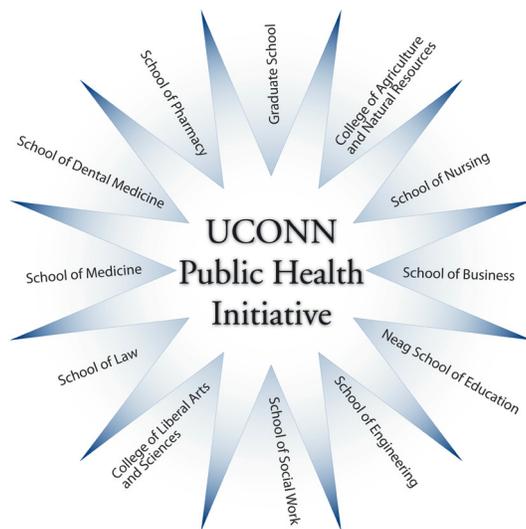


**Connecticut Mandated  
Health Insurance Benefits  
Reviews  
2010  
Volume I**



University of Connecticut

Center for Public Health and Health Policy



The Center for Public Health and Health Policy, a research and programmatic center founded in 2004, integrates public health knowledge across the University of Connecticut campuses and leads initiatives in public health research, health policy research, health data analysis, health information technology, community engagement, service learning, and selected referral services.

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# Connecticut Mandated Health Insurance Benefit Reviews

## Volume I. Introduction

Volume I contains eleven 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 I 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 I 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.

<b>Index of Mandates: Volume I</b>				
Chapter	Description	Individual policy statute	Group plan statute	Policy Types Applicable (Subsection)
1	Diabetes Self Management Training	§ 492e	§ 518e	1,2,4,11,12
2	Prostate Cancer Screening	§ 492g	§ 518g	1,2,4,11,12
3	Ostomy-Related Supplies	§ 492j	§ 518j	1,2,4,11,12
4	Hearing Aids for Children Twelve and Under	§ 490b	§ 516b	1,2,4,11,12
5	Craniofacial Disorders	§ 490c	§ 516c	1,2,4,11,12
6	Inpatient, Outpatient or One-day Dental Services	§ 491a	§ 517a	1,2,4,11,12
7	Diabetes Testing and Treatment	§ 492d	§ 518d	1,2,4,11,12
8	Birth to Three Program	§ 490a	§ 516a	1,2,4,11,12
9	Lyme Disease Treatments	§ 492h	§ 518h	1,2,4,11,12
10	Colorectal Cancer Screening	§ 492k	§ 518k	1,2,4,11,12
11	Tumors and Leukemia	§ 504	§ 542	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, equipment or supplies, 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 I

<b>Group Plans</b>		
Mandate	Per Member Per Month (PMPM)	Percent of Premium
Diabetes Self-Management Training	\$0.06	0.02%
Prostate Cancer Screening	\$0.19	0.06%
Ostomy-Related Supplies	\$0.06	0.02%
Hearing Aids for Children Twelve and Under	\$0.01	Less than 0.01%
Craniofacial Disorders	\$0.05	0.02%
Inpatient, Outpatient or One-day Dental Services	\$0.05	0.02%
Diabetes Testing and Treatment	\$4.60	1.50%
Birth to Three Program	\$0.22	0.07%
Lyme Disease Treatments	\$0.28	0.09%
Colorectal Cancer Screening	\$3.40	1.10%
Tumors and Leukemia	\$11.00	3.70%
<b>TOTAL</b>	<b>\$19.79</b>	<b>6.61%</b>

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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 I**  
**Chapter 1**  
**Diabetes Self-Management Training**

Review and evaluation of CGSA § 38a-518e and § 38a-492e  
Mandatory coverage for diabetes outpatient self-management training

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## 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-518e and § 492e mandate that group and individual health insurance policies issued, renewed or continued in this state provide coverage for diabetes self-management education to individuals with any form of diabetes if it is prescribed by a physician or licensed health care provider. Medical nutritional education is included as well as other types of self-management education. The mandated education includes 1) initial training and education at the time of diagnosis, 2) additional training and education made necessary by a change in condition and 3) training and education in new technologies and treatment methods.

