan offered through a new carrier. If for some reason the pregnancy is not covered by another health plan, the public sector, other private stakeholders, or the employee may assume the cost burden. Eligible pregnant women may enroll

in Medicaid for coverage, acquire care through sliding fee schedules at federally qualified health centers, or receive care that is otherwise subsidized by public dollars. Similarly, care for the pregnancy may be obtained through private entities, which may include hospitals. The MBC mandate appears to have the departing carrier continuing to assume the costs for maternity care to the extent such care was provided under the discontinued policy; thus the payer shifts described would not occur.

Volume IV
Appendix I

House Bill No. 5018

Public Act No. 09-179

An act concerning reviews of health insurance
benefits mandated in the State of Connecticut



House Bill No. 5018

Public Act No. 09-179

**AN ACT CONCERNING REVIEWS OF HEALTH INSURANCE
BENEFITS MANDATED IN THIS STATE.**

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective July 1, 2009*) (a) As used in this section:

(1) "Commissioner" means the Insurance Commissioner.

(2) "Mandated health benefit" means an existing statutory obligation of, or proposed legislation that would require, an insurer, health care center, hospital service corporation, medical service corporation, fraternal benefit society or other entity that offers individual or group health insurance or medical or health care benefits plan in this state to: (A) Permit an insured or enrollee to obtain health care treatment or services from a particular type of health care provider; (B) offer or provide coverage for the screening, diagnosis or treatment of a particular disease or condition; or (C) offer or provide coverage for a particular type of health care treatment or service, or for medical equipment, medical supplies or drugs used in connection with a health care treatment or service. "Mandated health benefit" includes any proposed legislation to expand or repeal an existing statutory obligation relating to health insurance coverage or medical benefits.

(b) (1) There is established within the Insurance Department a

House Bill No. 5018

health benefit review program for the review and evaluation of any mandated health benefit that is requested by the joint standing committee of the General Assembly having cognizance of matters relating to insurance. Such program shall be funded by the Insurance Fund established under section 38a-52a of the general statutes. The commissioner shall be authorized to make assessments in a manner consistent with the provisions of chapter 698 of the general statutes for the costs of carrying out the requirements of this section. Such assessments shall be in addition to any other taxes, fees and moneys otherwise payable to the state. The commissioner shall deposit all payments made under this section with the State Treasurer. The moneys deposited shall be credited to the Insurance Fund and shall be accounted for as expenses recovered from insurance companies. Such moneys shall be expended by the commissioner to carry out the provisions of this section and section 2 of this act.

(2) The commissioner shall contract with The University of Connecticut Center for Public Health and Health Policy to conduct any mandated health benefit review requested pursuant to subsection (c) of this section. The director of said center may engage the services of an actuary, quality improvement clearinghouse, health policy research organization or any other independent expert, and may engage or consult with any dean, faculty or other personnel said director deems appropriate within The University of Connecticut schools and colleges, including, but not limited to, The University of Connecticut (A) School of Business, (B) School of Dental Medicine, (C) School of Law, (D) School of Medicine, and (E) School of Pharmacy.

(c) Not later than August first of each year, the joint standing committee of the General Assembly having cognizance of matters relating to insurance shall submit to the commissioner a list of any mandated health benefits for which said committee is requesting a review. Not later than January first of the succeeding year, the

House Bill No. 5018

commissioner shall submit a report, in accordance with section 11-4a of the general statutes, of the findings of such review and the information set forth in subsection (d) of this section.

(d) The review report shall include at least the following, to the extent information is available:

(1) The social impact of mandating the benefit, including:

(A) The extent to which the treatment, service or equipment, supplies or drugs, as applicable, is utilized by a significant portion of the population;

(B) The extent to which the treatment, service or equipment, supplies or drugs, as applicable, is currently available to the population, including, but not limited to, coverage under Medicare, or through public programs administered by charities, public schools, the Department of Public Health, municipal health departments or health districts or the Department of Social Services;

(C) The extent to which insurance coverage is already available for the treatment, service or equipment, supplies or drugs, as applicable;

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

(E) If the coverage is not generally available, the extent to which such lack of coverage results in unreasonable financial hardships on those persons needing treatment;

(F) The level of public demand and the level of demand from providers for the treatment, service or equipment, supplies or drugs, as applicable;

(G) The level of public demand and the level of demand from

House Bill No. 5018

providers for insurance coverage for the treatment, service or equipment, supplies or drugs, as applicable;

(H) The likelihood of achieving the objectives of meeting a consumer need as evidenced by the experience of other states;

(I) The relevant findings of state agencies or other appropriate public organizations relating to the social impact of the mandated health benefit;

(J) The alternatives to meeting the identified need, including, but not limited to, other treatments, methods or procedures;

(K) Whether the benefit is a medical or a broader social need and whether it is consistent with the role of health insurance and the concept of managed care;

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

(M) The impact of the benefit on the availability of other benefits currently offered;

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

(O) The impact of making the benefit applicable to the state employee health insurance or health benefits plan; and

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

House Bill No. 5018

(2) The financial impact of mandating the benefit, including:

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

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

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

(D) The methods that will be implemented to manage the utilization and costs of the mandated health benefit;

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

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

(G) The impact of insurance coverage for the treatment, service or equipment, supplies or drugs, as applicable, on the total cost of health care, including potential benefits or savings to insurers and employers resulting from prevention or early detection of disease or illness related to such coverage;

House Bill No. 5018

(H) The impact of the mandated health care benefit on the cost of health care for small employers, as defined in section 38a-564 of the general statutes, and for employers other than small employers; and

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

Sec. 2. (*Effective July 1, 2009*) The commissioner shall carry out a review as set forth in section 1 of this act of statutorily mandated health benefits existing on or effective on July 1, 2009. The commissioner shall submit, in accordance with section 11-4a of the general statutes, the findings to the joint standing committee of the General Assembly having cognizance of matters relating to insurance not later than January 1, 2010.

Approved June 30, 2009

Volume IV

Appendix II

Ingenix Consulting

Actuarial Report

On set four, 34-45 of the 45

Health Insurance Mandates

Covered By Public Act

Number 09-179

for

The State of Connecticut

INGENIX CONSULTING—
ACTUARIAL REPORT For The STATE OF CT
On Set Four Of The HEALTH INSURANCE MANDATES
Covered By PUBLIC ACT NUMBER 09-179

December 28, 2010

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TABLE OF CONTENTS:

I. Introduction

1. Brief Description of Each Mandate
2. Cost Estimate Approach
3. Executive Summary of 2010 Medical Cost Assessment of the Mandates
 - A. Recap of Medical Cost of Each Mandate
4. The Data

II. Elaboration on the Set Four Mandates

1. Initial Commentary on the Administrative Cost of the Mandates
 - A. Total Cost Recap—Medical + Administrative Cost + Profit
2. Explanation of the Medical Aspects of the Benefits
3. Further Explanation of the Medical Cost of the Mandates
4. Differential Effect of the Mandates on Individual vs. Group Insurance
5. Differential Effect of Small Group vs Large Group
6. Effect of Mandates on the Availability and Cost of Health Insurance
7. Effect of Mandates on Public Health
8. Effect of Mandates on the Delivery of Health Care Including the Utilization and Unit Cost of Health Care Services, Medical Supplies, and Devices
 - A. Provider/Supplier Reactions

III. Economic and Financial Aspects of the Mandates

IV. Conclusions

V. References for Financial / Economic Report

VI. Appendices

1. Weighted Average Cost of Each Mandate
2. Cost Sharing for Each Mandate
3. Appendix to Financial / Economic Report

I. INTRODUCTION:

This report serves to record the findings of Ingenix Consulting (IC) pursuant to the 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 this work.

IC is pleased to have been chosen to serve the state of CT in this valuable project. A team approach has been used, both with IC and the workgroup that included the CT Department of Insurance and the Center for Public Health and Health Policy. A team approach was also used internally at IC. Daniel Bailey, FSA, MAAA managed the actuarial work for the project and worked on most of the mandates. James Drennan, FSA, MAAA provided guidance, expertise in individual insurance, and acted as consultant and peer reviewer. 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 IC's extensive commercial health claims databases.

The financial economic work was lead by health economist, Tanvir Khan, who worked with a team of associates located throughout the nation, including Jon Montague-Clouse, PharmD. The financial / economic report is embedded in section III of this Set Four report; it is not part of the actuarial report.

IC was retained by the state to assess 45 existing health insurance mandates. In this document, the findings and conclusions relating to the actuarial evaluation of each mandate in the fourth set—Set Four—will be presented. The mandates will be reviewed with respect to cost, socio-economic impact, and effect on the finance and delivery system.

For this project, the six health insurers domiciled in CT were asked to submit their medical claim data showing how much these mandates cost. This was an important step in determining how much the mandates add to the cost of health insurance premiums in CT. For some of the mandates, IC also supplemented the health carrier data with data from their CT and national databases.

Results are presented in several steps in this report. First, results are presented in summary form, and subsequently, some of the additional data and calculations that support the findings are layered into the document.

I.1 IC reviewed the following mandates (Section numbers, individual then group, and date of passage are shown in parentheses):

1. **Experimental Treatments:** Prohibits insurers from denying a procedure, treatment, or drug that has completed a phase three trial of the Food and Drug Administration (FDA) but has not yet been approved by the FDA for widespread distribution. Those with life expectancy of less than two years who have been denied a procedure, treatment, or drug because it is experimental, may request an expedited appeal. The reviewers shall consider whether its use has been approved by one of two medical organizations or is listed in any of several specified drug compendia, or is currently in a phase three clinical trial of the FDA. (38a-483c and 38a-513b; Jan. 2000)

2. **Coverage for Off-Label Cancer Drug Prescriptions:** Prohibits insurers that provide coverage for prescribed drugs approved by the federal Food and Drug Administration for treatment of certain types of cancer from excluding coverage of any such drug on the basis that it has been prescribed for the treatment of a type of cancer 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 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).

This mandate does not require coverage for 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. It also does not affect reimbursement for drugs used in the treatment of any other disease or condition. (38a-492b and 38a-518b; Oct. 1994)

3. **Cancer Clinical Trials:** Requires insurers to provide coverage for the routine patient care costs associated with cancer clinical trials. "Cancer 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 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 four entities identified in section b of the mandate and is conducted at multiple institutions. Routine patient care is also defined in the mandate in terms of what is included and what is not. For example, the mandate excludes from routine patient care the cost of 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. Routine care includes all the items and services that are generally available to the insured. This includes whatever is typically covered absent the trial. It includes whatever may be needed to provide the investigational item or service, such as administration of an experimental chemotherapeutic agent, clinically appropriate monitoring of the experimental item or service, and whatever is needed for prevention of complications. It includes whatever is needed for the diagnosis and treatment of complications. (38a-504a - g and 38a-542a - g; Jan 2002)
4. **Mandatory Coverage for Hypodermic Needles and Syringes:** Requires insurers to cover these items when prescribed by a provider for self-injected medication that is also covered by the policy. The same policy terms apply to these items as other benefits. (38a-492a and 38a-518a; July 1992).
5. **Prescription Drugs Removed from Formulary:** Prohibits insurers from denying coverage for a drug that is not or is no longer on the insurer's list of covered drugs when three conditions apply: 1) insured was using the drug prior to cessation of that drug's coverage, 2) insured was covered under the policy for that drug prior to cessation of that drug's coverage, and 3) insured's attending provider states in writing that it is medically necessary and lists reasons why it is more beneficial than the drugs remaining on the insurer's list of covered drugs. The same policy terms apply to these drugs as other covered drugs. (38a-492f and 38a-518f; Jan. 2000).

6. **Home Health Care:** Requires insurers to provide coverage for home health care to CT residents in lieu of continued hospitalization according to a written physician plan under stated conditions, such as within 7 days of discharge. Home care must be provided by a duly licensed federally certified agency meeting five specified criteria. The mandate defines home health care to include RN and LPN nursing, home health aides, PT/OT/ST, social services, and prescribed drugs, supplies, and medication. (38a-493 and 38a-520; Oct. 1975).
7. **Ambulance Services:** Requires coverage for medically necessary ambulance transportation to a hospital subject to a maximum allowable rate established by the Department of Health subject to the same policy terms as other benefits. Establishes that the hospital insurance policy is primary in the event the person is covered by more than one policy. Also states that payment shall be made directly to the ambulance provider as long as that provider complies with subsection provisions and has not received payment from another source. (38a-498 and 38a-525; Mar 1984 / revised Oct 2002).
8. **Prescription Drug Mail Order Prohibition:** Prohibits health insurance policies that cover prescription drugs from requiring that drugs be obtained from a mail order source as a condition for obtaining any drug. Does not prohibit the use of mail order drug filling. (38a-510 and 38a-544; Jul. 1989 Group / Jul. 2005 Individual)
9. **Imaging Services—Copayments for In Network Services:** Applies only to complex medical imaging—magnetic resonance imaging (MRI), computed axial tomography (CAT) scans, and positron emission tomography (PET) scans. Applies only to in network services. Prohibits insurers from charging one person more than \$375 annually in aggregate copayments for all in network MRI and CAT Scans, and prohibits charging more than \$75 for any single in network MRI or CAT scan. Also prohibits insurers from charging one person more than \$400 annually in aggregate copayments for all in network PET scans, and prohibits charging more than \$100 for any single in network PET scan. The copay limits are set and do not adjust for inflation over time. This mandate does NOT apply to high deductible plans. Stipulates that, in order for the copayment limit to apply, the physician ordering the scan is not the same person as the physician providing it or participating in the same group practice. (38a-511 and 38a-550; May 2007)
10. **Offer of Coverage for Comprehensive Outpatient Rehabilitation Services (CORF): (Group only)** Insurers must offer groups the opportunity to purchase a plan that includes coverage of comprehensive rehabilitation services as defined by the mandate. These must be provided in an accredited outpatient facility. Services include PT/OT/ST, physician, psychological, social services performed by a social worker, respiratory therapy, drugs and medication, prosthetics and orthotics, and other supplies and services prescribed by a physician for the rehabilitation of the patient. Unlike most of the mandates, which are required to be covered in all insurance plans, the tenth mandate is not. The insurer is required to offer a policy that covers it, but the group buyer can choose whether it wants a policy with such coverage. Insurers may include these CORF services in all their policies. (38a-523; latest revision in 1991)
11. **Mobile Field Hospital:** This mandate has never been activated because the mobile field hospital has never been deployed. The mobile field hospital is a public health program that provides on site care in the event of a natural disaster or other such catastrophic occurrence. This mandate stipulates that medical care provided by the mobile field hospital should also be covered by insurance. It also says that

insurers will reimburse providers at Medicaid rates. “The rates paid by group health insurance policies pursuant to this section shall be equal to the rates paid under the Medicaid program, as determined by the Department of Social Services.” Medicaid rates can be lower than commercial payments by 20% to 50%. (38a-498b and 38a-525b; July 2005)

12. **Pain Management:** Requires access to a pain management specialist and coverage for pain treatment. Insurers cannot require people to receive pain management services only from their primary care physician. The mandate defines “pain” and “pain management specialist.” It does not include non-physicians in the definition of pain management specialist. This mandate applies to acute care as well as chronic care. New pain interventions such as pain pumps and epidural pain management would also be covered. (38a-429i and 38a-518i; Jan. 2001)
13. **Continuation of Pregnancy Coverage in the Event of Termination of Insurance Coverage: (Group Only)** This mandate has not been activated because no carrier has withdrawn from the state and terminated all its insurance coverage in CT. This mandate only affects insurers that withdraw from the state and thereby terminate all their group policies. In the event this occurs, the withdrawing insurer must continue to cover pregnant policyholders until six weeks after delivery. (38a-547).

Note: Except for the tenth and thirteenth mandates, which are group only, all thirteen mandates apply the same to group and individual coverage. All thirteen mandates apply to comprehensive health insurance plans such as Health Maintenance Organizations (HMO) and Preferred Provider Organizations (PPO). The mandates do not apply to disability plans, workers compensation plans, or medical indemnity plans that pay a set amount for each day that someone is a hospital inpatient. The fourth, sixth, and seventh mandates specifically state that they also apply to limited medical benefit plans under individual policies. Only the fourth mandate, hypodermic needles & syringes, applies to limited medical benefit plans under group contracts.

I.2 IC Review of Cost of Mandates—Two Components:

With respect to the cost of the benefit mandates, two pieces were examined—medical and non-medical expenses, with much greater emphasis on the former since it involves the far larger portion of overall cost. The non-medical expense consists of administrative cost and profit. Elsewhere in this report, non-medical expense is also referred to as “retention.” The annual cost in 2007 and 2008 dollars, as reported by the carriers, was reviewed. The cost of administration and profit for the mandates is roughly 20% to 21% of their medical cost, which is about 17% of premium for group plans. Some mandates, however, may involve more administrative cost than others, especially at the time the mandate is implemented. This will be explained in further detail later in this report.

In reporting the medical cost of the mandate, the cost shown is Paid Cost, which is the cost actually borne (paid) by the medical insurers and HMOs. The focus is on the Paid cost because it is the primary ingredient of health insurance premiums. In addition to Paid cost, there is another cost that is the amount borne by the member in the form of deductibles, coinsurance, and copays. This cost, which is the responsibility of the insured members, is referred to as Cost Sharing. The sum of these two costs, Paid + Cost Sharing, is referred to

as Allowed cost in this report. Most of the focus of this report is on Paid cost, since that is what drives the cost of insurance—the premium. When the member’s financial burden is discussed later in this report, the focus will not be on Paid cost; in that case, the member cost-share, which is the difference between the Allowed and Paid Cost, is reported.

The primary data source was provided by the CT domiciled carriers, all of which are subject to the mandates for their fully insured business. These six carriers provided cost data for 2007 and 2008 on an allowed and on a paid basis for each mandate. There were more than twelve times as many members in the group data as in individual plans; thus the group data was substantially more “credible” than the individual data. (Credible is used here in a statistical and actuarial sense, as it relates to the law of large numbers.) The numbers referred to below in the cost summary of section I.3 are for **group** plans only. Later in the report, individual plans and the individual data are discussed at greater length. As a reference, IC’s internal commercial health claims data for 2007 and 2008, both CT-specific as well as national data in some instances, were extracted and reviewed for some mandates. Outside data sources were also reviewed for incidence and prevalence rates.

First, a summary of the expected 2010 medical cost is presented without detail or long-range projections. Later in this report, there is further elaboration on the medical cost of each mandate, and socio-economic consequences and ramifications on the finance and delivery system, including the effect on health insurance cost and availability. Finally, there are comments on the economic and financial aspects of the mandates.

I.3 EXECUTIVE SUMMARY OF 2010 MEDICAL COST ASSESSMENT AND MAJOR FINDINGS:

During the course of this project, each of the six insurance carriers domiciled in CT was asked to provide data showing their cost for each mandate. IC and the workgroup examined the carriers’ reported cost of the mandates. A weighted average was developed across all six carriers using the relative number of member months as the weights. If a carrier had 25% of the total member months, for example, then its PMPM was weighted at 25% in the average. The cost shown by the carriers represents the full cost of all care mentioned in the mandate, even though a significant portion of the mandated services might have been covered prior to or in the absence of the mandate.

Where available, IC’s own data for CT was evaluated to ascertain a separate estimate of mandate costs and provide a reasonability check. It was easier to determine the cost of some of the mandates, whereas others were more difficult and may have involved additional analytic complexity. The carriers generally provided the full gross cost of the services covered by the mandate. This does not mean that carriers did not cover some or all of the mandated services prior to the mandate.

In the estimates below, an attempt has been made to use a point estimate of cost. This is not meant to imply a false sense of precision by providing a best estimate. When carriers selected the claims covered by the mandate, the variation reported likely represents some degree of judgment affecting that selection. While the actual 2008 cost is known, the projected 2010 cost may be somewhat greater or less than the values projected.

The term *de minimis* is used to describe the projected incremental cost of any mandate that we expect to be \$0.05 per member per month (PMPM) or less when the cost is spread to all the insured people covered by the plan. The terms per person per month and per insured person per month mean the same thing as per member per month (PMPM).

The mandates reviewed showed significant variation in the populations affected and produced different effects.

The following mandates are the fourth subset of the 45 mandates, all of which will be reviewed by the end of 2010. **The PMPM costs presented in this section are for group insurance. Individual data and costs will be discussed later in this report in Sec II.4.**

Note: The numbering of the following mandates does not reflect their relative importance.

1. Mandate one covers experimental treatments. Only half of the insurers submitted an estimate of the claims cost for this mandate, and it was *de minimis* in all three cases. The other insurers stated that they could not estimate a claims cost for this mandate. Since experimental treatments are not yet FDA approved, there can be no charge for them. The drug or device manufacturer must provide it to the patient for free under a “compassionate use” program. The only potential medical cost that could occur would be due to an adverse reaction to the experimental treatment or other side effect. Some cancer drugs, for example, may have pulmonary or cardiac side effects. If such an adverse event occurred, the patient would normally be treated for it under the appropriate standard of care. It would be considered routine care. Because there is no record of such side effects, it is extremely difficult to quantify the cost of this mandate. Very few members actually receive experimental treatments, and only a small percentage of them have side effects. For this reason, it is estimated that the cost is *de minimis*. Since the experimental treatment is provided for free, there is no member cost-sharing that goes along with these treatments, that is, they are free to the patient.

2. Mandate two covers off-label use of cancer drugs. None of the carriers was able to supply data for this mandate. Based on IC data, the 2009 paid cost for all cancer drugs is \$5.44 PMPM. This is expected to be \$5.71 PMPM in 2010, which is about 1.9% of overall medical cost. In order to estimate the cost of off-label cancer drug use only, a percentage was applied to the total cancer drug cost. Medical literature cites that 50% to 70% of cancer drugs are used off-label. It is also known that there is a greater tendency to use older drugs off-label than newer ones, and the unit cost of older cancer drugs tends to be less than that of newer cancer drugs. For this reason, off-label cost was estimated as 50% of the total cancer drug cost. The estimated 2010 paid cost is \$2.86 PMPM ($\$2.86 = \$5.71 \times 50\%$). Using a range of 40% to 60%, the range is \$2.28 PMPM to \$3.43 PMPM. Most of these costs were billed under medical HCPCS codes as medical expenses. The amount of cost sharing was not determined. Pharmaceuticals often have higher cost-sharing than medical expenses do. High cost cancer drugs may be assigned to a specialty drug tier with a higher copay level. This can add to the patient's level of cost-sharing. Since off-label cancer drug use may be a patient's only alternative, people with cancer are usually more willing to endure side effects for the chance to prolong their post diagnosis survival time. Cancer drugs tend to be higher priced than most pharmaceuticals. If people with cancer have to pay for these off-label cancer drugs entirely out of their own pocket, their utilization would likely be reduced due to affordability. Most of the cost that showed up for this mandate, however, is duplicative of the cost that was already included with the cancer, leukemia, tumors mandate in Set One.

3. Mandate three covers cancer clinical trials. None of the carriers was able to supply cost data for this mandate. Based on IC data, 0.023% of all insureds in CT had a diagnosis code of V70.7 for participation in a clinical trial. Some of these trials are not for cancer, but most of them are. Similar to experimental treatments above, the additional paid cost that would arise for the insurer would be due to 1) the side effects and adverse reaction to the treatment, and 2) routine care that results from longer post-disease onset survival time. During a clinical trial, it is the sponsor that assumes responsibility for the cost of the trial treatment. The only cost that the patient's insurance may be asked to cover is that of 1) normal routine care, and 2) side-effects or adverse reactions. Under this mandate, the normal routine care during a trial is covered by insurers. It would be difficult for an insurer to isolate the routine care claims of people who participate in clinical trials. Given the low participation rate in clinical trials, the cost is estimated to be *de minimis*. Even if every participant in a clinical trial had \$1,000 of additional expense in a year, the cost would be about \$0.02 PMPM. ($\$0.02 = \$1,000 \times 0.00023 / 12 \text{ months.}$) The actual average cost of additional medical treatment for a clinical trial participant is unknown. Although the cost to the insurer is relatively low when spread to all insureds, there may be significant cost burden to the patient, however, during a clinical trial. A patient may be asked to travel a long distance and reside in another location while the trial is conducted. These life expenses are not typically paid by the trial sponsor. Participation in the clinical trial may be a cancer patient's last hope. It can make a life or death difference to the patient, particularly one whose life expectancy is short. For this reason, patients are often willing to endure greater hardship and expense for an alternative that could extend their survival time.

4. Mandate four requires coverage of hypodermic needles and syringes. Based on the insurers' data, the weighted average for 2008 paid cost is \$0.05 PMPM. This is expected to be \$0.05 PMPM in 2010. This mandate requires that the needles and syringes be covered for a covered injectable medication. The cost of those medications, however, is not included here. Only the cost of the needles and syringes is included. The average member cost-sharing for this mandate was difficult to determine because the overall cost is so low. One of the carriers had substantially higher cost than the others because they included the cost of a) dialysis syringes and b) needles that are part of an insulin pump, which is considered a piece of durable medical equipment. When these items were excluded, their cost for this mandate was in line with the others.

5. Mandate five involves coverage for certain prescription drugs removed from formulary. Based on the insurers' data, the weighted average for 2008 paid cost is \$ 0.02 PMPM. Only two of the carriers supplied data for this mandate, and both their cost submissions were *de minimis*. This is expected to be about the same in 2010. There are several restrictive criteria that need to be met before this mandate is applicable to an individual, thus few people actually qualify to receive non-formulary drugs under this mandate. The carriers commented that it would be difficult to estimate the cost of this mandate. The cost is estimated to be *de minimis*.

6. Mandate six requires coverage for home health care. The carrier data showed a 2008 weighted average paid cost of \$1.34 PMPM. The 2010 cost is projected to be \$1.47 PMPM. Although there was variation of PMPM from carrier to carrier, this may reflect the differing degrees to which insurers rely on home health to reduce the length of inpatient stays. Some insurers and HMOs encourage early discharge by providing discharged patients with support in the home. This home health medical management strategy helps those carriers reduce the higher per day amount they spend on inpatient care. The average cost-sharing was 8% of

allowed cost. The \$1.47 does not include any savings that may result from home health in lieu of inpatient care.

7. Mandate seven requires insurers to pay for ambulance services when medically necessary. Based on the insurers' data, the weighted average 2008 paid cost is \$2.06 PMPM. This is expected to be \$2.27 PMPM in 2010. The average cost sharing was 1% of allowed cost, which means that relatively little cost is shared with the patient in the form of deductibles, coinsurance, or copays.

8. Mandate eight is prescription drug mail order prohibition. This mandate prohibits carriers that provide coverage for prescription drugs from requiring that any drug be obtained from a mail order pharmacy as a condition of obtaining that drug. None of the insurers submitted data for the cost of the mandate itself, and some commented that it would be impossible to estimate the cost of this mandate. Several insurers submitted mail order data. Mail order represented anywhere from 5% to 34% of the overall cost of their prescription drug plans. Since there is little if any reason to require that some drugs be obtained from mail order, the cost of this mandate has not been estimated. Many drugs cost less through mail order, but some do not. Many prescriptions need to be filled sooner than the time it takes to obtain them via mail order. Certain long-term chronic medications are better suited to mail order purchase, however, and insurers in cooperation with pharmacy benefit managers will create incentives in their health plans to encourage mail order dispensing of those medications.

9. The ninth mandate, copayments for in-network imaging services prohibits insurers from charging more than a maximum aggregate amount of \$375 annually for MRIs and CAT scans as well as an individual image copay limit of \$75. For PET scans the aggregate is \$400 and individual scan copay limit is \$100. The weighted average of the carriers for 2008 for all scans was \$11.25 PMPM, which is about \$12.38 PMPM on a 2010 basis. This is the cost of all MRI, CAT, and PET scans. Considering that the use of these recently invented services has come about over the past thirty years, this is a significant portion (almost 5%) of medical cost. The utilization of these complex imaging services has been increasing at a much faster rate than other services. The average cost sharing was 13% of the allowed cost, which was \$1.67 PMPM on a 2008 basis, and \$1.84 on a 2010 basis. The estimated cost of this mandate should represent the cost that is shifted from the insured back to the insurer. That is, if the copay limits on complex imaging were not in place, members would spend more on these services, and insurers would pay less. This mandate limits the member cost-sharing just for these imaging services. If there were no cost sharing whatsoever on these services, they would cost another \$1.84 PMPM on a 2010 basis. If the copay limits were not in place, however, the cost sharing would increase from \$1.84 to a higher level. If the cost sharing as a percentage of allowed cost increased from 13% to 20%, such as is the coinsurance for these services under traditional A/B Medicare, then the cost sharing would be \$2.84 PMPM. The difference of **\$1 PMPM** is a reasonable approximation for the cost of this mandate. ($\$1 = \$2.84 - \$1.84 = [(\$12.38 + \$1.84) / .87] - [(\$12.38 + \$1.84) / .80]$). It is likely that this was a difficult mandate for insurers to implement because of the technical nature of the mandate—changing claims adjudication systems to accommodate an aggregate copay limit of this nature can be problematic. Without the individual and aggregate cost sharing limits that apply to complex imaging under this mandate, some very sick patients who need multiple complex images could be burdened by a higher and perhaps prohibitive level of cost sharing. Benefit plans with an out of pocket spending maximum for all services will help those patients. Such an out of pocket maximum is more common with coinsurance plans than it is with HMO copay

plans, although the latter are moving in this direction as copay amounts rise to levels that approach the cost sharing levels of coinsurance plans. Those who benefit most from this mandate are insured people who must undergo multiple MRI, CAT, and PET scans in a year due to a serious illness or disease, especially those without an out of pocket maximum in their insurance plan. As a consequence of this mandate, some people may be inclined to utilize more complex imaging services.

10. The tenth mandate is comprehensive outpatient rehabilitation facility services. It requires coverage of these services on an outpatient basis only. Based on the insurers' data, the weighted average 2008 paid cost is \$2.20 PMPM. This is expected to be \$2.42 PMPM in 2010. The average cost-sharing was 40%. This mandate applies to group plans only. The carriers' data includes physical, speech, and occupational therapy claims. It is not clear whether all of these services were performed on an outpatient basis only. The cost of this mandate includes costs that were already reported for the birth to three, occupational therapy, and autism spectrum disorder mandates. We are including this mandate at the cost indicated by the carrier data. It is possible that the carriers consistently overstated the cost of this mandate by employing a broad definition of the term CORF.

11. This mandate covers services rendered in the mobile field hospital which is the property of the state of CT and is a public health measure. It has never been deployed. In the event it is, it will help increase access to care during a temporary period of highly increased demand due to a catastrophic event. This event could be a natural disaster, pandemic, or some type of terrorist event. During such a period, one or more hospitals could become incapacitated, and the mobile hospital would provide a portable solution. To date, this mandate has not increased the cost of care in CT. The initial cost of purchasing and equipping the modular-based portable hospital under the Department of Public Health was paid with \$8.4 million in bond funding. The state may bear some cost associated with maintaining the mobile field hospital in storage, but this cost would not be directly charged to people with health insurance.

12. Pain Management involves the access to pain specialists who are trained to deal with acute and chronic pain. It is those who live with long-term pain that can benefit the most from this mandate. Many medical conditions are accompanied by short-term pain, which does not typically require a pain management specialist—these people are generally not affected by this mandate, except insofar as newer technologies for acute pain care are covered, such as post-operative pain pumps. To the extent that insurers did not previously cover patient controlled analgesics, this mandate adds a de minimis cost. Some people, however, have medical issues that are accompanied by long-term pain. These people benefit from this mandate. The potential problem of opioid addiction arises in a long-term pain treatment program. While there is a cost associated with the office visits to such specialists and the medications they prescribe, no cost is reported here because this mandate simply permits the patient to receive care from the best type of provider for their condition. Addiction to pain medications has become a serious social problem. New opioid pain drugs can be highly addictive. There may be offsetting medical cost savings caused by this mandate because pain specialists can treat the patient with long-term pain at a lower cost in the long term than a primary physician. Although this mandate does not include non-physicians in the definition of pain specialist, there are Nurse Practitioners who practice in this field and have prescribing authority.

the Off-label Use of Cancer Drugs mandate in Set Four overlaps costs already reported for the Cancer, Tumors, and Leukemia mandate of Set One.

A reasonable range of medical cost for all thirteen mandates would be \$8 PMPM to \$12 PMPM. In terms of three scenarios, low, medium, and high, \$8 PMPM is the low estimate and \$12 PMPM is the high estimate. The cost estimate for the medium scenario is **\$10 PMPM**.

In calculating the percentage of overall medical cost, a denominator of **\$300 PMPM** is used for all calculations. This is medical cost only and does not include administrative cost or profit.

If an assumed premium cost of \$360 PMPM (based on a medical cost ratio of about 83%) is used, then the \$10 represents about 2.8% of the total health insurance premium for a group plan. It should be noted that the top half of the fraction (\$10) does not include administrative cost and profit, but the bottom half (\$360) does. For this reason it is not an appropriate measure to use. For additional details, see section II.1.A.

I.4 THE DATA

MANDATE COST DATA:

Two major data sources were used for this project to obtain the cost by mandate. Each of the six carriers domiciled in CT was asked to supply a cost estimate of each mandate. This data was collected from the carriers and examined. Ingenix Consulting data was also used as reference point to compare with the carrier data. Carriers were asked to provide diagnosis and procedure codes and national drug codes associated with each mandate, where available.

The carrier data for some mandates revealed variation of cost in the initial submission. Some of the variation was attributable to differences in codes gathered and the approach each carrier used to gather the data used to calculate the mandate cost.

The final cost estimates are based on both carrier data and Ingenix data. The data shown on the previous page in table I.3A is paid basis carrier data projected to a 2010 PMPM level. The purpose of the analysis was to produce a reasonable estimate of the actual cost. A weighted average of carrier data was obtained. For some of the mandates, it was then compared with the mandate cost produced by the Ingenix data.

The workgroup also met with outside experts, such as providers who are experts in the clinical areas addressed by the mandates. These meetings also provided insight into the aspects of utilization and unit cost that drive the cost of the mandates as well as their socio-economic ramifications and effects on the system for the finance and delivery of health care.