Specifically, CGSA § 38a-518e provides that:

- (a) Each group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of § 38a-469 delivered, issued for delivery, renewed or continued in this state on or after January 1, 2000, shall provide coverage for outpatient self-management training for the treatment of insulin-dependent diabetes, insulin-using diabetes, gestational diabetes and non-insulin-using diabetes if the training is prescribed by a licensed health care professional who has appropriate state licensing authority to prescribe such training. As used in this section, «outpatient self-management training» includes, but is not limited to, education and medical nutrition therapy. Diabetes self-management training shall be provided by a certified, registered or licensed health care professional trained in the care and management of diabetes and authorized to provide such care within the scope of the professionals practice.
- (b) Benefits shall cover: (1) Initial training visits provided to an individual, after the individual is initially diagnosed with diabetes, that are medically necessary for the care and management of diabetes, including, but not limited to, counseling in nutrition and the proper use of equipment and supplies for the treatment of diabetes, totaling a maximum of ten hours; (2) training and education that is medically necessary as a result of a subsequent diagnosis by a physician of a significant change in the individual's symptoms or condition which requires modification of the individual's program of self-management of diabetes, totaling a maximum of four hours; and (3) training and education that is medically necessary because of the development of new techniques and treatment for diabetes totaling a maximum of four hours.
- (c) Benefits provided pursuant to this section shall be subject to the same terms and conditions applicable to all other benefits under such policies.  
(P.A. 99-284, S. 44, 60.)

§ 38a-492d 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 January 2000 (P.A. 99-284).

### *Premium impact*

**Group plans:** On a 2010 basis, the medical cost of this mandate is estimated to be \$0.06 PMPM. Estimated total cost to insurers (insurance premium, administrative fees, and profit) of the mandated services on a 2010 basis in group plans is \$0.07 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 \$0.01 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 \$0.02 PMPM. Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services in 2010 in individual policies is \$0.03 PMPM, which is less than 0.1 percent of estimated total premiums in individual policies. Estimated cost sharing on a 2010 basis in individual policies is *de minimis*. Individual policies data is less credible than group plans 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 61 percent of members in self-funded plans have coverage for the benefit.

## II. Background

Diabetes (also called diabetes mellitus) is a condition characterized by hyperglycemia (high blood glucose or high blood sugar) resulting from the body's inability to use blood glucose for energy.<sup>1</sup> In 2007, 1.6 million new cases of diabetes were diagnosed in people ages 20 and over in the United States.<sup>2</sup>

In Type 1 diabetes, the pancreas no longer makes insulin, which is a hormone that helps the body use glucose; therefore, blood glucose cannot enter the cells to be used for energy. In Type 2 diabetes, either the pancreas does not make enough insulin or the body is unable to use insulin correctly. A third type of diabetes, gestational diabetes, sometimes develops during pregnancy. It is generally disappears after delivery, but it may pre-dispose a woman to develop diabetes later in life.

The goal of diabetes treatment is to maintain optimum levels of glucose in the blood and to avoid, delay or minimize the severity of the serious complications of diabetes.<sup>3</sup> These include cardiovascular disease, kidney

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<sup>1</sup> US Department of Health and Human Services, NIH National Diabetes Information Clearinghouse (NDIC). Diabetes Dictionary, 2007. Available at: <http://diabetes.niddk.nih.gov/dm/pubs/dictionary/pages/e-k.htm#I>. Accessed on: April 27, 2010.

<sup>2</sup> US Department of Health and Human Services, NIH National Institute of Diabetes and Digestive and Kidney Diseases. National Diabetes Statistics, 2007 fact sheet. Last updated June 2008. Bethesda, MD: U.S. DHHS. Available at: <http://diabetes.niddk.nih.gov/dm/pubs/statistics/index.htm#allages>. Accessed on: June 16, 2010.

<sup>3</sup> American Diabetes Association. 2007. Third-party reimbursement for diabetes care, self-management education, and supplies. *Diabetes Care* 30(Supp 1):S86.

disease, blindness, nerve damage and amputation of the extremities.<sup>4</sup>

The success of diabetes treatment depends in large part on the ability of the patient to self-manage medication, food intake and life style changes in between medical appointments. According to the American Diabetes Association, “Diabetes self-management education (DSME) is a critical element of care for all people with diabetes and is necessary in order to improve patient outcomes....Diabetes self-management education (DSME) is the ongoing process of facilitating the knowledge, skill and ability necessary for diabetes self-care... The overall objectives of DSME are to support informed decision-making, self-care behaviors, problem-solving and active collaboration with the health care team and to improve clinical outcomes, health status and quality of life.”<sup>5</sup>

The elements of effective diabetes education include:

1. Describing the diabetes disease process and treatment options,
2. Incorporating nutritional management into lifestyle,
3. Incorporating physical activity into lifestyle,
4. Using medication(s) safely and for maximum therapeutic effectiveness,
5. Monitoring blood glucose and other parameters and interpreting and using the results for self-management decision making,
6. Preventing, detecting, and treating chronic complications,
7. Developing personal strategies to address psychosocial issues and concerns, and
8. Developing personal strategies to promote health and behavior change.<sup>6</sup>

A team of instructors who are certified diabetes educators or who have experience in diabetes management and education should provide DSME. Teams usually include a registered nurse, a dietitian and/or a pharmacist.<sup>7</sup>

### 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 Systematic Review
- CINAHL
- Government Agency/Associations/Society Websites
- General Internet

General search terms used included: “Diabetes Mellitus,” “Health Services Needs and Demand,” “Health

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<sup>4</sup> US Department of Health and Human Services, NIH National Institute of Diabetes and Digestive and Kidney Diseases. National Diabetes Statistics, 2007 fact sheet. Last updated June 2008. Bethesda, MD: U.S. DHHS. Available at: <http://diabetes.niddk.nih.gov/dm/pubs/statistics/index.htm#allages> . Accessed on: June 16, 2010.