CARRIER DATA ON TOTAL MEDICAL COST AND INSURED MEMBER MONTHS:

The carriers were also asked to supply member months and total claims dollars associated with 2007 and 2008. A weighted average paid medical cost was developed for **group plans** as follows:

	<u>2007</u>	<u>2008</u>
MEDICAL	\$263.03	\$284.76
<u>PHARMACY</u>	<u>\$46.83</u>	<u>\$49.10</u>
TOTAL	\$309.86	\$333.86

The same was also provided for **individual plans**:

	<u>2007</u>	<u>2008</u>
MEDICAL	\$162.92	\$177.82
<u>PHARMACY</u>	<u>\$19.52</u>	<u>\$20.14</u>
TOTAL	\$182.44	\$197.96

In both the group and individual data, a significant number of members have medical coverage but not pharmacy coverage (Rx).

The group paid cost is more than 50% greater than the individual. Note that there were more than ten times as many group members as individual in the 2007 and 2008 carrier data submitted. There were about 1.2 million group members but only about 92,000 individual members in the 2007 medical data. Of these members, only 829,000 and 79,000 respectively also had RX coverage. The following chart shows the 2007 and 2008 average member counts for both medical and RX split by 2007 vs. 2008 and group vs. individual.

AVERAGE MEMBERS	<u>2007</u>	<u>2008</u>
MEDICAL		
GROUP	1,197,282	1,155,892
INDIVIDUAL	91,625	95,208
PHARMACY		
GROUP	829,041	804,438
INDIVIDUAL	79,430	82,568

Due to the large difference in the number of insured lives, the Group data is much more "credible" than the Individual data. The term credible is used here in the actuarial and statistical sense that is an aspect of data validity; it relates to our confidence in the data in relation to the law of large numbers. Due to the far greater number of lives associated with Group plans, the average for Group is expected to fluctuate less than the average for individual if this study were repeated year after year. For this reason, we have more confidence in the statistics calculated from the Group data. When looking at the cost of a single mandate, credibility is a more significant issue for the Individual data than for the Group data, especially for low-cost mandates.

II. ELABORATION ON THE MANDATES:

II.1 COMMENTARY ON ADMINISTRATIVE COST:

The premium dollar can be thought of as composed of three pieces. The first is medical cost; the second is administrative cost; and the third is profit (or contribution to surplus for carriers that are not for-profit). Sometimes the term retention is used to mean the combined cost of administration and profit. The term “non-medical expense” is also used for administrative cost and profit.

The cost of mandates is part of the overall cost of health care. As such, they come with an administrative cost. This reflects, in part, the cost of covering more benefits and processing additional claims, but that is not all. When mandates are introduced, they necessitate changes in various operational and technological processes, such as premium billing and claims payments systems. These are set-up costs. Health insurers 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 (admin) cost involved in implementation. Various functions within the insurance company need to be made aware of the change in minimum coverage, and there is an associated cost. This set-up cost is not unique to commercial insurance and a similar process occurs when plan changes are introduced into Medicaid or Medicare. Some mandates, such as the maximum aggregate and individual copays for in network imaging services, may involve a greater percentage of administrative cost than average, particularly when the mandate is first implemented. This stems from the complexity of implementing such a copay limit in the claims adjudication system of the insurer or HMO. Due to differences in the claim systems from company to company, some insurers may find it easier to accommodate such a change than others.

Separate from the one-time administrative cost is the ongoing administrative cost that occurs in subsequent years. This is the case for all the mandates in this report. Most health insurance companies, HMOs, and third party administrators have become adept with the operational aspects of benefit changes, although some systems and companies may accommodate change more easily. The systems modifications associated with a benefit change may vary in complexity as may the ongoing operational cost associated with mandates.

Since all the mandates are ongoing, the administrative costs were estimated using a percentage of the medical cost. For the sake of simplicity, assume administrative cost including profit is 20% of every dollar of premium, and medical cost is 80%. In this case, retention would be 25% of medical ($25\% = 20\% / 80\%$). In this report, across all carriers, a medical cost ratio of about 83% of premium was used for group coverage. That is, the paid medical cost is about 83% of premium. The other 17% is administrative cost and profit. Embedded in the administrative cost for fully insured plans is state premium tax.

Retention as a percent of premium varies from carrier to carrier and is different for group than for individual coverage. Companies may target a specific medical cost ratio ($MCR = \text{Claims} / \text{Premium}$). Since retention is $1 - MCR$, the target MCR can be used to estimate the administrative cost plus profit of the book of business.

In addition to administrative cost, insurers build a profit charge into their premiums in order to cover their cost of capital and assure their financial security. In the case of for-profit insurers, their profits also benefit their shareholders. In the case of not-for-profit insurance companies, they also have capital costs and must contribute to surplus in order to maintain financial stability. The term retention is used to describe administrative cost plus profit, which is all non-medical cost.

The vast majority of the incremental expense for the mandates is medical cost.

For all the mandates combined, the cost of administration plus profit is about \$2 PMPM. This is approximately 0.6% of overall premium and about 0.7% of the total medical cost. As a range, this total retention is about \$1.40 PMPM to \$2.75 PMPM. As a percent of premium, one might expect this percentage to decrease over time as medical cost increases at a rate faster than the ordinary inflation that drives the cost of administration.

At the time the mandates were first introduced, there were likely one-time set up costs for the insurers. It is also possible that the mandates may have reduced some relatively minor administrative cost at the time they were introduced by preventing claim denials and appeals. No such reductions to administrative cost have been included in the range above because it is believed to be inappropriate to do so at this point in time.

On average, the portion of the health insurance premium dollar that is assumed to apply to administrative cost, excluding profit, is approximately as follows:

Admin as Percentage of Total Premium

Individual	16% to 24%
Small Group	10% to 18%
Large Group	6% to 14%

This is reasonably consistent with the 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 increase, 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 employers buying insurance plans that shift more of the cost to their employees at renewal, but it is not entirely eliminated.

II.1.A SUMMARY OF EXPECTED TOTAL COSTS OF MANDATES IN 2010, INCLUDING ADMINISTRATIVE COST AND PROFIT

For 2010 medical cost, a projected range of \$8 to \$12 PMPM was used, and a point estimate of \$10.09 PMPM, which was rounded to \$10 for a medium-cost scenario. For retention, administrative cost plus profit, a range of \$1.40 to \$2.75 PMPM is assumed, with a point estimate of **\$2**. The expected total cost, including all retention, for these mandates in 2010 on a paid basis is **\$12.09 PMPM**. (\$12.09 = \$10.09 + \$2). For future calculations later in this

report, 3.4% of premium is used as the incremental cost of insurance due to the mandates of Set Four (3.4% = \$12.09 / \$360). This is sometimes rounded to \$12 elsewhere in this report.

It is expected that most of this mandate cost would be part of insurance plans today, regardless of whether the mandates exist or not. This is not to deny that the mandates generated new financial liability for the CT carriers, nor is it suggested that the mandates did not expand essential services provided to those insured. The \$12 represents the full cost of the mandates as written, using the medical cost data provided by the carriers and the IC data, and adding in the cost of administration and profit. Included in administrative cost is state premium tax, which is 1.75% of premium.

II.2 BRIEF EXPLANATION OF THE MEDICAL ASPECTS OF THE MANDATES:

This section is intended to provide enough medical information about the mandates that the reader of this report can put them into context. Since all of the mandates are currently required under CT insurance law, it was possible to see the effects of some mandates on medical practice and patient health.

1. **EXPERIMENTAL TREATMENTS:** These treatments have not (yet) been fully accepted by the medical community as proven and effective methods of care. They are not (yet) approved by the Food and Drug Administration (FDA) or other responsible organization. They are provided through clinical trials, or may be in a stage between successful completion of the final phase of a clinical trial, phase three, and FDA approval. This interim period can last about 1 – 2 years. It is hoped that these experimental treatments will eventually prove to be better than the current standard of care and serve as a replacement or supplement to current treatments. Most experimental treatments are directed at cancer, but they target other diseases also. In the case of cancer, treatments are often specific to a particular type of cancer or even a particular stage.

In order for a new treatment to be approved, it must complete all three phases of a clinical trial that establishes its safety and effectiveness. This process of scientific proof is the foundation of evidence based medicine. Sometimes a new treatment is found whose superiority seems so compelling that there is a rush to judgment. The bone marrow transplant (BMT) for breast cancer patients is an example of such a treatment that was prematurely accepted. Some states went so far as to mandate that insurers provide BMTs for breast cancer. Later, it was determined that these BMTs were not helping and in fact, were hastening the patient's death in some instances.

For those cancer patients with limited life expectancy and no other treatment alternative, an experimental treatment may represent their one chance of prolonged survival. In the case of a new drug or chemotherapeutic agent, if it has not been approved by the FDA yet, it cannot be sold—it must be provided to the patient for free under a “compassionate use” program.

The primary focus of the experimental treatments mandate is the requirement that insurers cover treatments that have successfully completed a phase three trial and are awaiting official FDA approval. The secondary focus is on those expected to have less than two years to live, who may be authorized to receive additional treatments

including those in a phase three trial or otherwise endorsed by other specified medical organizations.

In order to understand what costs might accrue to the insurer for experimental treatments, a couple facts should be understood. First, if a drug or treatment is not yet approved by the FDA, the drug manufacturer cannot charge for it. The manufacturer may make it available for free under “compassionate use” as mentioned earlier, but it cannot bill for it. Second, any care that an individual needs while receiving an experimental treatment would be rendered as standard of care and is normally covered by their insurer. If a person has an adverse reaction to the experimental treatment, an insurer might argue that it should not be covered, but it could be difficult for the insurer to prove the adverse reaction was in fact caused by the treatment. Moreover, if a drug or treatment is administered as part of a phase three trial, certain medical services are provided and paid for by the manufacturer as part of the trial.

This mandate is related to the two mandates that follow it in this report. This first mandate applies primarily to drugs that have successfully completed a phase three trial prior to FDA approval. The next mandate involves off-label use of cancer drugs—38a-492b and 38a-518b. The off-label cancer drug mandate establishes conditions under which a cancer drug or chemotherapeutic agent may be prescribed for a type or stage of cancer other than that for which it was FDA approved. It applies mainly to cancer drugs that have been FDA approved already for a particular type of cancer, and the oncologist has recommended their use for another type of cancer. Off-label use also could mean prescribing the drug at a higher or lower dosage than the label suggests, although that would be less common. The third related mandate involves coverage of clinical trials for cancer patients—38a-504a-g and 38a-542a-g. The cancer clinical trials mandate is the broadest of all three, and it involves all three phases of clinical trials for cancer.

2. OFF-LABEL USE OF CANCER DRUGS: When a drug is used in a different way than explained on the FDA approved “label”, it is referred to as off-label use. This is not an actual label on the pill container, but a report of specific information. The FDA must approve this report, which is then made available to health professionals who will dispense and prescribe the drug. The drug label contains information about the drug, including the approved doses and how it should be administered to treat the medical condition for which it was approved. Off-label use means that the drug is:
 - Used for a different disease, medical condition, or stage of a disease,
 - Administered in a different way (such as by a different route), or
 - Administered at a higher or lower dosage than in the approved label

If a chemotherapy drug is approved for treating one type of cancer, but is used to treat a different cancer, it is off-label use.

Over the past few decades, the fight against cancer has taken a favorable turn. Due to early detection and improved treatment methods, the survival rates for many types of cancers have improved. Some drugs that were developed to treat one type of cancer subsequently prove effective in treating other types as well. Avastin is an example; it is a tumor starving therapy, not a chemotherapeutic, and it was approved to treat metastatic colorectal cancer and lung cancer in 2004 in combination with

chemotherapy. It was FDA approved for metastatic breast cancer in 2008 under accelerated approval, but there is some controversy currently regarding its cost benefit in view of the limited extension of life that Avastin provides, its cost, and its side effects. Nonetheless, Avastin is now used for many solid tumor cancers.

Another example is Gleevec (Imatinib), which was FDA approved in 2001 to treat a rare cancer called Chronic Myeloid Leukemia (CML), which affects between 5,000 and 8,000 patients each year. This was a breakthrough drug that employed a new targeting mechanism to stop cancer by inhibiting an enzyme characteristic of a particular cancer cell. The product label was revised in late 2006 to include gastrointestinal stromal tumors. The cost of Gleevec is about \$30,000 to \$100,000 per year. Sunitinib and Bendamustine are two more examples of drugs initially approved for one type and or stage of cancer only to be applied later to additional forms of cancer because they prolong the progression-free survival period.

New uses for these drugs are typically found through a clinical trial, which provides the medical evidence necessary to support the new use. The makers of the drugs, however, might not have put them through the formal, lengthy, and often costly studies required by the FDA to officially approve the drug for these new uses. According to the American Cancer Society, off-label drug use is common in cancer treatment. There are many reasons for this:

- Some cancer drugs are found to work against many different kinds of tumors.
- Chemotherapy treatments often use combinations of drugs. These combinations might include one or more drugs not approved for that disease. Also, drug combinations change over time as doctors try different ones to find out which work best.
- Cancer treatment is continually changing and improving.
- Oncologists and their patients are often faced with few approved treatment options, and they may be more willing to try off-label drugs since their options are limited.

Insurers have denied claims for off-label use on the basis that it is investigational or experimental. It is not always possible for insurers to detect when a drug is being used off-label. Off-label cancer treatment is supported by 1993 federal legislation that requires coverage of medically appropriate cancer therapies. This law includes off-label uses provided that the treatment has been tested in research studies and written up in accepted drug reference books or the medical literature. Medicare rules were changed to cover more off-label uses of cancer treatment drugs in 2008.

The oncologist who was interviewed as part of this study remarked that she sends the insurer copies of peer-reviewed journal articles or other authoritative sources that support her off-label use in order to obtain pre-certification.

It is estimated that at least half of cancer drug use is off-label. Studies have reported that about half of the chemotherapy used is given for conditions not listed on the FDA-approved drug label. The National Cancer Institute (NCI) has stated, "Frequently the standard of care for a particular type or stage of cancer involves the off-label use of one or more drugs." The American Cancer Society asserts that actual off-label use is likely much higher because chemotherapy is only one aspect of cancer treatment--

studies that look at all the drugs used in cancer treatment, such as anti-nausea drugs and pain medicines, have yet to be done.

Similarly, the Journal of Clinical Oncology reported in 2006 that “approximately half of the uses of anticancer chemotherapy drugs are for indications other than those referenced in the United States Food and Drug Administration approved label. Some managed care organizations and private health insurance plans have declined to reimburse the cost of drugs used off-label to treat cancer on the ground that these uses are experimental or investigational.” Other sources report that more than half of chemotherapy is off-label.

Some off-label use may have adverse side effects. Those who use cancer drugs off-label typically have a short life expectancy, and they accept this risk in hopes of extended survival. In fact, although rare, death could be caused or hastened by experimental drugs or those used off-label for cancer. The insurer covers the cost of routine care for people in clinical trials, experimental drug programs, or using cancer drugs off-label. This also means that it is the insurer that absorbs the cost of treatment for adverse side effects. These side effects may arise in a number of ways. A drug for treating cancer, for example, may aggravate a co-morbid cardiac condition of the patient, such as congestive heart failure. Other toxicities of the drug may also be revealed.

3. **CANCER CLINICAL TRIALS:** The National Cancer Institute has over 8,000 clinical trials in which people with cancer may enroll. Clinical trials are research studies that test new ways to prevent, detect, diagnose, or treat diseases. People who take part in cancer clinical trials receive state-of-the-art care from cancer experts. Although treatment trials are generally of greatest interest to people with cancer, there are actually several different types of trials:

- Treatment
- Screening
- Prevention
- Diagnostic
- Quality of Life

- Treatment trials test the effectiveness of new treatments or new ways of using current treatments in people who have cancer. The treatments tested may include new drugs or new combinations of currently used drugs, new surgery or radiation therapy techniques, and vaccines or other treatments that stimulate a person’s immune system to fight cancer. Combinations of different treatment types may also be tested in these trials.
- Prevention trials test new interventions that may lower the risk of developing certain types of cancer. Most cancer prevention trials involve healthy people who have not had cancer; however, they often only include people who have a higher than average risk of developing a specific type of cancer. Some cancer prevention trials involve people who have had cancer in the past; these trials test interventions that may help prevent the return (recurrence) of the original cancer or reduce the chance of developing a new type of cancer
- Screening trials test new ways of finding cancer early. When cancer is found early, it may be easier to treat and there may be a better chance of long-term

survival. Cancer screening trials usually involve people who do not have cancer. Participation is often limited to people who have a higher than average risk of developing a certain type of cancer because they have a family history or exposure to a known carcinogen, such as cigarette smokers.

- Diagnostic trials study new tests or procedures that may help identify or diagnose cancer more accurately. Diagnostic trials usually involve people who have some signs or symptoms of cancer.
- Quality of life trials focus on the comfort of cancer patients and cancer survivors. New ways to decrease the number or severity of side effects of cancer or its treatment are often studied in these trials.

Clinical trials enable the evolution and further development of evidence-based medicine. For those people with cancer and limited life expectancy, a clinical trial could be their only hope for prolonging life. It is estimated that 3% to 5% of cancer patients participate in clinical trials.

The National Cancer Institute says the following regarding the cost of clinical trials: “The costs of care for people participating in a clinical trial fall into two general categories: 1) **routine** care costs and 2) **research** costs. Routine care costs are costs associated with treating a person’s cancer whether or not they are in a trial. These costs are usually covered by health insurance, but requirements vary by state and type of health plan. Research costs are costs associated with conducting a clinical trial; these costs may include the costs of extra doctor visits, extra tests, and procedures that are required for the trial but would not be part of routine care. Research costs are usually covered by the organization that sponsors the trial.