<sup>5</sup> Funnell M, Brown T, Childs B et al. 2009. National standards for diabetes self-management education. *Diabetes Care* 32 (Supp 1):S87.

<sup>6</sup> Funnell M, Brown T, Childs B et al. 2009. National standards for diabetes self-management education. *Diabetes Care* 32 (Supp 1):S89.

<sup>7</sup> *Ibid.*

Services Accessibility,” “Healthcare Disparities” and “Insurance.”

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

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

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

With the assistance of the Connecticut Insurance Department (CID), CPHHP and Ingenix Consulting 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.***

The CDC Behavioral Risk Factor Surveillance System reported that, in 2008, 6.8 percent of Connecticut residents had been told by their doctors that they have diabetes.<sup>8</sup> Connecticut Department of Public Health estimates that 163,000 Connecticut residents have diagnosed diabetes and 48 percent of people with diabetes in Connecticut have received diabetes self-management education.<sup>9</sup> The Ingenix Consulting report found that approximately 1.3 percent of people with diabetes in its Connecticut claims database availed themselves of self-management training in 2007 and 2008.<sup>10</sup>

### ***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.***

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<sup>8</sup> US Department of Health and Human Services, CDC National Center for Chronic Disease Prevention and Health Promotion. Behavioral Risk Factor Surveillance System, Prevalence and Trends Data, Connecticut – 2008 Diabetes. Available at: <http://apps.nccd.cdc.gov/brfss/display.asp?cat=DB&yr=2008&qkey=1363&state=CT> . Accessed on October 7, 2010.

<sup>9</sup> Connecticut Department of Public Health. 2006. The Burden of Diabetes in Connecticut; Surveillance Report. Available at: [http://www.ct.gov/dph/LIB/dph/hisr/pdf/Diabetes\\_surveillance\\_2006CT.pdf](http://www.ct.gov/dph/LIB/dph/hisr/pdf/Diabetes_surveillance_2006CT.pdf). Accessed on November 29, 2010.

<sup>10</sup> Ingenix Consulting Report, Appendix II, p.21.

## *Medicare*

Medicare Part B <sup>11</sup> covers the cost of diabetes outpatient self-management training provided by a certified diabetes self-management education program (as certified by the American Diabetes Association or the Indian Health Service) if: a) the doctor prescribes the training for the patient and b) the patient meets or has met one of the following conditions in the previous 12 months:

1. The patient was diagnosed with diabetes.
2. The patient began taking diabetes medication after previously not taking it.
3. The patient switched from oral diabetes medication to insulin.
4. The patient has diabetes and recently (in the last 12 months) became eligible for Medicare.

Certain risk factors may classify the patient as being high risk, and may also make the patient eligible for Medicare coverage of the training. <sup>12</sup>

Medicare coverage is limited to a maximum of a total of ten hours of initial training within a continuous 12-month period, and 2 hours of follow-up training each subsequent year, not including medical nutrition therapy services (which are covered separately).<sup>13</sup> Of the initial ten hours, one of the covered hours is a “one-on-one” training session; the additional 9 hours of training are given in group classes, with some exceptions.<sup>14</sup> The patient is responsible for paying 20 percent of the Medicare approved amount for outpatient facility charges or physician’s services.

Medicare also covers medical nutrition therapy services for diabetics with fasting blood sugars that meet certain criteria as prescribed by the patient’s physician. Medicare covers three hours of one-on-one medical nutrition therapy services the first year, and two hours of follow-up each subsequent year.

## *Medicaid*

Medicaid typically does not cover self-management education programs such as the American-Diabetes-Association-certified training offered by Medicare for clients with diabetes. “Per Medicaid regulations, Medicaid does NOT cover any procedure or service of an unproven, educational, social, research, experimental or cosmetic nature; for any diagnostic, therapeutic or treatment service in excess of those deemed medically necessary and medically appropriate by the department to treat the client’s condition; or for services not directly related to the client’s diagnosis, symptoms or medical history.”<sup>15</sup>

There is one exception to this policy: Medicaid covers medically necessary and medically appropriate “diabetic teaching for thirty consecutive days per diabetic client” if the teaching is provided by a home health agency.<sup>16</sup>

Medicaid traditionally does not cover nutritionist services for clients diagnosed with diabetes.<sup>17</sup> However, a diabetic client may be able to obtain DSS coverage for nutritional training through outpatient hospital

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<sup>11</sup> Center for Medicare Advocacy. 2010. Medicare Coverage Guidelines for Diabetes Self-Management Training. Available at: <http://www.medicareadvocacy.org/InfoByTopic/CTConsumersGuide.htm>. Accessed on November 29, 2010.

<sup>12</sup> US Department of Health and Human Services, Centers for Medicare and Medicaid Service. Publication # 11022: Medicare Coverage of Diabetes Supplies and Services. pp. 3, 15-16. Available at: <http://www.medicare.gov/Publications/Pubs/pdf/11022.pdf>. Accessed on November 29, 2010. pp. 16-17.

<sup>13</sup> *Ibid.* p. 19.

<sup>14</sup> *Ibid.* p 17.

<sup>15</sup> *Ibid.*

<sup>16</sup> CONN. AGENCIES REGS. § 17b-262-728(a) (1) (c).

<sup>17</sup> Personal correspondence with Nina Holmes, Connecticut Department of Social Services Medical Policy Unit, April 16, 2010.

settings known as “clinic group services,” provided that the services are rendered by an APRN or physician.<sup>18</sup>

### ***Connecticut Department of Public Health***

The Connecticut Department of Public Health works with provider groups, local health departments and other associations to make educational information and curricula available. The Connecticut Diabetes Prevention and Control Plan includes a list of ADA recognized diabetes education programs in the state and community-based programs that offer diabetes support and education.<sup>19</sup>

#### ***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 2000 (P.A. 99-284) 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.***

A significant proportion of people who have been diagnosed with diabetes have reported that they have not received diabetes self-management education. Connecticut Department of Public Health reported in 2006 that only 48 percent of people diagnosed with diabetes in Connecticut had attended a diabetes self-management class.<sup>20</sup> The CDC reported that 51.9 percent of people ages 18-64 who had diabetes had received such training.<sup>21</sup> No data was found on whether or how much the lack of third-party funding contributes to this low percentage.

However, a Statistical Brief issued in 2000 and based on data developed through the Medical Expenditure Panel Survey (MEPS) indicated that national MEPS data showed that uninsured individuals with diabetes were less likely to have had other recommended diabetes services, including A1c tests, foot exams, dilated eye exams and routine check-ups than those with private insurance.<sup>22</sup>

#### ***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.***

Diabetes self-management education and training programs generally are not expensive;<sup>23</sup> however, they can pose other barriers for people with diabetes. They require a commitment of time over several sessions, and can involve transportation costs and lost income due to absence from work.

#### ***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 Diabetes Association includes diabetes self-management education as part of its treatment

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<sup>18</sup> *Ibid.*

<sup>19</sup> Connecticut Department of Public Health. The Connecticut Diabetes Prevention and Control Plan 2007-2010. 2006. Appendix D.

<sup>20</sup> Connecticut Department of Public Health. 2006 Connecticut Diabetes Prevention and Control Program Diabetes Preventive-Care Practices. Available at: <http://www.ct.gov/dph/LIB/dph/hisr/pdf/DBpreventivepractices.pdf>. Accessed on October 7, 2010

<sup>21</sup> US Department of Health and Human Services, NIH Centers for Disease Control and Prevention: National Diabetes Surveillance System. Available at: <http://www.cdc.gov/diabetes/statistics/index.htm>. Accessed on October 27, 2010.

<sup>22</sup> Stagnitti, M. Dept. of Health and Human Services, Agency for Healthcare Research and Quality. *Medical Expenditure Panel Survey, Stat. Brief #5: Medical Care; and Treatment for Chronic Conditions, 2000.* Available at: [http://www.meps.ahrq.gov/mepsweb/data\\_stats/MEPS\\_topics.jsp?topicid=7Z-1](http://www.meps.ahrq.gov/mepsweb/data_stats/MEPS_topics.jsp?topicid=7Z-1). Accessed on September 29, 2010.

<sup>23</sup> Ingenix Consulting Report, Appendix II, p.44.

guidelines for diabetes,<sup>24</sup> as does the American Association of Clinical Endocrinologists.<sup>25</sup>

The Center for Disease Control and Prevention, as part of its Healthy People 2010 program,<sup>26</sup> and the Connecticut Department of Public Health, in its Diabetes Prevention and Control program,<sup>27</sup> have set goals for increasing the number of people with diabetes who have received diabetes self-management education.

**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<sup>28</sup> has called for third party reimbursement of diabetes self-management education, including medical nutrition education.

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

Forty-five states and the District of Columbia mandate insurance coverage of diabetes self-management education. These states (plus Arizona) also mandate coverage of diabetes treatment and supplies. Only Alabama, Arizona, Idaho, North Dakota and Ohio do not mandate diabetes education.<sup>29</sup> Consequently, most states that mandate both requirements choose to consolidate the two into one mandate. As a result of the uniqueness of Connecticut's separate mandates for training and supplies, research revealed no mandated benefit reviews exclusively of diabetes self-management training (without also including the cost of diabetes supplies).