Many states require that insurance companies operating in those states cover routine care costs; in other states, voluntary agreements between the states and insurance companies include such a provision. In states without these requirements or agreements, health plans may not cover routine care costs for people taking part in cancer treatment trials if the interventions being tested are considered experimental or investigational. States also vary in their requirements for covering costs associated with participation in cancer screening and prevention trials.”

4. **HYPODERMIC NEEDLES and SYRINGES:** Although the vast majority of drugs are taken orally, there are some drugs that may be administered by injection. This usually occurs in a doctor’s office or in a facility, but can sometimes take place outside of these settings. Certain injections may need to be taken daily. An example of this is insulin for some people with diabetes. It would be impractical for a patient to return to the doctor every time an injection is needed. This category is called self-injectable drugs because they are administered outside a physician’s office by the patient or a caregiver. There are self injectable drugs for arthritis, hemophilia, multiple sclerosis, and other conditions. Only those who have been prescribed a self-injectable drug can receive a prescription for needles and syringes. Moreover, the patient must also have a prescription for a covered drug in order for the needles and syringes to be covered. The cost of a single syringe and needle is far less than the injected drug itself. The needle and syringe are two parts of one device. The syringe is the part with a piston and cylinder; the hypodermic needle is a hollow needle mounted at the end of it. They are often sold together as one unit. Needles and syringes are billed using HCPCS codes A4206 to A4215 and A4232.

5. **PRESCRIPTION DRUGS REMOVED FROM FORMULARY:** A formulary is the list of drugs that an insurer covers under its prescription drug benefit. Insurers evaluate their formulary by therapeutic class to make sure they have adequate coverage for each class. An insurer may update its formulary periodically and drop or replace certain drugs. When that occurs, patients may continue to receive the same medications as previously provided they meet all the conditions in the mandate. This mandate does not prevent an insurer from moving a drug to a higher or lower copay tier—that is a separate issue.
6. **HOME HEALTH CARE:** Home care follows an inpatient hospital stay. Inpatient care is relatively expensive, and when a patient’s condition has improved sufficiently, it may be less expensive to send the patient home under the transitional care of a visiting nurse who makes house calls occasionally, depending on the patient’s need. Other types of providers may also visit the patient in their home, and a home health aide may assist the patient with activities of daily living while they are recovering at home. A social worker may also help the patient understand what support they can obtain from their community and what resources may be available. The social worker can also assist the patient with various problems that arise out of the patient’s illness or treatments. Home health services cross a range of provider types, and carriers submitted many different codes for this mandate. One of the main providers of home health services are visiting nurses.
7. **AMBULANCE:** Covers emergency transportation of patients to hospital emergency rooms by ground or air. Ambulance services are billed as HCPCS codes in the range A0000 to A0999. Most of the cost is for ground services. They are billed by the mile. Advanced life support during the trip is billed at a higher cost than basic life support.
8. **MAIL ORDER PROHIBITION:** Prescriptions can be filled either at retail, such as from a pharmacy, or by mail-order. Depending on the insurer and pharmacy benefit manager of a prescription drug program, anywhere from 0% to 35% of the total drug cost can arise from prescriptions filled by mail order.

This mandate prohibits insurers from requiring prescriptions to be filled via mail order only. This mandate effectively requires insurers to allow prescriptions to be filled through retail pharmacies also. There are advantages and disadvantages to each of the two prescription filling channels—retail and mail order. These involve convenience, cost, and turn-around time to dispense the prescription. The tradeoffs vary by person, by drug, by plan, and by insurance carrier.

The reasons why prescription drugs cost less through a mail order channel are as follows:

1. Often, the mail order discounts are better due to bulk purchasing, and
2. Mail order involves a 3 month supply, thus lower dispensing fee per pill.

People tend to fill different types of prescriptions through mail order than retail. Mail order makes more sense for maintenance drugs used on an ongoing basis. If a new prescription or refill is needed urgently, even for a maintenance drug, the member might not have the time to wait to fill it using mail order.

Mail order pharmacies can effectively provide maintenance drugs for chronic conditions, but not every drug or class of drug will be less expensive in mail order. It is feasible for health plans to lower overall pharmacy cost by encouraging the greater use of mail order over retail, but they are already doing so because of the competitive pressures that force them to control cost wherever possible. Some carriers may be able to save more via mail order than others depending on the pharmacy benefit manager they work with. Plans may charge lower copayments for mail order drugs or use other incentives to encourage mail order use for maintenance medications. For multiple reasons, some insurers have more to save by shifting cost from retail to mail order.

This mandate protects retail pharmacies from a largely non-existent threat of competitive takeover by mail order distribution. The retail pharmacy industry has undergone enormous consolidation over the past thirty years as family businesses have been superseded by larger chains.

Retail and mail order are two very different ways to fill a script. Unlike mail order, retail pharmacies may provide personalized service at the time the script is picked up. This may involve professional instruction and information from a pharmacist or pharmacy technician. When scripts are dispensed today, written information is also automatically provided that informs the user about dosage, timing, possible side effects, etc.

It is highly unlikely that any carrier would require all prescription drugs to be filled via mail order to the exclusion of retail. It would not make sense. Doing so for certain specific drugs under certain circumstances, however, could lead to a more cost-effective pharmacy plan; it is part of a utilization management program that encourages the use of lower cost alternative drugs. In states where there is no mandate that bars them from doing so, some carriers have programs requiring that certain specific high cost drugs be filled via mail order if there is an equivalent lower cost alternative. This would apply to one or a limited number of high cost drugs such as specialty medications. This program may also occur in the self insured market, where the mandates do not apply. This program applies only when 1) there is an equivalent lower cost alternative, and 2) the member has opted for the higher cost drug and already filled it one or more times at retail. Such a program is a carrot and stick approach. The higher cost alternative is made less expensive to the person who buys the drug by mail order. Nonetheless, it is still higher cost to the member and insurers than the lower cost alternative. Such a program is more about encouraging the member to use the lower cost alternative than it is about encouraging the use of mail order.

9. COPAYMENT LIMITS FOR IMAGING SERVICES: This mandate applies only to three types of “complex” imaging—magnetic resonance imaging (MRI), computerized axial tomography (CAT) scans, and positron emission tomography (PET) scans. All three types produce three dimensional images that reveal more than traditional x-rays. PET scans reveal functional aspects of anatomy, such as blood flow. MRI and CT scans produce much more detailed images allowing the ability to differentiate at a more granular level, as well as differentiate tissue types better. The cost per complex imaging service is considerably more than an x-ray, as is the cost of the apparatus.

A PET scan can distinguish between normal cells and cancer cells. It is sometimes a follow-up to other types of diagnostic tests. All three types of complex imaging may be used as a follow-up to a simpler diagnostic test. There may be a small percentage of patients with cancer, for example, who need multiple complex scans done in the course of the year.

By limiting the aggregate annual and individual service copays that the member is responsible for, the demand for these complex imaging services is expected to increase. Since the mandate applies to in network services only, the cost sharing differential between in and out of network is increased, thereby driving more of the care to in network providers. This helps keep cost down because insurers have reimbursement arrangements with network providers that limit the cost of these services when provided in network.

10. **COMPREHENSIVE OUTPATIENT REHABILITATION FACILITY SERVICES:** These are sometimes referred to as CORF services by Medicare. They involve an outpatient facility in which multiple types of providers are employed to perform a wide range of rehabilitative services. Medicare requires that a CORF provide three types of core CORF services: a) physician services, b) physical therapy (PT) services, and c) social and or psychological services. PT should constitute the majority of services. The physician must certify that the individual requires skilled rehabilitation services; these are defined to include occupational therapy (OT) and speech therapy (ST) in addition to PT. Additionally, respiratory therapists (RT) are recognized to provide only skilled respiratory therapy services under the CORF benefit. That is, RT services are included, but an RT may perform only RT, and not PT, OT, or ST.
11. **MOBILE FIELD HOSPITAL:** This is a public health measure designed to improve access to emergency care in the event of a disaster. It could also cover isolation care in the event of a pandemic of infectious disease. The mobile field hospital has never been deployed in CT.
12. **PAIN MANAGEMENT:** This is a provider mandate; it covers the specialized services of a pain management specialist who has advanced training in dealing with patients in pain. It covers diagnosis and treatment. This mandate affects those in chronic pain over the long-term more so than those in acute pain following an operation or other short-term medical condition. As it is written, it may also cover certain recent developments in medical technology such as pain pumps, which may be used for acute temporary or chronic pain. There is a growing problem throughout the US with addiction to opioid pain medication. From a public health perspective, this mandate can help alleviate this problem. Pain specialists are generally better able to manage dosing of pain medication than most PCPs. They may work with a patient's PCP to improve the patient's overall pain management program. The mandate defines all pain specialists as physicians. There are some nurse practitioners, however, who serve in this capacity and have the authority to prescribe. They are generally associated with a hospital or medical center rather than working in independent practice, and they fill a specialized role on behalf of a multi-specialty center of care.
13. **CONTINUATION OF PREGNANCY COVERAGE FOLLOWING PLAN TERMINATION DUE TO CARRIER WITHDRAWAL FROM STATE (Group Only):** This mandate has never been activated. It would provide continuation of care for pregnant women until

six weeks following delivery if the insurer terminated all group policies in the state due to a withdrawal from the CT insurance market. Roughly 1% of the insured population gives birth each year in CT at a cost of about \$10,000.

II.3 FURTHER EXPLANATION OF THE MEDICAL COST OF THE MANDATES:

Note: The term PMPM (per member per month) and per insured person per month have been used to mean the same thing in the following projections. The latter term is meant to convey that the cost of the mandated benefit, which is intended for a small and vulnerable subgroup, has been spread to the entire insured population.

In this report, the PMPM has been used as the main measure to represent mandate cost. In this report, the effect the mandate has on health insurance premiums is measured. The best way to assess this is to evaluate the cost of the mandate on a PMPM basis. Each mandate has also been reviewed on a percent of total premium basis.

The primary data used for this project was supplied by the six health insurance carriers domiciled in CT. A data survey spreadsheet was developed for each mandate to collect carrier-specific data separately for 2007 and 2008 dates of services, as well as separately for individual and group policies. Carriers were provided with the spreadsheets and requested to complete them. The results were collected, interpreted, and analyzed. The carrier data was sent to a point person on the workgroup who de-identified the carriers and then passed the carriers' data along to the workgroup.

To supplement the carrier data, IC produced CT and national data when necessary. For example, the carriers were asked to provide the allowed and paid PMPMs for each mandate by year by group vs. individual. This allowed us to infer the average member cost-sharing (Cost-sharing = Allowed – Paid), but it did not allow the workgroup to see the distribution of cost-sharing by member for each and every member. For the latter, IC data and outside literature were used. This gave us a better understanding of the financial burden of cost-sharing for some of the mandates, in addition to knowing the average PMPM cost-sharing. Also, a model was used that examined the effect of benefit richness on member cost-share as well as the effect of member income on member cost-share.

For some of the mandates, it was difficult for the carriers to produce an estimate of the mandate cost with a high degree of accuracy. One of the issues we encountered in tracking claims by diagnoses and procedure codes is that not every diagnosis is 100% certain. Other ambiguities made it difficult to determine the cost of some mandates, and these are discussed in section I.3 and II.3.

In this report, the terms *gross cost* and *net new cost* are sometimes used. Gross cost is the total cost involved in the mandate. Net new cost is the incremental cost of the mandate in comparison with the absence of the mandate. Distinguishing between the two is an extremely difficult task because it is unclear what insurers did cover prior to the mandate, or would cover today in the absence of the mandate.

In the section that follows, each mandate is looked at, and the comments made in the executive summary are expanded upon.

1. Experimental Treatments: Only three of the carriers provided claims for this mandate. In general, the carriers had difficulty with it, and some could not estimate the claims cost of this mandate. There are not specific codes that can be used to isolate claims for experimental treatments. The cost of this mandate is *de minimis* because relatively few people obtain experimental treatments and, when they do, the cost of the treatment itself is free.

2. Off-Label Use of Cancer Drugs: A study was performed using IC data, and it was determined that the 2010 spending for all cancer drugs is \$5.71 PMPM on a paid basis (net to member cost-sharing). Although carriers may know some of the claims for which cancer drugs are used off-label, they do not generally track these claims in such a way that they can isolate all of them. Using a factor assumed to be 50%, the cost of this mandate is estimated to be \$2.86 PMPM. If the actual factor is 40%, the cost is \$2.28. If the factor is 60%, the cost is \$3.43. This cost reflects only those drugs and chemotherapeutic agents which are used for cancer off-label. It does not include any cost for additional care that is made necessary by adverse side-effects of off-label use. It is likely that there are more people taking cancer drugs off-label than there are those in cancer clinical trials. Unlike cancer clinical trials, however, the cost of cancer drugs used off-label is not free under compassionate use programs. It is the same cost as for on-label use.

3. Cancer Clinical Trials: In the absence of carrier data, IC data was relied on to determine the prevalence rate of people involved in clinical trials. The incidence of cancer is about 10 times greater for those 65 years or older than it is for those under 65. According to the National Cancer Institute, the incidence rate for all types of cancer for both sexes in CT is roughly 0.26% for those under age 65. Assuming a prevalence rate that is double the incidence rate, and assuming 4% of those with cancer enter a clinical trial, then approximately 0.02% of the population would be involved in a cancer clinical trial. This is very close to the prevalence rate of 0.023% that IC obtained from its CT data using the diagnosis code of V70.7 explained earlier in this report. This prevalence is so small, that even two years of group data is still a very small sample.

4. Hypodermic Needles and Syringes: This mandate is of *de minimis* cost. All of the services were billed as HCPCS (HealthCare Common Procedure Coding System). One of the carriers included the cost of the injectable drugs themselves, but they are beyond the scope of the mandate. Another carrier included a couple of codes that are not for self-injection; once they were excluded, their cost was in line with that submitted by the other carriers for this mandate.

5. Prescription Drugs Removed from Formulary: Requires insurers to cover drugs that have been removed from their formulary if all of a restrictive set of conditions are satisfied. Since this situation does not arise often in the course of practice, it is of *de minimis* cost.

6. Home Health: This mandate was covered in entirety in the executive summary.

7. Ambulance: This mandate was also covered in entirety in the executive summary.

8. Mail Order Prohibition: The carriers were asked to provide data about their mail order (MO) programs, such as the percentage of total drug cost that is filled via mail order and the percentage of total pharmacy claims cost associated with mail order. While the average cost of MO (as a percentage of all pharmacy) was somewhere in the neighborhood of 20%, it

ranged from 6% to 34% in the individual carrier data. Most carriers showed slightly lower unit cost for mail order than retail, although one carrier had a higher MO cost percentage than its MO script utilization percentage. Two of the carriers did not submit any data for this mandate and claimed that they had never required their members to purchase scripts through the MO distribution channel; in this case, their net new cost is zero. By encouraging mail order utilization of certain drugs, carriers may increase the amount of rebate revenue they receive from Pharmacy Benefit Managers.

9. Copayment Limits for Imaging Services: IC data was analyzed for this mandate in order to better understand the effect this mandate has on member cost sharing. In the IC claims, some of the cost sharing was attributed to claims with a positive allowed amount for which the payment was \$0. Also, the cost sharing for PET scans, as a percentage of allowed cost, was less than that for MRI and CT scans.

All CT, MRI, PET scans involve two components to the fee—1) a technical facility component for capturing the image, and 2) a professional fee for reading the image and interpreting the results. PET scans also involve a fee for the use of a radioactive pharmaceutical. Some MRIs and CT scans may involve the use of a dye that increases the cost. On average, ultrasound treatment costs less than a CT scan, which costs less than a MRI, which costs less than a PET scan. CT scans may range from about \$1,200 to \$3,200 depending on location and type. MRI may be \$1,200 to \$4,000, and PET scans \$3,000 to \$7,000. These are the all inclusive allowed costs of these services, some of which is paid by the patient in the form of cost-sharing; the rest is paid by the insurer. The allowed amount for in network scans will be a reimbursement rate based on agreement between the insurer and the provider. The carriers were asked to submit all the data for their complex imaging. This gross data was then used to estimate the net new cost of this mandate due to the limitation applied to the copays.

10. Comprehensive Outpatient Rehabilitation Facility: One carrier identified seven different providers in 30 CT locations that submitted claims for CORF services. The claims gathered for this mandate were for outpatient services only, although some of these facilities may offer rehabilitation services on an inpatient basis as well.

Some hospitals are equipped to provide comprehensive outpatient rehabilitation services on an inpatient or outpatient basis. Inpatient claims should not be included for this mandate. Although the services are similar, this mandate applies only to facilities that deliver these services on an outpatient basis only. Some of the carriers' data was higher or lower than the average. There may have been differences in the definition of CORF used. All carriers are able to extract data based on procedure code, but some might not be able to do so based on place or type of service. It is possible that the estimated cost of this service has been overstated. One of the six CT carriers looked at the cost of these services three different ways. The broadest definition of CORF they used produced a 2010 estimate of about \$2.75 PMPM which is higher than the average by about 14%, and likely includes individual practitioners of rehabilitation services that are unaffiliated with comprehensive rehabilitation centers. There were over 4,000 individual CT providers listed in conjunction with this larger data set. Carriers may have overstated the cost of this mandate.