Mandated benefit reviews from Maryland,<sup>30</sup> Ohio<sup>31</sup> and Utah<sup>32</sup>, footnoted below, contain projected cost estimates based on mandatory coverage of both diabetes testing/treatment and self-management training.

Li, et al., analyzed data from the Behavioral Risk Factor surveillance system between 1996 and 2000 to determine the impact of the passage of mandates for diabetes treatment and preventive care in the 16 states that passed such mandates between 1997 and 1999. Fifteen of these states included diabetes self-management education in their mandates. They found small increases in the number of people with diabetes who performed daily self-monitoring of blood glucose after passage of the mandated benefit.<sup>33</sup>

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<sup>24</sup> American Diabetes Association. 2010. Standards of Medical Care in Diabetes-2010. *Diabetes Care* 33(Supp1);S26.

<sup>25</sup> American Association of Clinical Endocrinologists. 2007. Medical Guidelines for Clinical Practice for the Management of Diabetes Mellitus. *Endocrine Practice* 13(Supp 1); 16.

<sup>26</sup> Center for Disease Control and Prevention. Healthy People 2010. Available at: [http://www.healthypeople.gov/Document/HTML/Volume1/05Diabetes.htm#\\_Toc494509747](http://www.healthypeople.gov/Document/HTML/Volume1/05Diabetes.htm#_Toc494509747) . Accessed on October 7, 2010.

<sup>27</sup> Connecticut Department of Public Health. 2006. The Connecticut Diabetes Prevention and Control Plan 2007-2010, p.39.

<sup>28</sup> American Diabetes Association. 2007. Third-Party Reimbursement for Diabetes Care, Self-management Education, and Supplies. *Diabetes Care* 30(Supp 1):S86.

<sup>29</sup> National Council of State Legislators. 2010. Providing Diabetes Health Coverage: State Laws and Programs. Available at: <http://www.ncsl.org/default.aspx?tabid=14504>. Accessed on October 7, 2010.

<sup>30</sup> 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](http://mhcc.maryland.gov/health_insurance/mandated_1207.pdf). Accessed on November 29, 2010.

<sup>31</sup> Ohio Legislative Service Commission. 2007. Fiscal Note and Local Impact Statement, pursuant to S.B. 99 of the 127<sup>th</sup> General Assembly of Ohio. Report published November 13, 2007. Available at: <http://www.lbo.state.oh.us/fiscal/fiscalnotes/127ga/SB0099IN.htm>. Accessed on November 29, 2010.

<sup>32</sup> Utah Insurance Department. 2003. Diabetes Mandate Report. Available at: <http://www.insurance.utah.gov/docs/2003DiabetesRpt.pdf>. Accessed on November 29, 2010.

<sup>33</sup> Li R, Zhang P, Barker L and Hartsfield D. 2010. Impact of state mandatory insurance coverage on the use of diabetes preventive care. *BMC Health Serv Res* 10;133. Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2881060>. Accessed on October 7, 2010.

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

The Connecticut Department of Public Health lists diabetes as the seventh leading cause of death in Connecticut.<sup>34</sup> It participates in the CDC-funded Diabetes Prevention and Control program and its current plan includes increasing the percentage of people with diabetes who participate in diabetes self-management education programs.<sup>35</sup> This report estimates that diabetes cost Connecticut \$1.7 billion in direct and indirect costs in 2003. It recognizes the importance of patient self-management and the role of self-management education in determining diabetes-related health outcomes.

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

Self-management skills can be taught by the medical provider. Many insurance companies and managed care companies have diabetes management support programs. A number of internet resources on diabetes are available; however, these do not provide individually-tailored self-management plans.

**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.***

Diabetes self-management education is an integral part of the medical management of diabetes as a chronic disease. Research has shown that effective glucose control can avoid or delay the most common complications of diabetes, and diabetes self-management education has been shown to improve diabetes self-management by the patient.<sup>36</sup>

**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 chronic disease management education programs, e.g., asthma. This is especially true where medical treatment for the chronic disease relies at least in part on patient self-management.

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

To the extent that effective self-management can reduce the incidence and severity of the medical complications of diabetes, over the long term the cost of diabetes self-management education is likely to be out-weighed by these savings. The impact on other benefits may therefore actually be a positive one, potentially freeing up claim dollars for the treatment of other conditions. However, because the complications of diabetes develop over a long period of time, the immediate savings may be small.

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

Many self-funded employers include this coverage in their plans, and have instituted programs to help employees manage their diabetes at work.<sup>37</sup>

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<sup>34</sup> Connecticut Department of Public Health. 2006. The Burden of Diabetes in Connecticut, 2006 surveillance Report P.4.

<sup>35</sup> Connecticut Department of Public Health. 2006. The Connecticut Diabetes Prevention and Control Plan 2007-2012. P.vii.

<sup>36</sup> Norris S., Lau J, Smith, SJ et.al. 2002. Self-management education for adults with type 2 diabetes. *Diabetes Care* 25(7);1159-1171.

<sup>37</sup> US Government Accounting Office. 2009. Managing Diabetes-Health Plan Coverage of Services and Supplies. Available at: <http://gao.gov/new.itunes/d05210.pdf>. Accessed on October 8, 2010.

Information received from five insurers/MCOs domiciled in Connecticut representing an estimated 47 percent of the total self-funded population in Connecticut shows that 61 percent of members in self-funded plans have coverage for the 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, the claims data from the carriers and the cost projections, which 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 \$96,220 for active employees and \$21,600 for the retiree medical plans (n.b., the cost may be somewhat higher for the retiree plans, since the incidence of diabetes increases with age). 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 133,334 covered lives for the active employee plans and 30,000 covered lives under the retiree medical plans who are not eligible for Medicare, as reported by the State Comptroller's Office.<sup>38</sup>

**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.***

A number of studies have documented the positive relationship between diabetes self-management education and control of glycemic levels in the blood of people with diabetes.<sup>39</sup> It is recommended by the American Diabetes Association and the Centers for Disease Control and Prevention.

## **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***

There are many resources available for diabetes education. The Connecticut Department of Public Health Diabetes Prevention and Control Plan includes a list that is not exhaustive, but indicates widespread availability.

***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 National Council of State Legislatures studied the impact on utilization of mandates for diabetes

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<sup>38</sup> Personal Communication with Scott Anderson, Connecticut State Comptroller's Office, September 14, 2010.

<sup>39</sup> Norris S., Lau J, Smith, SJ et al. 2002. Self-management education for adults with type 2 diabetes. *Diabetes Care* 25(7);1159.

services and self-management education in 16 states that passed such mandates between 1996 and 2000. The NCSL found evidence of small, but not significant, increases in utilization after passage. The Connecticut Department of Public Health has an objective in its Connecticut Diabetes Prevention and Control Plan, 2007-2012 to increase by 5 percent the proportion of people with diabetes who participate in diabetes self-management education.

***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.***

Diabetes self-management education programs are a less expensive alternative to education provided to the individual patient by the medical diabetes-care provider. Portions of them can be offered in group settings, which make them cost-effective.

Information on self-management of diabetes is also available on the internet from sources such as the National Institute of Diabetes and Digestive and Kidney Diseases,<sup>40</sup> which is one of the National Institutes of Health, and the Centers for Disease Control and Prevention.<sup>41</sup> However, these cannot be personalized to the individual patient and do not provide ongoing support.

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

The mandate is limited to education that is prescribed by a licensed health care provider. It is also limited as to the circumstances under which it may be prescribed and as to the hours covered in each circumstance. 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 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 medical cost of the mandate is spread to all insureds in group plans, medical costs are estimated to be \$0.06 PMPM and retention costs are estimated to be \$0.01 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$0.07 PMPM in 2010, which is less than 0.1 percent of premium.

**Individual policies:** When the medical cost of the mandate is spread to all insureds in individual policies, medical costs are estimated to be \$0.02 PMPM and retention costs are estimated to be \$0.01 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$0.03 PMPM in 2010, which is less than 0.1 percent of premium.

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<sup>40</sup> US Department of Health and Human Services, NIH National Institute of Diabetes and Digestive and Kidney Diseases. Treatments for Diabetes. Available at <http://diabetes.niddk.nih.gov/treatments/index.htm>. Accessed on October 27, 2010.

<sup>41</sup> US Department of Health and Human Services, Centers for Disease Control and Prevention. Diabetes Public Health Resource: Diabetes and Me. Available at <http://www.cdc.gov/diabetes/consumer/index.htm>. Accessed on October 27, 2010.

It is unclear how much of this cost would be covered by employers and insurance carriers even without the mandate since it is included in nearly all self-funded plans in Connecticut.

For further information, please see Appendix II: Ingenix Consulting Actuarial and Economic Report.<sup>42</sup>

***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.***

Diabetes self-management education programs are not expensive and are sometimes offered at no cost.<sup>43</sup> The American Diabetes Association recommends it as an integral part of any diabetes treatment plan.

Alternatively, self-management education can be provided by the health care provider during office visits and information on self-management is available on the internet from sites such as the NIDDK<sup>44</sup> and the CDC.<sup>45</sup> Training by the health care provider can be more expensive than certified DSME programs, and internet materials do not provide the opportunity to individually tailor a self-management program to the needs and circumstances of individual patients.