The cost of this mandate may overlap some costs already reported for the mandates for Occupational Therapy, Birth to Three, and Autism Spectrum Disorder. Although it is a "must offer mandate," it appears all CT carriers include it as a base benefit in fully insured plans.

11. Mobile Field Hospital: It should be again noted that Medicaid provider reimbursement rates are typically lower than Medicare reimbursement, which is lower than commercial reimbursement. In this respect, in the event of a disaster, despite a surge in utilization, the unit cost of reimbursement for provider services would be decreased. Otherwise, this mandate is covered in entirety in the summary section.

12. Pain Management: IC conducted a study using its own data to determine a 2010 PMPM cost of pain medications. It is understood that pain medications were already a required benefit prior to the enactment of this mandate, so they are not included as part of the cost of this mandate. These pain medications cover all types including opioids and non-opioids, such as analgesics, non-steroid anti-inflammatory agents, anti-convulsants, anti-depressants, and corticosteroids. Some of these types have non-pain-relieving applications which are not included in the cost estimate.

13. Continuation of Pregnancy Coverage on Termination of Insurance Coverage Due to Insurance Carrier Exiting CT Market: Covered in entirety in summary section.

PERCENTAGE CALCULATIONS

Denominator Used in Medical Cost Percentage Calculations:

From the CT DOI, these arithmetic (not weighted) averages were obtained 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. To compute the premium, the following average retention factors (administrative cost plus profit) are assumed:

Individual	25%
SG	18%
LG	14%

Using these admin percentages multiplied by the premiums provided by the CT DOI, yields the following average PMPM medical costs rounded to the nearest dollar:

Individual	\$184
SG	\$259
LG	\$301

The HMO premiums are expected to be less than the non-HMO plans, but non-HMO rates are not filed in CT, so it was assumed that on average they are 10% more costly than HMO.

In view of these numbers, a decision was made to use **\$300** for the 2010 group medical cost in the denominator of our percentage calculations, which is within the range of the various filed and calculated 2010 medical cost amounts above. Note that this \$300 is the medical cost and

does not include administrative cost and profit. The fully loaded premium we used is **\$360** for group plans. This assumes a medical loss ratio of 83.3%. ($\$300 / \$360 = 83.3\%$).

II.4 DIFFERENTIAL EFFECT OF THE MANDATES ON INDIVIDUAL vs. GROUP INSURANCE:

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. 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 they can pass initial underwriting for coverage, individuals can purchase individual health insurance when they think they will need it. More importantly, they may drop coverage when the economic value diminishes and renew coverage when they become sick and 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 allowed based on the CT data across all six carriers. 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.

As explained in the prior section, \$300 PMPM was used as the assumed average medical cost for the CT insured population in 2010, since the exact amount is unavailable. Each carrier provided medical costs for 2007 and 2008. A weighted average paid medical cost for **group plans** was developed as follows:

	<u>2007</u>	<u>2008</u>
MEDICAL	\$263.03	\$284.76
<u>PHARMACY</u>	<u>\$46.83</u>	<u>\$49.10</u>
TOTAL	\$309.86	\$333.86

The same was also provided for **individual plans**:

	<u>2007</u>	<u>2008</u>
MEDICAL	\$162.92	\$177.82
<u>PHARMACY</u>	<u>\$19.52</u>	<u>\$20.14</u>
TOTAL	\$182.44	\$197.96

In both the group and individual data, a significant number of members have medical coverage but not pharmacy coverage.

Bearing in mind the relativities of the filed insurance premiums, it is assumed this medical cost breaks down roughly as follows:

	<u>PREMIUM</u>	<u>MEDICAL COST</u>
Individual Policies	\$280	\$210
Small Group	\$340	\$275
Large Group	\$375	\$320

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 2010 projected paid cost for all 13 mandates was \$10.09 PMPM for group coverage, which is 3.4% of total medical cost. (The \$10.09 is medical cost only and excludes administrative cost and profit.) If mandate number 10 for CORF is excluded, since it pertains to group only and not individual, the 2010 paid cost for group is \$7.67 PMPM. This is a more appropriate number to use for group for the sake of fair comparison with individual plans. **For individual health insurance, for the twelve applicable mandates, the 2010 projected paid cost was \$4.60 PMPM, which represents 2.2% of the total medical cost (2.2% = \$4.60 / \$210).** It is also 60% of the group cost (60% = \$4.60 / \$7.67). As a percent of total medical cost, individual (2.2%) is less than group (2.6%) for this fourth set of mandates.

Some of the mandates may be less desirable to the purchasers of individual coverage than group coverage by virtue of the fact that individual policyholders pay the full cost of premium and may approach the purchase knowing they have a specific medical need. For example, a single male might prefer a basic policy that does not cover infertility.

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. This would be particularly true for a mandate such as maternity in Set Two, but less so for the Set Four mandates. The first three mandates, which concern cancer, are the most applicable in Set Four. 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 SMALL GROUP vs. LARGE 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. The mandates in Set Four do not invite as much adverse selection as did the maternity and newborn mandates in Set Two, since the latter two involve a known upcoming medical event of large cost.

The small group market is more sensitive to the cost of health insurance. A 20% 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. Insureds 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 insureds 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 show 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 an issue at the time a mandate is first introduced or revised, but less so once the mandate cost has been embedded in the cost of coverage for several years.

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-insureds will tend to forego some necessary services, such as immunizations, diabetic medications and supplies, and other preventive 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.) However, out of the 45 mandates covered under PA 09-179, there are three mandates that cover preventive services for which there will be zero member cost-sharing beginning in 2012. These are colorectal cancer screening, mammography, and preventive pediatric care. Prostate cancer screening by PSA test is also a zero cost sharing service under PPACA, but it is usually performed as part of a physical examination, and often there is not a copay charged that is specific to the PSA test.)

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.” In this study, for these thirteen mandates, the cumulative incremental value of the mandates is significant, but the mandates have been part of CT insurance plans for so long that there is little lapsation specifically on account of them. The level of cost of health insurance plans is high enough today, however, that some groups can not afford coverage.

The other group response to consider 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 and that they perceive as low value. By switching to self-funding, groups can avoid mandates. Roughly half of the commercial health coverage in CT is now self-funded. The carriers were surveyed to determine whether they already provide these mandated benefits in their self-funded plans. The majority of CT mandates are included. That being the case, there is little evidence to support the claims 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 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.

These 13 mandates add approximately 3.4% to the cost of group health insurance plans on an adjusted gross basis. Some groups or individuals might choose to purchase or retain coverage if the financial burden of the insurance premium were less. Nonetheless, it would not be practical for an insurer to remove the benefits covered by most of the mandates as they are written. In other words, these are not entirely avoidable costs for a health insurer due to the breadth of the mandate language, which covers much of the benefit that insurers covered prior to the passage of the mandate. Since all carriers in CT are subject to the mandates, the playing field is level and affects all insurers equally.

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 PMPM medical cost of \$300 and a PMPM premium of \$360, the following costs by tier are approximated: (Employee is EE)

	<u>MONTHLY</u>	<u>ANNUAL (rounded)</u>
Single EE	\$430	\$5,000
EE + Spouse	\$930	\$11,000
EE + Child(ren)	\$860	\$10,000
Family	\$1,250	\$15,000

(Note that the Single Employee cost is different than the PMPM because the average member is a mix of adults and children, whose average medical costs 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. To reiterate the example described in the earlier Set Two report for infertility, an additional 1% of cost per year adds about \$150 annually to the cost of a family plan. 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 ambulance or home health, which are set four mandates, those individuals who need these services may end up with significant personal out-of-pocket expense.

Excluding some benefits from the package of essential benefits covered by the health plan is a complex problem. If insureds 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 would 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 they receive 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.

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 first three mandates pertaining to cancer drugs, cancer clinical trials, and experimental treatments have helped raise the bar of evidence based medicine. Such programs have helped to extend the survival time following the diagnosis of many types of cancer.

Other mandates, such as drugs moving off formulary and mail order prohibition help to assure a level of convenience and access to medications.

The cost of the Home Health and Ambulance mandates is greater than \$1 PMPM each. Like the services rendered by Comprehensive Outpatient Rehabilitation Facilities, these have come to be considered part of the package of essential benefits of a health insurance plan.

The mandate on pain management has the potential to address the growing problem of addiction to opioid pain medication, which is sometimes allied to the problem of substance abuse and drug addiction in general.

The mandate involving the mobile field hospital also has the potential to make a significant difference in improving public health in the event that there is a disaster in CT.

The mandate covering pregnant women insured by group policies from carriers that exit the CT market is intended to provide some health security for a vulnerable subpopulation of insureds in the unlikely and rare event of carrier termination.

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:

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; other times 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.

The first three mandates are expected to encourage further use of experimental procedures and clinical trials, which advance our knowledge of cancer treatment.

II.8.A Based on a review of each mandate, these provider and supplier reactions are described:

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. The conventional wisdom maintains that private payers must pay more because public payers

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.

III. FINANCIAL AND ECONOMIC ASPECTS OF THE MANDATES

In this section of the report, the financial burden of the services covered by the mandates is considered. This will be done both in the presence and absence of the mandate. A broad interpretation of the financial burden analysis was developed that includes socioeconomic factors in addition to cost burden considerations. Medical and actuarial aspects of the mandates were covered in the actuarial section of this report and are therefore not reported here.

In 2008, about two-thirds of Connecticut residents were covered¹ 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 third² 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. 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 the uninsured 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)

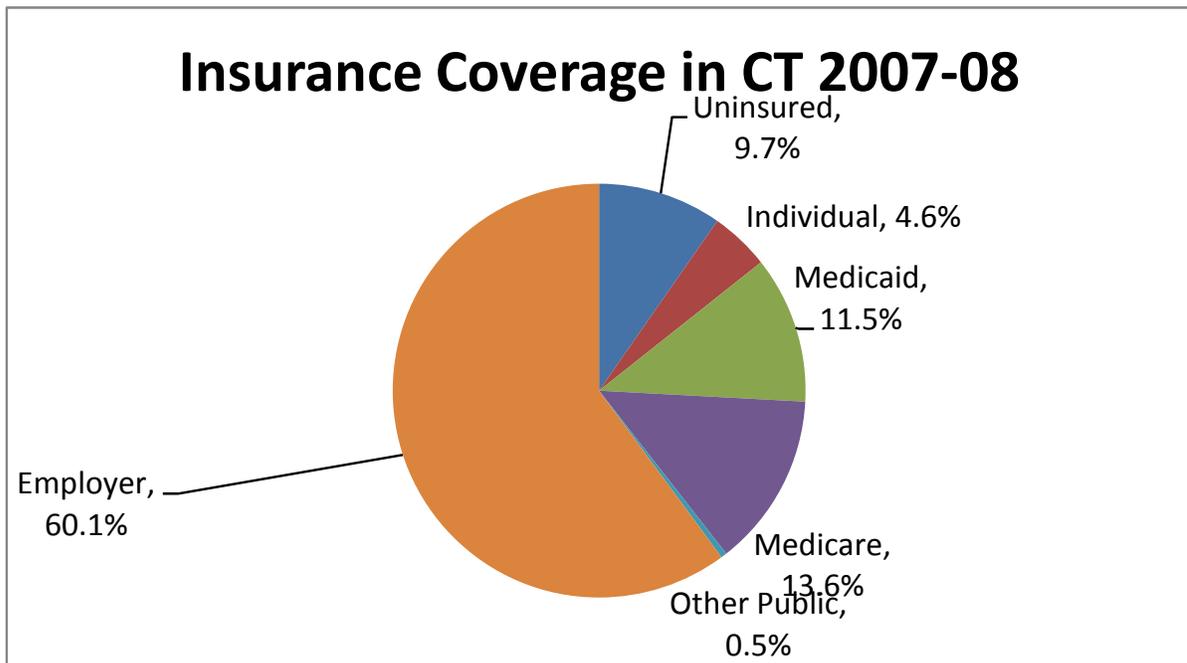


FIGURE 1(b)

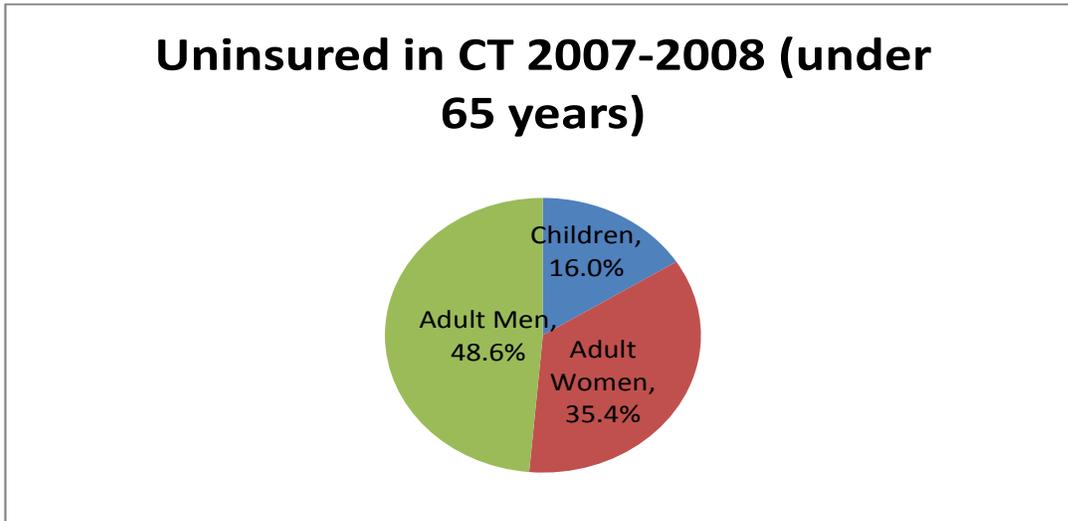
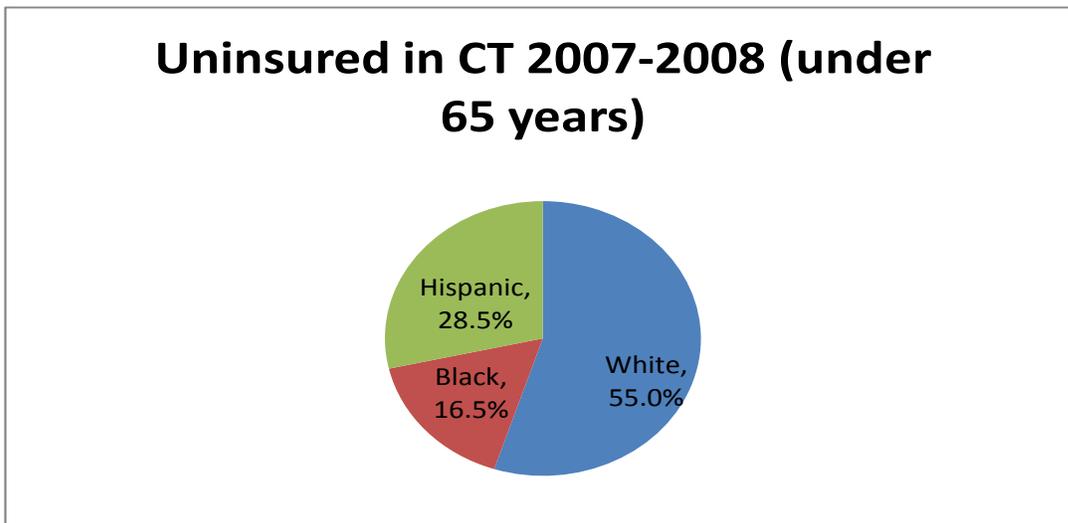


FIGURE 1(c)



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 August 20th, 2010
<http://www.statehealthfacts.org/profileind.jsp?ind=125&cat=3&rgn=8>

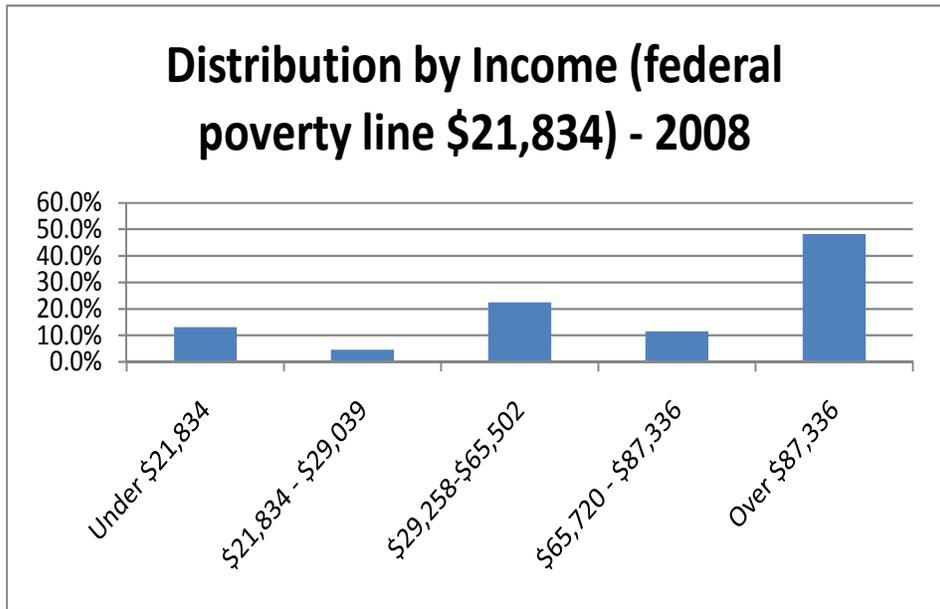
The healthcare landscape has changed significantly since most of the mandates considered in this report were enacted. For instance, the high deductible plans were not very common at the time most of the mandates under consideration were implemented. America's Health Insurance Plans (AHIP) estimates that 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 an HSA plan. These plans have an inflation indexed minimum deductible 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, as time has gone by, some of the mandates are less readily accessed than they were when introduced. Similarly, the impact of those mandates that are mainly a pharmacy benefit has been somewhat reduced by the introduction of fourth or even fifth copayment tiers in pharmacy plans. These higher tiers involve greater cost-sharing than lower tiers and may require members to pay \$100 or more for a prescription. Some of the mandates in Set Four pertain to pharmacy, such as those regarding experimental use of medication, off-label use of cancer medications, drugs taken off the formulary, and the mail order prescriptions.