***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.***

Insurance coverage for diabetes self-management education adds an estimated \$1,032,614 to the total cost of health care in Connecticut. To the extent that it results in better self-management of blood glucose levels for patients with diabetes, it is expected to result in savings to insurers and employers by delaying and/or reducing the development of the medical complications of diabetes, which can be very expensive to treat. However, it is difficult to calculate the cost of illnesses or conditions that do not develop.

***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.***

This mandate adds an estimated \$0.07 PMPM to the cost of group insurance coverage for both small employers and other employers.<sup>46, 47</sup>

***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

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<sup>42</sup> Ingenix Consulting Report, Appendix II, p.6.

<sup>43</sup> Ingenix Consulting Report, Appendix II, p. 42.

<sup>44</sup> US Department of Health and Human Services, NIH National Institute of Diabetes and Digestive and Kidney Diseases. Treatments for Diabetes. Available at <http://diabetes.niddk.nih.gov/treatments/index.htm>. Accessed on October 27, 2010.

<sup>45</sup> US Department of Health and Human Services, Centers for Disease Control and Prevention. Diabetes Public Health Resource: Diabetes and Me. Available at <http://www.cdc.gov/diabetes/consumer/index.htm>. Accessed on October 27, 2010.

<sup>46</sup> Ingenix Consulting Report, Appendix II.

<sup>47</sup> Ingenix Consulting Report, Appendix II, p. 30.

\$1,222,009.<sup>48</sup> 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 CT plans continue to comply with this mandate even though these plans are now self-funded and therefore are not required to include it.

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<sup>48</sup> Ingenix Consulting Report, Appendix II.

# Volume I

## Chapter 2

### Coverage for Prostate Cancer Screening

Review and Evaluation of Connecticut Statute  
§ 38a-518g and § 38a-492g

Mandatory Coverage for Prostate Cancer Screening

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## 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 insurance benefits existing 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-492g and §38a-518g mandate individual and group health policies delivered, issued for delivery or renewed in Connecticut on or after October 1, 1997 to provide coverage for laboratory and diagnostic tests for certain men to screen for prostate cancer, including prostate specific antigen (PSA) tests.

Specifically, CGSA § 38a-518g 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, shall provide coverage for laboratory and diagnostic tests, including, but not limited to, prostate specific antigen (PSA) tests, to screen for prostate cancer for men who are symptomatic, whose biological father or brother has been diagnosed with prostate cancer, and for all men fifty years of age or older.

(P.A. 99-284, S. 46, 60.)

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

In March 2010, the University of Connecticut Center for Public Health and Health Policy (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 January 1, 2000 (P.A. 99-284).

### *Premium impact*

**Group plans:** On a 2010 basis, the medical cost of this mandate is estimated to be \$0.19 per member per month (PMPM). Estimated total cost to insurers (medical cost, administrative fees, and profit) of the mandated services on a 2010 basis in group plans is \$0.23 PMPM, which is approximately 0.1 percent of estimated total premium costs in group plans. Estimated cost sharing for 2010 in group plans is \$0.03 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 \$0.11 PMPM. Estimated total cost (medical cost, administrative fees, and profit) of the mandated services in 2010 in individual policies is \$0.14 PMPM, which is less than 0.1 percent of estimated total premiums in individual policies. Estimated cost sharing on a 2010 basis in individual policies is \$0.08 PMPM. Individual policies data is less credible than group plans

data primarily due to small sample size.

### ***Self-funded plans***

Five insurers/MCOs domiciled in Connecticut provided data on their self-funded plans for this mandate, which represents an estimated 47 percent of the total population in self-funded plans in Connecticut. For these five carriers, 95 percent of members in their self-funded plans have benefits at least equal to 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 which is included as Appendix II.

## **II. Background**

### **Prostate cancer**

Prostate cancer is the most frequently diagnosed cancer among men and the second leading cause of cancer death in men in the United States.<sup>1,2</sup> It is a cancer that forms in tissues of the prostate gland, which is part of the male reproductive system, and usually occurs in older men. Some prostate cancers are aggressive and life-threatening. Others grow so slowly that they may never produce symptoms or may not become life-threatening before a man dies from other causes.<sup>3</sup> The National Cancer Institute estimates that 217,730 new cases will be diagnosed nationally and 32,050 deaths will occur as a result of prostate cancer in 2010.<sup>4</sup>

Prostate cancer generally occurs in men over 50 years of age and its incidence increases with age. The lifetime risk of death due to prostate cancer is about 3 percent.<sup>5</sup> There has been a gradual but steady decline in prostate cancer mortality in the U.S. of approximately 30 percent. As the American Urological Association notes, this trend began fairly soon after the introduction of PSA testing, which may have played a role. However, two recent major studies, the European Randomized Study of Screening for Prostate Cancer (ERSPC) and the Prostate, Lung, Colon, and Ovary Trial of the National Cancer Institute (NCI), found that there was little or no difference in the rate of prostate cancer deaths between those men screened for PSA levels and those men who were not screened.<sup>6,7</sup>