Insurers recognized this 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 a 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.

From the carrier data, we were able to establish average cost-sharing for each mandate using the PMPM difference between allowed and paid claims for each mandate. Even for a seemingly low-cost mandate, the cost-sharing can be significant to the family. In examining the financial and economic aspect of the mandates, and in particular, the burden of cost on patients and their families, Ingenix Consulting adopted an approach that makes use of a model. We examined the cost burden with respect to two primary variables—1) member or family income level, and 2) level of cost-sharing in the member's benefit plan. Those with the lowest income who are enrolled in plans with high cost-sharing have the largest cost burden of care. With respect to family income, a member in the lowest income bracket will pay a larger percentage of their income toward cost-sharing. The income distribution in Connecticut in 2008 is shown in Figure 2. For our analysis we modeled the percent of income that families with an income of \$50,000, \$80,000, and \$160,000 would spend on services associated with each mandate. These illustrative family incomes were chosen to show the cost burden for a family with income slightly below, and a little above the median income in CT (\$68,595), and for a high income family. Our cost burden analysis was done for the incremental cost of each mandate only and did not include the member contribution to the premium. Families benefiting from the mandates would have paid the premium even in the absence of the mandates. We did not find a usable source for the information regarding the copayments, coinsurance, and other forms of member cost-sharing which would represent the State averages. Therefore we used our knowledge of health insurance plans to define a "rich" plan with member cost-sharing of 10% and a representative plan with member share of 20%. Our model also looked at the high-deductible plans, and we used AHIP data as the source for the annual deductible limit. We assumed that the members in a high deductible plan will pay a copayment/coinsurance of 20% after meeting the annual deductible limit. Detailed results of our calculations are presented in the Appendix.

FIGURE 2



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 August 20, 2010. <http://www.statehealthfacts.org/profileind.jsp?ind=9&cat=1&rgn=8>

EXPERIMENTAL TREATMENTS

This mandate requires insurers to define the extent to which experimental treatment is covered under a policy. The mandate prohibits the denial of coverage of a procedure, treatment, or a drug as experimental if it has successfully completed phase III of a clinical trial for the illness or diagnosis for which it is being prescribed. For people whose illness or condition has created a life expectancy of less than two years, an expedited process¹ to appeal against experimental treatment-based denial of coverage is specified.

A treatment can be “experimental” or “investigational” in two ways. It can either be a new drug, device, or procedure undergoing the FDA approval process, or it could be an existing treatment approved by the FDA to treat a different condition or a different stage of a condition. The latter view of experimental treatment is more relevant to the mandate pertaining to the off-label use of cancer drugs and is discussed under that heading. The experimental treatment mandate under discussion here is focused more on new treatments. A brand new treatment, yet to be approved by the FDA for general availability and marketing, can be made available to a small number of people through a number of mechanisms. A person with a condition expected to be treated by the treatment undergoing a clinical trial can be inducted into the clinical trial study. Since the 1980’s, the FDA has allowed access to experimental treatments through its expanded access program. This program is a result of the HIV/AIDS epidemic and

¹ The appeal/review process described in the mandate language specifies three drug compendia as sources of scientific evidence of the clinically accepted use of the medications. The use of these compendia is discussed under the analysis of the mandate on off-label use of cancer medications.

allows people who do not meet the criteria set forth for a clinical trial study to become part of “expanded access studies.” Since 1987, a small number of patients may be allowed access, on a case by case basis, to experimental treatment through the “compassionate use” program. The people affected by the experimental treatment mandate will typically fall under this last category.

It is not possible to compute the cost burden associated with the absence of this mandate, either at the individual or the health care system level. There are three types of costs associated with the compassionate use of experimental treatments (there may sometimes be a cost associated with administering the treatment). These include the direct medical cost of the experimental drug or device, an indirect medical cost for the treatment of any side or adverse effects, and the non-medical costs like any travel expenses, etc. to get to the site of treatment administration. The cost of the medication is borne by the drug manufacturer and is hard to quantify because the drug manufacturers do not make that cost information public and also because the cost to a manufacturer at the clinical trial or pre-FDA approval stage may be very different from the market price following approval. As discussed in the actuarial part of this report, the cost associated with any side/adverse effects is hard to compute as insurers may not know if a provided service is needed as a consequence of an experimental use of a treatment or not. Even if this link can be established, there are no specific codes that a carrier can use in order to be reimbursed. The third cost, that is, the cost of access to the treatment site, varies from case to case.

The main issues related to the effectiveness of this mandate revolve around the definition of experimental treatment in insurance policies and around the access to these treatments. Many insurance policies have a provision that serves as an exclusion for experimental treatments. However, the definition for this exclusion varies considerably and can consist of a brief mention or it can be very specific, lengthy, and detailed. This lack of clarity and uniformity concerning the exclusion clause and when it can be invoked became the cause for many legal disputes. These disputes were centered primarily on the treatment of HIV/AIDS in the 1980’s, on the treatment of breast cancer using high dose chemotherapy and autologous bone marrow transplant in the 1990’s, and other forms of cancer and other conditions in the last 2 to 3 years, and in general, over the last 2 to 3 decades⁴⁻⁵. This mandate requires all carriers in Connecticut to 1) define the coverage of experimental treatment, and 2) define certain conditions for that coverage. The mandate on the off-label use of cancer treatment further defines the minimum “experimental” treatment which must be provided.

Even if insurance carriers define their coverage of experimental treatment in the most generous language, the scope of this mandate will be primarily limited by the difficulties associated with accessing the treatment. First, drug or device manufacturers have little incentive to allow for the compassionate use of their products. The cost of the product, fear of litigation, and fear of the FDA asking for additional studies are some of the factors a manufacturer has to consider before allowing access to an experimental treatment. Once the treating physician and the manufacturer have agreed to the use of the treatment, a formidable amount of paperwork and approvals have to be completed and obtained. This includes preparing a very detailed treatment protocol, the approval of the Institutional Review Board, and the approval of the FDA. The FDA formalized and clarified the experimental use process in 2009 and expects the annual use of these provisions to increase from about 300 to 3,000⁶.

OFF-LABEL USE OF CANCER PRESCRIPTION DRUGS

Unlike the mandate on experimental treatments, this mandate covers drugs which are already on the market and available with a prescription. The mandate requires coverage of cancer medications for a type of cancer different from the type for which the FDA had originally approved the drug as long as the use of the medication is recognized by one of the three compendia specified in the mandate language. The language of this 1994 mandate reflects the provision of a 1993 federal law directing CMS to use the same three compendia in making Medicare reimbursement decisions regarding off-label use of cancer medications. Since then, CMS has dropped one of the three original compendia from its list and has added three more.

The off-label use of cancer medications is widespread. Studies show the prevalence of the off-label use to range between 25% and 75% depending on the cancer agent being studied. For instance, a recent study⁷ by researchers at MD Anderson found that 35% of the women treated for breast cancer used an off-label cancer agent. Of the 36 medications used by the women in the study, only 8 (22%) of the drugs were approved for breast cancer. Another study looking at off-label use of five specific cancer drugs found the range of off-label use between 40% and 71%⁸.

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 stakeholders⁹ 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 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. This lag between the marketing of a new drug for one condition and the subsequent FDA approvals for additional conditions is often a life and death issue for people with cancer. People with cancer and their doctors have little choice available for treatment. Furthermore, life expectancy with some types and stages of cancer is so limited that waiting for FDA approval is not an option. Hence, there is widespread use of off-label treatment. Realizing the gap between the patients and their providers' need for quick access to cancer drugs on one side and the financial concerns of payers to allow for unchecked use of expensive medications on the other, the Congress asked CMS in 1993 to allow for Medicare reimbursement for the use of off-label cancer medications as long as there was

scientific evidence to support it in one of three specific drug compendia. Connecticut (1994) and many other states passed similar laws thereafter.

Cancer medications, especially the newer agents, can be very expensive. For instance, a new drug, Folutyn, approved last year for the treatment of a rare type of blood cancer can cost around \$90,000 for a little over a year's therapy. Similarly, Avastin, a popular cancer drug can cost \$8,800 a month for treating lung cancer. A colon cancer drug, Erbitux, can cost around \$10,000 a month. Some of the older chemotherapy agents cost less, but even the patients on these drugs may face tens of thousands in cost. In the absence of this mandate, it is very likely that a person with cancer would have to make a choice between paying the full price of the drug or foregoing treatment that could potentially save or prolong life. Using a conservative cost of \$50,000 for the annual drug use, an uninsured family with an income of \$50,000 will end up spending its entire income to pay for just one medication. If this family has health coverage, it may end up spending \$10,000 to \$15,000 on this drug alone depending on the member share provisions of the plan (assuming 20% and 30% cost-sharing respectively). The actual cost-sharing may be less than this, however, if the person has a plan with an out-of-pocket maximum. Once the maximum is satisfied, there is no further cost-sharing required of the member. This out-of-pocket maximum, which is a feature of many health insurance plans, saves the person from personal bankruptcy in the event of a catastrophically expensive illness such as some types of cancer.

This high 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 significant financial burden due to this mandate. In a sense, these private insurers, as well as Medicare and Medicaid, are funding "clinical trials" for drug manufacturers by covering the off-label use of cancer medications.

The scope and utility of this mandate is linked to three drug compendia containing scientific evidence for a particular off-label use of a therapy. The idea behind this provision is sound in that evidence-based scientific criteria should be used to distinguish between a clinically acceptable use of a drug and an inappropriate use. However, the reality is that scientific evidence available from these three specific sources (or from any other drug compendia) is often incomplete, out of date, or not up to date. For instance, two of the three compendia (the AMA-DE and the USP-DI) have ceased publication. Even if the mandate allows for the use of more up to date compendia (CMS has added three – DrugDex, National Comprehensive Cancer Network Drugs and Biologics Compendium, and Clinical Pharmacology), research¹⁰ shows that these compendia use different reference sources, lack a standard for updating the information, and have other issues related to their method of identifying the evidence for off-label drug use.

HYPODERMIC NEEDLES AND SYRINGES

This mandate requires insurers to cover the cost of hypodermic needles and syringes needed to deliver a covered medication prescribed by a physician. The mandate mainly applies to self injectable drugs, which are usually administered by the patient or a caregiver in the home or

settings other than a hospital or physician's office. Examples include insulin, human growth hormones, and therapies to treat osteoporosis, rheumatoid arthritis, multiple sclerosis, and psoriasis, etc. These therapies are administered via injection, rather than orally, for several reasons.

The cost burden of this mandate is minimal. Even for the uninsured, the cost of a full year supply of hypodermic needles and syringes could be less than \$100 (a box of 100 single unit disposable needle-syringe costs as low as \$25). Among the self injectable medications requiring syringes and needles, insulin is by far the most widely and frequently used. However, there is a separate mandate (covered under Set One of this project) in Connecticut which covers diabetes treatment and supplies. For drugs other than diabetes treatment, the cost of the drug itself is significantly higher than the needles or the syringes. For instance, a month supply of growth hormone costs between \$550 and \$1000, and a month supply of Forteo, an osteoporosis therapy, costs \$700 or more.

Historically, this mandate may have helped reduce the overall cost of health care. At the time of its passage in 1992, the cost of syringes and needles was significantly higher than the price today. To the extent this mandate reduced the cost burden and hence financial barrier to the use of self injectables (instead of injections at a medical facility), the cost burden for the individual, the insurance industry, and society was reduced. This is because self administration of medications avoids costly office or hospital visits. In the future, however, this mandate could add cost to the system. The delivery mechanism for self injectable medications has been evolving, and this raises questions regarding the relevance and future scope of this mandate. For instance, self injectable medications are increasingly becoming available in pre-filled single dose syringes. Therefore the cost of the delivery device can not be separated from the cost of the drug itself. Moreover, single and multi-use pens and auto-injectors are increasing their market share over the traditional needle and syringe device.

PRESCRIPTION DRUGS REMOVED FROM FORMULARY

This mandate requires insurers to continue covering a medication through the prescription drug benefit even after dropping that medication from its formulary, as long as certain specified conditions are met. The medication has to be a treatment for a chronic condition, the patient for whom an exception is needed had to be on that medication prior to the drug being removed from the formulary, and a physician treating the patient has to state in writing the need for that medication for the particular patient rather than any other drug remaining on the formulary.

Insurers providing a prescription drug benefit manage that benefit through lists of drugs and the conditions for using those drugs. These lists are called formularies. A typical formulary lists the drugs included or excluded from coverage, the copayment or coinsurance tiers, and other conditions of coverage, such as prior authorization requirements, use of one drug before taking another drug for the same medical condition (step therapy), quantity or number of days supply covered under a single prescription, etc. Changes to a drug formulary can be made due to drug safety, medical efficacy, or financial reasons. Usually the changes are related to member cost share (copayment tier changes) or related to the coverage rules (prior authorization, etc.)

Outright removal of a drug from a formulary is not common. It can occur for various reasons. It could simply be due to safety concerns. For instance, a popular anti-inflammatory drug, Vioxx, was removed from formularies by insurers in 2004 due to safety concerns and was ultimately taken off the market. A drug could also be removed from an insurer's formulary due to financial considerations. Some of the scenarios where a drug may be removed from coverage due to cost reasons are:

1. A particular brand of drug is removed while its generic form is still covered (an example is the removal of Prilosec, a popular gastrointestinal medication, after widespread use of its generic version, omeprazole). This may become an access issue due to real or perceived problems when a patient tries to switch from a brand chronic medication to a generic one.
2. A more expensive combination drug (for example, a new drug combining an existing hypertension and an existing cholesterol lowering drug) may appear in the market. Insurers will sometime keep individual drugs on the formulary but may not cover, or drop from coverage, the combination drug. This may be a more beneficial step for the insurer (if the combined cost of two drugs is lower than the cost of the combination drug) but may increase the cost burden for the patient as the patient may have to pay two copayments for two separate prescriptions.
3. A drug is removed from the formulary because that particular therapeutic area of the formulary has many clinically equivalent options available. The payer (insurer) will have a financial incentive to remove a drug from the formulary if it costs significantly more than rest of the drugs in the class. There are a number of therapeutic classes of drugs in which the patient's response to therapy may be drug specific, and from which not all drugs in the class will perform equally well for the individual patient. This type of patient specific response to therapy may occur with psychiatric medications (antidepressants, antipsychotic drugs) and neurologic treatments (anti-seizure medications), among other classes.

There may be a significant cost burden for individuals and their families in the absence of this mandate. Without the mandate, scenarios 1) and 3) above would effectively mean that the patient has no insurance for a particular chronic medication. Using \$2,400 - \$4,800 as the annual cost of a drug dropped from the formulary (many brand drugs used to treat chronic conditions like diabetes, hypertension, and high cholesterol, etc. cost in this range), a family with annual income of \$50,000 could spend up to 10% of their income on the non-covered drug regardless of insurance status or the type of insurance. The cost burden would be higher for people with significant other medical costs (which is not unusual for people with chronic conditions) or with a lower income level.

Even though the non-coverage of drugs removed from a formulary affects a small number of people, and therefore, has low societal cost and low average cost for the health care system, the cost burden for the affected person and family can be non-trivial. This impact may become even larger if the cost burden reduces the drug adherence. The relation between higher cost burden and reduced medication usage as well as between less than optimal use of chronic medications and eventual long term medical and other costs is well documented in the literature.

HOME HEALTH CARE

This mandate provides coverage for an alternative to a lengthy hospital stay. After an initial hospitalization, a patient can (with a written treatment plan from their physician) receive the rest of the treatment at home. The mandate specifies the terms of such treatment as well as defines the type of providers whose care is covered. The intention of the mandate is to cover specific, limited duration continuation of treatment rather than long term rehabilitative care or other purely custodial care.

This mandate covers the situation where patients and their physicians may want to shorten a hospital stay if equivalent treatment is available at home. On a per day basis, home health care is typically much less expensive than inpatient care. Home care may be preferable to inpatient care for a number of reasons. Patients may feel more comfortable in the familiar home setting, may want to get on with their home based activities, or may want to reduce the inconvenience for their family of being in the hospital setting. Physicians may prefer early discharge to reduce the risk of hospital based infections or reduce the pressure on bed shortage. Health insurers prefer early discharge and continuation of treatment at home because the cost of treatment per day is usually lower than the cost of inpatient stay. There may be rare instances where the cost of care at home, however, exceeds that at a hospital. If the person under treatment lives in a remote area, the cost of multiple care providers may be significant. This is not the situation in CT, however, since CT is not a rural state.

It is difficult to quantify the cost burden for an individual if the mandate did not exist. In the absence of the mandate, the person under treatment could have a longer inpatient stay, creating in most cases a higher cost burden for the insurer. The financial impact on the patient, however, is not clear and may vary by case. For a person with fixed copayment type benefits, the out-of-pocket cost is probably going to be about the same regardless whether the service is provided at home or in a hospital. A patient with a coinsurance plan will probably end up paying a higher amount for inpatient care since it costs more than home care. Also, a person with a high deductible plan would potentially end up paying higher out-of-pocket costs in the absence of this mandate. A more likely scenario for the high deductible plan is that the deductible requirement would have been met by paying for the initial surgery or other treatment so that the choice between inpatient stay or home treatment will have little or no impact on out-of-pocket costs. A person without insurance will also not be affected by the absence of this mandate, as this person would generally choose the less expensive option (home-based care).

As explained, home based treatment is usually less expensive than similar treatment in an inpatient setting. To the extent this mandate moves some of the medical care to a less expensive setting, the overall cost of health care is reduced. Insurers are the biggest financial beneficiary of this cost reduction. The consumer may have less financial burden depending on the specifics of the treatment, the benefits, member cost-sharing provisions of the plan, and the availability of the home care service providers. A number of studies have examined clinical outcomes for patients who received home health care after an initial hospital stay. Most of the recent studies reviewed were done using British or Canadian data, since the public financed health care system in those countries uses home care after short hospitalization as a formal tool for cost saving as well as way to mitigate a shortage of hospital beds. One study¹¹ reviewed published research conducted through 2008 regarding the outcomes comparison between completion of treatment in hospital and the British “Early Discharge Hospital at Home” service. Among other findings, the study did not find sufficient evidence of differences

between the re-hospitalization rates or mortality between the two groups of patients recovering from surgery. The patient satisfaction was higher in the group with home care. Other studies have focused on the outcomes of a specific disease or a specific population segment. For instance, one such study¹² found no difference in clinical outcomes in people recovering from complete knee replacement. Another study¹³ found home health care cheaper with no difference in clinical outcomes for children undergoing chemotherapy induced febrile neutropenia.

It is reasonable to conclude that even in the absence of this mandate, insurers would have covered home care as an alternative to prolonged hospitalization since this care setting is less costly. The impact of the mandate may, however, become more pronounced in the future. There are a number of forces¹⁴ driving the increased use of home-based medical care. First, advances in technology are making surgeries less invasive and converting serious diseases like cancer and HIV/AIDS into chronic conditions requiring less acute and longer term low intensity care. Second, the aging of the population and people living longer active lives with chronic conditions is increasing the demand for home based care. Third, the supply of non-physician care providers is increasing and their acceptability as main stream care providers is on the rise. These providers, in general, are more willing and able to provide home services. Although it is likely in the short term, it is not clear whether these factors will result in home care remaining less expensive than hospital based care. If home care becomes more expensive, insurers will have an incentive to limit it. In that case, the mandate would become a crucial tool for ensuring that patients are able to secure home based care when that is the best setting determined by the patient-physician team. In the meanwhile, medical care provided in the alternative setting of the home remains a lower cost alternative, and for some, it is a preferable setting for end of life care rather than the unfamiliar surroundings of a hospital.

AMBULANCE SERVICES

The mandate regarding ambulance services requires insurers to provide medically necessary ambulance services. Connecticut is a small but densely populated state; it has a land area of 4,845 square miles. 85% of the population lives within 15 minutes of the main interstates that cross the state. The state has a well established pre-hospital system¹⁹ with four levels of emergency medical services (EMS) providers and 31 acute care hospitals plus one VA facility. The ambulance services are both ground as well as air-based; all hospitals having helipads. The state is divided into 5 EMS regions. In 2009, the EMS responded²⁰ to over 250,000 service requests with 55% of the requests related to emergency patients. The response time varied from an average of 7.2 minutes to 8.7 minutes across the five EMS regions.

The mandate does not require the insurers to pay for ambulance services above the maximum allowable rates set by the Department of Public Health (DPH). The DPH sets annual rates based on eight types of services ranging from basic life support or BLS (the 2009 rate was \$468) to specialty care transport (\$1052)²¹ which requires the presence of a care giver above paramedic level. Service providers can also get paid for ancillary charges like waiting time, per mile charge, etc. A separate rate list is set for non-emergency services. Medicare and Medicaid each set separate payment rates for their members, and private insurers negotiate rates directly with the providers. In general, these rates are lower than the State limits, and only the uninsured pay the full cost²².

As stated in the actuarial part of the report, the carrier data did not show significant member cost-sharing for ambulance services, which implies that people using these services through insurance plans do not incur substantial out-of-pocket expense. There is a financial burden on the uninsured paying the state maximum allowable cost. An uninsured family with an annual income of \$50,000 would end up paying 1% of income for a one time use of an ambulance costing \$500. That ambulance use would typically be associated with further cost for additional emergency care and other hospital or medical expense.

We did not find any evidence of racial or socioeconomic disparities related to access to ambulance services. However, there is a rural-urban disparity related to response time. For instance, in 2009, the average response time²³ in Stratford, which is located in the urban-based EMS Region 1, was 2.6 minutes, while the average response time in Colebrook was 19 minutes. Colebrook is part of the mostly rural-based Region 5. According to a 2007 Government Accountability Office report,²⁴ the average urban transport was 7 miles in 2004, while the average distance travelled was 13 miles for rural areas and 20 miles for the “super-rural” areas. This difference in distance and, more importantly, response time, can make a significant difference in mortality and other outcomes associated with emergency medical services. One study found that reducing ambulance response time by 5 minutes could almost double the survival rate for cardiac arrests²⁵.

MAIL ORDER PRESCRIPTIONS

This mandate prohibits insurers that offer prescription drug plans from requiring mail order dispensing of prescription drugs. The mandate addresses economic and operational issues rather than providing for a medical need. Prior to the mandate, no insurer required all drugs to be purchased via mail order. On the other hand, almost all plans covering drug benefits allow some mail order dispensing. The evolution of managed care, as it applies to prescription drugs, has created major financial stakes for insurers, PBMs, drug manufacturers, pharmacy chains, care providers, and patients. This evolution has been strongly affected by the emergence and dominance of pharmacy benefit managers (PBMs). Mail order dispensing provides savings to insurers and those people who use pharmacy benefits, which is almost everyone insured.

Managed care pharmacy benefits is a high volume business. A large insurer may adjudicate several hundred million drug claims in a year. This volume creates saving opportunities due to the economies of scale. PBMs provide administrative services to insurers by using their large scale transactions systems to work with thousands of retail pharmacies to adjudicate drug claims in real time. PBMs also provide savings for the insurers and payers by passing on some of the volume discounts they receive from the retail pharmacies (network discounts), from the drug manufacturers (rebates), and by purchasing large volumes of medications directly from the manufacturers or the wholesalers and then providing price discounts to the insurers. The PBMs perform this last service through their mail order facilities. Volume purchase discounts and low overhead (due to maintaining one or two large automated facilities rather than brick and mortar retail shops) allows PBMs to offer savings not only to their insurer clients but also to the insured members often in the form of lesser copayment. Mail order prescriptions are usually filled for 90 or more days of medication as compared to a one month supply that is typically dispensed through a retail pharmacy. Thus the mail order option is used more often for chronic than acute medications. Lower copayments, less

frequent refills, and the convenience of home delivery make mail order an attractive option for some patients.

Critics of the mail order channel, including community pharmacists, retail pharmacies, and consumer advocacy groups, argue that mail order dispensing eliminates the chance of face to face consultation with and advice from the pharmacist. The lack of personal contact is alleged to cause confusion and medication errors, especially in the older population and people on multiple medications. These detractors of mail-order claim that 24/7 call centers provided by mail order facilities are not a good substitute for a face to face interaction with a pharmacist. Providers of care for serious and rare conditions like oncology and multiple sclerosis, etc., point to some of the safety issues related to the mail delivery of certain medications, such as very expensive and temperature sensitive medications. Often, these providers compete with PBMs in supplying these specialty medications. Thus, mail delivery of these medications competes with these providers and retail pharmacies.

If this mandate did not exist, there would not be a direct financial burden on individuals. It is highly unlikely that a mail order only drug benefits could emerge--competition and member backlash would prevent it. To the extent that mail order saves money for insurers in the case of many chronic and specialty medications, insurers would have pushed for mail order utilization in the absence of this mandate. But the most likely way this would have been done is the same approach that it is used today, regardless of the mandate. Insurers and PBMs push for mail order through financial incentives, like lower copayment and/or through forced mail order utilization for a selected number of drugs. The latter type of benefit, called "mandatory mail order", usually works in the form of allowing a newly diagnosed patient to take a limited number of prescriptions (usually the first or the first two fills) using a retail chain before requiring the member to switch to the mail order route.

Although the debate regarding the pros and cons of mail order distribution has been going on for decades in the media and in professional conferences, there is a lack of scientific peer-reviewed literature regarding clinical effectiveness. One recent exception is a paper²⁶ by Kaiser Permanente researchers showing that certain members with diabetes were more adherent to their medications using a mail order benefit than were those using retail pharmacies. The more adherent members were mostly white and relatively more affluent. It is not clear, however, if certain inherent characteristics of this population (better educated, higher income, etc.) would make them more compliant, or if they were more compliant because of mail order usage, which involves lower cost-sharing than retail, and a larger supply of medication per script filled.

OUT-OF-POCKET MAXIMUM FOR IMAGING SERVICES

This mandate provides out-of-pocket limits for people using three specific forms of medical imaging. Insurers can not charge more than \$75 for a single CAT scan or a MRI (and a \$375 limit for all MRI and CAT scans for full year) and \$100 for a single PET scan (\$400 annual limit for all PET scans). The payment limits do not apply to high deductible plans, nor do they apply if the physician ordering the imaging service is the same as the one providing the service, or if the two physicians belong to same practice.

The three types of imaging services covered under the mandate are more effective but more expensive diagnostic tools than the older services like X-Ray and ultrasound. The utilization

of these newer tests has increased significantly over the last decade even though their use is still small as compared to X-Ray and ultrasound. The table below provides 2008 estimated utilization for various imaging tests:

Imaging Service Type	2008 Estimated Utilization (in million)	2008 Utilization per 1000 Persons
CAT	87	287
MRI	26	86
PET	2	8
X-Ray (including mammography)	332	1,091
Ultrasound	159	522

Source: American College of Radiology

<http://www.acr.org/SecondaryMainMenuCategories/SocioeconomicResearch/utilization.aspx>

The high-tech imaging services covered under this mandate are quite expensive. A CAT scan can cost up to \$3,000, while a MRI scan with stain can cost \$4,000. A PET scan can cost anywhere from \$3,000 to more than \$12,000 (a PET scan for the brain is usually the least expensive and that of the heart is the most expensive). By placing a ceiling on how much the person undergoing the scan pays for the service, the mandate can significantly reduce the financial burden for the patient depending on their income and benefit structure. For the cost burden modeling, it was assumed that a person undergoes three MRI scans @\$3,000/scan. Thus the total cost of the services was \$9,000. For an individual with an annual income of \$50,000 and an insurance policy with 20% member cost-sharing, the mandate could reduce the cost burden from 3.6% to 0.45% of income, even if no global maximum out-of-pocket applies to the plan. If such a cost-sharing maximum applies to all medical expenses, the out-of-pocket expenditure will be less. Since the mandate does not apply to HSA-type high deductible plans, a person with the same level of income and a high deductible plan will bear a larger portion of the cost. The table below shows the financial burden for a person with a \$50,000 annual income and various types of insurance with or without the mandate. It is assumed that the high deductible plan has 40% coinsurance and no out-of-pocket maximum. If it has such a maximum, cost-sharing will be less than 7.2%, but in all likelihood, it will be greater than 0.45%.

	Insurance with 10% Cost Sharing	Insurance with 20% Cost Sharing	High Deductible Plan	No Insurance
Without Mandate	1.8%	3.6%	7.2%	18%
With Mandate	0.45%	0.45%	7.2%	18%

The numbers show percent of \$50,000 income spent on 3 MRI scans worth \$9,000

The “without mandate” line above does not reflect how a global out-of-pocket maximum would affect cost-sharing. For a plan with an out-of-pocket maximum equal to the \$2,400 deductible, there would no cost-sharing beyond the deductible. This is the lowest that the maximum could be set. Anything higher increases the member cost-sharing.

The demand for these expensive diagnostic tests has some price elasticity, that is, people may underutilize the more expensive tests. One study²⁷ has shown that people with lower income utilize fewer MRI services than those with higher income (there was no significant

difference in relatively lower cost CAT scans or traditional X-Ray tests). Another study²⁸ found not only the same income and socioeconomic level based disparity in the use of MRI services, but also in the use of radiology services in general. Other studies²⁹ have documented racial and ethnic disparities in the use of medical imaging services.

With the exception of people with high deductible plans, one of the effects of this mandate is that it has shifted some cost from people using these services to insurers. It is also possible that, by reducing the cost to individuals, the mandate may have induced some extra demand for these complex imaging services. No studies were found which directly compare utilization in the presence and absence of this type of mandate. There are, however, a number of studies including a report by the HHS Office of Inspector General³⁰, showing evidence of overutilization generated by physicians. These studies have found that self employed physicians³¹ order more high-tech imaging services than salaried physicians, and same-specialty referrals cause more utilization³² than radiologist referrals. The main reason for this overutilization is the financial incentives created by the reimbursement system. One additional factor is defensive medical practices. One such study estimated the annual cost of overutilization of imaging services to be \$16 billion³³.

COMPREHENSIVE OUTPATIENT REHABILITATIVE SERVICES

This mandate requires the insurers to *offer* group insurance plans coverage of services provided by comprehensive outpatient rehabilitation facilities (CORFs). The covered services are provided according to a plan of care prepared, supervised, and reviewed at 30 day intervals by a physician. The services provided by a CORF and covered under the mandate include physician services, nurse care, physical and occupational therapy, respiratory therapy, audiological services and speech therapy, psychological services, and social services. Non-self-administered medications, prosthetic and orthotic devices, and other supplies related to rehabilitation and ordered by a physician are also covered. The nature of illness or disability requiring comprehensive rehabilitative services is not defined by the mandate indicating that a broad spectrum of needs is to be covered. While rehabilitation services may be necessary for brief follow-up care for injuries or post-surgery, they may also be useful to improve functional status and performance in patients having chronic illnesses, particularly those that are debilitating. People with chronic progressive disorders that interfere with functional capacity may, over time, become less able to work; this leaves them less able to afford the costs of rehabilitative services in the absence of this mandate.

Connecticut has a number CORFs serving all parts of the state. CT Bureau of Rehabilitative Services lists more than fifty community rehabilitative services providers³⁴. The costs of rehabilitative services covered by this mandate can add up to significant amount. Some of the indicative charges are illustrated in the table³⁵ below:

Service Type	Service	Cost
Occupational Therapy	Community/Work Reintegration Training Per 15 Min	\$92
	Self Care/Home Training Per 15 Min	\$49
Physical Therapy	Electrical Stimulation Manual Per 15 Min	\$126
	Exercise Per 15 Min	\$92
	Neuro-Muscular Re-Education	\$126

	Per 15 Min	
	Physical Therapy Evaluation	\$162
Respiratory Therapy	Chest Physiotherapy	\$163
	Non Invasive Ventilation (Initial)	\$835
	Spirometry Study Routine	\$453

Source: Akron General Health System, Ohio

As an example of the financial burden associated with this mandate, the cost of recovery after a stroke was modeled. Stroke is the leading cause of disability in America. About 75% of stroke victims survive with almost complete recovery, recovery with minor impairments, or recovery with severe impairments requiring special care; most of these people would go through some rehabilitative care. The cost of care for the first 90 days after stroke can range from \$15,000 to \$35,000 or more³⁶. On average, 16% of this cost is for rehabilitative services. For the purpose of financial burden modeling, a cost of \$2,500 was used. A family with annual income of \$50,000 would have to spend from 0.5% to 2% of their income² for rehabilitative services. For a person with a high deductible plan, the cost burden could be up to 4.7% of income, and for an uninsured person the financial burden could be as high as 5%. The financial burden is computed based on rehabilitative services only and does not include the cost of transportation and other expenses.

In comparison with a prior time when these services were not covered by insurance, this mandate could be thought of as shifting cost from the public to the private health sector. In the absence of this mandate, some people may have sought this care in federal and state programs.

MOBILE FIELD HOSPITAL

This mandate is related to mobile field hospital which could be deployed in the case of an emergency like a natural disaster, a pandemic, or a terrorist attack. Although field hospitals have long existed in military settings, various events in the past decade have helped make them part of contingency planning in federal, state, and local governments. The mandate requires insurers to cover any and all treatment in the field hospital setting and reimburse providers at Medicaid rates, which is usually lower than the commercial insurance rate. Therefore, in the event that the mobile field hospital is activated, the insurers will actually benefit from the lower reimbursement rate.

Since the mobile hospital is owned by the state government, in the absence of this mandate, the government might have had to pay for the entire cost of disaster care. From that perspective, it could be argued that this mandate may shift public cost to private insurers. However, the insurers get some protection in the form of lower provider reimbursement rates. If there is a disaster and the field hospital is deployed, the net impact will likely be a higher cost for insurers due to the additional one-time utilization of services performed in the mobile field hospital.

² The lower figure is for a generous plan with 10% cost-sharing. Unlike most of other mandates we used 40% and not 20% cost-sharing as an example of a high cost-sharing plan in the light of the data provided by the carriers.

PAIN MANAGEMENT

The pain management mandate is a provider mandate in the sense that it does not require coverage by insurers of any previously non-covered medical service. Rather, it allows access to physicians specializing in pain management. The treatment of pain is covered under the medical and prescription drug benefits even in the absence of this mandate. Pain treatment under certain conditions is also covered under some of the other mandates. For instance, the prescription drugs mandate covers most of the drugs including drugs for pain management. Similarly, the mandate regarding cancer treatment would cover pain medications and other pain treatment for people with cancer.

As mentioned in the actuarial part of the report, people with chronic pain are more likely to benefit from this mandate. Pain management specialists are more likely to treat people with chronic pain rather than acute pain. Those people suffering with acute pain are treated more frequently by primary care providers or specialists, but not pain management specialists. It is estimated that about 28% of American adults suffer from some form of chronic pain³⁷. Among the more common forms of chronic pain, 48 million have arthritis, 16 million experience low-back pain, 25 million suffer migraine headaches, and 20 million have jaw and lower-facial pain³. The incidence of pain is about the same in different age groups, but the type of pain varies with age³⁸. For instance, headaches are more common in people in their 20's and 30's, whereas back pain is more prevalent in middle age. Arthritis is more common in the elderly. Just as there are numerous causes and types of pain, there is a wide variety of treatments ranging from meditation to advanced pain pumps. The cost of pain medications can vary from a couple of pennies for an over the counter aspirin to \$10 - \$30 for a unit of fentanyl, a common pain medication for cancer-related pain. All these variations and choices, plus issues like proper dosage of pain medications and potential addiction and abuse, have led to the rise of pain specialist physicians. By ensuring access to these pain specialists, the mandate seeks to improve the treatment of pain. The mandate does not define pain management physician in such a way that it includes the services of nurse practitioners and physician assistants with specialized training in pain management. Some of these providers have the expertise to serve as pain management specialists and the authority to prescribe. Moreover, their services may cost less per visit than those of physicians, especially specialists.

This mandate generates no additional expense to individuals or insurers since the services of pain specialists are covered regardless of the mandate. By providing access to better pain management, however, the mandate lowers the societal cost of pain treatment. The pain management system in U.S. suffers from two opposing problems, both of which have significant financial and social cost implications. On the one hand, pain is significantly undertreated, and on the other hand, there is widespread overuse and abuse of pain medications. It is estimated that between \$80 and \$100 billion are lost every year due to productivity loss and other factors associated with chronic pain. For individuals, the cost of pain comes in the form of lost productivity, income, depression, and lack of sleep, etc. Adequate and proper pain treatment can reduce some of this burden. Similarly, overdose and abuse of pain medications has a high societal cost in the form of deaths and hospitalizations, incarcerations, and lost productivity. Details of this aspect have been discussed in the analysis of the Set 3 mandate regarding accidental ingestion of prescription medications.

Pain is not only undertreated in general, but socioeconomic and demographic disparities in treatment make it an even bigger issue. A number of studies have shown disparities in the

³ Same person may have multiple forms of pain and therefore may be treated more than once

diagnosis and treatment of pain among people with lower socioeconomic status^{39,40}. Some disparity in the treatment of pain in minorities⁴¹ has also been reported.

CONTINUED COVERAGE OF PREGNANCY

This mandate requires an insurer terminating its group insurance business in Connecticut to continue providing coverage for pregnant women until six weeks after the end of their pregnancies. As mentioned in the actuarial part of this report, such a departure of a carrier from Connecticut has not occurred, and thus there is no historical cost associated with this mandate. A sale of the insurance business or other orderly transition of care generally occurs in such circumstances.

There are over forty thousand births in Connecticut in a year. It is hard to estimate how many pregnancies would be covered under this mandate if any insurers were to simply cease operations in the state. The cost of a pregnancy can vary from \$8,000 - \$10,000 (for a normal delivery of a healthy newborn) to over a hundred thousand dollars (for complicated childbirth and subsequent neonatal care). In the absence of this mandate, the cost burden for a family affected by their insurer leaving the state could vary from little (the case of a normal healthy childbirth) to potentially tens of thousands (early stage of an eventually expensive pregnancy and post partum care). The former case of healthy newborn is more likely than the latter.

IV. CONCLUSION OF ACTUARIAL REPORT:

These thirteen mandates were examined and evaluated as Set Four of the CT health benefit mandates. Their expected 2010 paid costs were calculated. For group plans, this was \$10.09 PMPM—about 3.4% of the per member medical cost. There is also administrative cost and a profit charge associated with the medical cost of these mandates. It is \$2 PMPM. The total cost that these Set Four mandates add to the cost of health insurance is \$12.09 (= \$10.09 + \$2). These mandates add 3.4% to the cost of group health insurance. Most of the cost comes from just a few of the mandates. The \$12.09 PMPM total excludes any cost for the Clinical Trials and Experimental Treatments mandate. Although their cost is believed to be *de minimis*, due to uncertainty about them, their cost could be greater. The language of some of these thirteen mandates is broad, however, and covers many medical expenses that carriers were already covering prior to the passage of the mandates. Thus, the net new cost of the mandates is less than the gross cost.

The data for individual plans was considerably less credible than for group plans because there are more than 12 times as many group members as individual members in the submitted carrier data. These mandates represented about 2.2% of the cost of individual plans, however, the CORF mandate does not apply to individual plans—it applies to group plans only. The 2.2% for individual for the 12 mandates is somewhat smaller than the 2.6% for group plans for the same 12 mandates (excluding CORF).

Some of the mandates have a more positive effect on public health than others. Most affect a small but vulnerable special population, such as those with cancer and those people involved in clinical trials for cancer. These affected subgroups are often so small that the mandate cost is small or *de minimis* when spread to the entire pool of insureds. People who need ambulance or home health services in any given year do not represent the majority of the insured population, nor do those who receive services from a comprehensive outpatient rehabilitation facility. Relatively few insured people utilize cancer drugs off-label or experimental treatments. The same is true for hypodermic needles and syringes. Although the number of CT, MRI, and PET scans themselves has increased substantially over the past twenty years, it is still a relatively small number of people who need more than several of any type of scan per year. Several mandates in Set Four are *de minimis* in cost. None of the thirteen mandates in Set Four cost more than 1% of medical cost.

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 Set Four of the forty-five mandates covered by Public Act Number 09-179. This report is not intended for any other application or purpose. The financial / economic report contained in this Set Four report is not part of the actuarial report.

I, Daniel Bailey, am 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

A handwritten signature in cursive script that reads "Daniel Bailey".

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VI. APPENDIX ONE

PMPM MEDICAL COST

**WEIGHTED AVERAGE COST OF EACH MANDATE
ACROSS ALL CARRIERS**

MANDATE	DESCRIPTION	GROUP			
		ALLOWED		PAID	
		2007	2008	2007	2008
1	Experimental Treatment	\$ 0.01	\$ 0.01	\$ 0.01	\$ 0.01
2	Off Label Cancer Drugs	n/a	n/a	n/a	n/a
3	Clinical Trials	n/a	n/a	n/a	n/a
4	Coverage for Hypodermic Needles and Syringes Mandatory coverage for certain prescription drugs removed from formulary	\$ 0.07	\$ 0.09	\$ 0.05	\$ 0.05
5	Home Health Care	\$ 0.03	\$ 0.03	\$ 0.02	\$ 0.02
6	Ambulance Service	\$ 1.61	\$ 1.46	\$ 1.50	\$ 1.34
7	Prescription Drug-mail order prohibition	\$ 2.02	\$ 2.15	\$ 1.95	\$ 2.06
8	Access to Imaging Services *	\$ -	\$ -	\$ -	\$ -
9	Coverage for comprehensive rehab services (group 38a-523; mandatory offer)	\$ 0.99	\$ 1.04	\$ 0.87	\$ 0.91
10	Mobile Field Hospital	\$ 3.21	\$ 3.57	\$ 1.88	\$ 2.20
11	Pain Specialist	n/a	n/a	n/a	n/a
12	Continued Pregnancy Coverage	n/a	n/a	n/a	n/a
13		n/a	n/a	n/a	n/a

* Calculated net new cost

MANDATE	DESCRIPTION	INDIVIDUAL			
		ALLOWED		PAID	
		2007	2008	2007	2008
1	Experimental Treatment	\$ -	\$ -	\$ -	\$ -
2	Off Label Cancer Drugs	n/a	n/a	n/a	n/a
3	Clinical Trials	n/a	n/a	n/a	n/a
4	Coverage for Hypodermic Needles and Syringes Mandatory coverage for certain prescription drugs removed from formulary	\$ 0.01	\$ 0.06	\$ 0.00	\$ 0.01
5	Home Health Care	\$ 0.00	\$ 0.00	\$ 0.00	\$ -
6	Ambulance Service	\$ 0.76	\$ 0.74	\$ 0.71	\$ 0.68
7	Prescription Drug-mail order prohibition	\$ 1.23	\$ 1.34	\$ 1.06	\$ 1.13
8	Access to Imaging Services *	\$ -	\$ -	\$ -	\$ -
9	Coverage for comprehensive rehab services (group 38a-523; mandatory offer)	\$ 0.73	\$ 0.79	\$ 0.59	\$ 0.63
10	Mobile Field Hospital	n/a	n/a	n/a	n/a
11	Pain Specialist	n/a	n/a	n/a	n/a
12	Continued Pregnancy Coverage	n/a	n/a	n/a	n/a
13		n/a	n/a	n/a	n/a

APPENDIX TWO

**AVERAGE COST SHARING
ACROSS ALL CARRIERS**

COST SHARING AMOUNTS PMPM

MANDATE	DESCRIPTION
1	Experimental Treatment
2	Off Label Cancer Drugs
3	Clinical Trials
4	Coverage for Hypodermic Needles and Syringes Mandatory coverage for certain prescription drugs
5	removed from formulary
6	Home Health Care
7	Ambulance Service
8	Prescription Drug-mail order prohibition
9	Access to Imaging Services Coverage for comprehensive rehab services
10	(group 38a-523; mandatory offer)
11	Mobile Field Hospital
12	Pain Specialist
13	Continued Pregnancy Coverage

GROUP		INDIVIDUAL	
2007	2008	2007	2008
\$ 0.00	\$ 0.00	\$ -	\$ -
n/a	n/a	n/a	n/a
n/a	n/a	n/a	n/a
\$ 0.03	\$ 0.04	\$ 0.01	\$ 0.05
\$ 0.01	\$ 0.01	\$ 0.00	\$ 0.00
\$ 0.11	\$ 0.11	\$ 0.05	\$ 0.06
\$ 0.07	\$ 0.08	\$ 0.17	\$ 0.21
\$ -	\$ -	\$ -	\$ -
\$ 0.11	\$ 0.14	\$ 0.13	\$ 0.17
\$ 1.33	\$ 1.38	n/a	n/a
n/a	n/a	n/a	n/a
n/a	n/a	n/a	n/a
n/a	n/a	n/a	n/a

COST SHARING AS % OF ALLOWED CHARGES

MANDATE	DESCRIPTION
1	Experimental Treatment
2	Off Label Cancer Drugs
3	Clinical Trials
4	Coverage for Hypodermic Needles and Syringes Mandatory coverage for certain prescription drugs
5	removed from formulary
6	Home Health Care
7	Ambulance Service
8	Prescription Drug-mail order prohibition
9	Access to Imaging Services Coverage for comprehensive rehab services
10	(group 38a-523; mandatory offer)
11	Mobile Field Hospital
12	Pain Specialist
13	Continued Pregnancy Coverage

GROUP		INDIVIDUAL	
2007	2008	2007	2008
24.7%	15.1%	0.0%	0.0%
n/a	n/a	n/a	n/a
n/a	n/a	n/a	n/a
38.0%	41.5%	60.8%	89.4%
34.1%	32.9%	34.1%	38.4%
6.7%	7.9%	6.6%	8.0%
3.5%	3.8%	14.0%	15.4%
n/a	n/a	n/a	n/a
11.6%	13.0%	18.3%	20.8%
41.4%	38.6%	n/a	n/a
n/a	n/a	n/a	n/a
n/a	n/a	n/a	n/a
n/a	n/a	n/a	n/a

APPENDIX THREE TO FINANCIAL / ECONOMIC REPORT

Appendix
Percent of Family Income Spent on Mandate Related Services
Results of the Income - Benefit Modeling

Global Assumptions

- 1 A variety of sources were used for the cost assumptions including the Carriers' data, assumptions used in the actuarial report or in the previous phase of the project, and service cost in the literature

- 2 Calculations shown here for the high deductible plans are for group insurance. The cost burden will be higher for the individual insurance plans because the deductible levels are higher for individual plans. For a broader discussion of how group plans compare to the individual plans, please see the actuarial report.

MEDICAL IMAGING SERVICES

Cost Burden Without Mandate

Assumptions:

- 1 We have assumed 3 MRI Scans @\$3,000 each
- 2 High-ded plan family has not met any ded prior to this service

		BENEFIT →			
INCOME		Generous Plan (10% Mbr Share)	Member Share 20%	HD Plan	Uninsured
↓	50,000	1.80%	3.60%	7.20%	18.00%
	80,000	1.13%	2.25%	4.50%	11.25%
	160,000	0.56%	1.13%	2.00%	5.63%

Cost Burden with Mandate

Assumptions:

- 1 We have assumed 3 MRI Scans @\$3,000 each and mandated out-of-pocket max of \$225
- 2 High-ded plan family has not met any ded prior to this service

INCOME	BENEFIT →				
		Generous Plan (10% Mbr Share)	Member Share 25%	HD Plan	Uninsured
↓	50,000	0.45%	0.45%	7.20%	18.00%
	80,000	0.28%	0.28%	4.50%	11.25%
	160,000	0.14%	0.14%	2.00%	5.63%

COMPREHENSIVE REHABILITATIVE SERVICES

Assumptions:

- 1 We have assumed cost of stroke related rehab services to be \$2,500
- 2 High-ded plan family has not met any ded prior to this service

INCOME	BENEFIT →				
		Generous Plan (10% Mbr Share)	Member Share 40% (Reflects Carriers' Data)	HD Plan	Uninsured
↓	50,000	0.50%	2.00%	4.70%	5.00%
	80,000	0.31%	1.25%	2.94%	3.13%
	160,000	0.02%	0.63%	1.47%	3.13%

Rest of the mandates did lend themselves to cost burden analysis

Appendix III
Index of Health Insurance Mandates



INDEX OF MANDATES

Volume I	
Chapter	Description
1	Diabetes Self Management Training
2	Prostate Cancer Screening
3	Ostomy-Related Supplies
4	Hearing Aids for Children Twelve and Under
5	Craniofacial Disorders
6	Inpatient, Outpatient or One-day Dental Services
7	Diabetes Testing and Treatment
8	Birth to Three Program
9	Lyme Disease Treatments
10	Colorectal Cancer Screening
11	Tumors and Leukemia

Volume II	
Chapter	Description
1	Mammography and Breast Ultrasound
2	Maternity Minimum Stay
3	Mastectomy or Lymph Node Dissection Minimum Stay
4	Prescription Contraceptives
5	Infertility Diagnosis and Treatment
6	Autism Spectrum Disorder Therapies
7	Coverage for Newborn Infants
8	Blood Lead Screening and Risk Assessment
9	Preventive Pediatric Care and Blood Lead Screening
10	Low Protein Modified Food Products, Amino Acid Modified Preparations and Specialized Formulas
11	Neuropsychological Testing for Children Diagnosed with Cancer

INDEX OF MANDATES

Volume III	
Chapter	Description
1	Psychotropic Drug Availability
2	Mental or Nervous Conditions
3	Accidental Ingestion or Consumption of Controlled Drugs
4	Denial of Coverage Prohibited for Health Services to People with Elevated Blood Alcohol Content
5	Treatment of Medical Complications of Alcoholism
6	Occupational Therapy
7	Services of Physician Assistants and Certain Nurses
8	Services Provided by the Veterans' Home
9	Direct Access to OB/GYNs
10	Chiropractic Services

Volume IV	
Chapter	Description
1	Experimental Treatments
2	Off-label Use of Cancer Drugs
3	Cancer Clinical Trials
4	Hypodermic Needles and Syringes
5	Prescription Drugs Removed from Formulary
6	Home Health Care
7	Ambulance Services
8	Prescription Drug Coverage/Mail Order Pharmacies
9	Copayments Regarding In-Network Imaging Services
10	Comprehensive Rehabilitation Services (mandatory offer)
11	Mobile Field Hospital
12	Pain Specialist
13	Maternity Benefits and Pregnancy Care Following Policy Termination



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