Benign prostatic hyperplasia (BPH), a non-malignant enlargement of the prostate gland that may interfere with urination, has many of the same symptoms as prostate cancer and is common in older men. Both of these conditions, as well as infection or inflammation of the prostate, can cause elevated PSA levels.<sup>8</sup>

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<sup>1</sup> U.S. Preventive Services Task Force. 2008. Screening for Prostate Cancer: U.S. Preventive Services Task Force Recommendation Statement. *Ann. Int. Med.* 149(3);185.

<sup>2</sup> Lin M, Ball R, Maradiegue A. 2007. *Urologic Nursing* 27(6);481.

<sup>3</sup> Smith R, Cokkinides V, Brawley O. 2009. Cancer screening in the United States, 2009, A review of current American Cancer Society guidelines and issues in cancer screening. *CA Cancer J Clin* 59;27-41.

<sup>4</sup> U.S. National Institutes of Health, National Cancer Institute. 2010. Prostate Cancer. Available at: <http://www.cancer.gov/cancertopics/types/prostate>. Accessed on December 14, 2010.

<sup>5</sup> American Urological Association. 2009. AUA New Guidelines on Prostate Cancer Screening. Available at: <http://www.psa-rising.com/mednews/component/content/article/38-screening/78-uaa-new-guidelines-on-prca-screening>. Accessed on December 14, 2010.

<sup>6</sup> Schroder, F.H., Hugosson, J., Roobol, M.J., et al. 2009. Screening and prostate-cancer mortality in a randomized European study. *New England Journal of Medicine*, 360: 11320-8.

<sup>7</sup> Andriole, G.L., Grubb, R.L., Buys, S.S., et al. 2009. Mortality results from a randomized prostate cancer screening trial. *New England Journal of Medicine*, 360: 1310-19.

<sup>8</sup> U.S. National Institutes of Health, National Cancer Institute. 2010. Prostate Cancer. Available at: <http://www.cancer.gov/cancertopics/types/prostate>. Accessed on December 14, 2010.

## Types of prostate cancer screening<sup>9</sup>

### *Digital Rectal Exam*

In a digital rectal exam (DRE), a physician palpates the prostate through the rectum to determine if there is any lumpy, hard or otherwise irregular tissue. Prior to the discovery of PSA, this was the main method to check for prostate cancer. As a general rule, irregularities in the prostate from cancer are likely to be more advanced before they can be detected by DRE. Evidence is mixed on whether combining Digital Rectal Exam (DRE) with PSA tests increases the detection of prostate cancer. The ERSPC found that DRE combined with PSA tests did not increase the rate of prostate cancer detection over PSA tests alone.<sup>10</sup>

### *Prostate-specific antigen test*

Prostate-specific antigen (PSA) test is a test that measures the level of PSA in the blood. PSA is a substance made by the prostate that may be found in an increased amount in the blood of men who have prostate cancer. PSA levels may also be high in men who have an infection or inflammation of the prostate or BPH.

### *Transrectal ultrasound*

Transrectal ultrasound is a procedure in which a probe that is about the size of a finger is inserted into the rectum to check the prostate. The probe is used to bounce high-energy sound waves (ultrasound) off internal tissues or organs and make echoes. The echoes form a picture of body tissues called a sonogram. Transrectal ultrasound may be used during a biopsy procedure.

## Treatments for prostate cancer

Current treatments for prostate cancer include “watchful waiting” for very slow growing cancers or cancers in men over 75, active surveillance for newly diagnosed or early stage cancers, radiation therapy, hormone therapy to block hormones that contribute to the growth of prostate cancer, and surgery. The American Cancer Society, as well as the U.S. Preventive Services Task Force (USPSTF), acknowledges that treatment for prostate cancer can cause moderate to substantial harms, including erectile dysfunction, urinary incontinence, bowel dysfunction, and death.<sup>11</sup> A number of new treatment options are currently in clinical trials.<sup>12</sup>

## Prostate cancer screening recommendations

The goal of early detection is to reduce the overall morbidity and mortality of prostate cancer. The ERSPC trial demonstrated that screening decreases the risk of being diagnosed with metastatic prostate cancer and that screening is associated with a modest 20 percent reduction in prostate cancer deaths, albeit at a cost of overdiagnosis and overtreatment.<sup>13</sup> However, there is no agreement as to what constitutes a clinically significant or insignificant prostate cancer. Over-detection or over-diagnosis refers to the ability of a screening test to identify a condition that would have remained silent and caused a patient no morbidity during his lifetime. While the risks of prostate cancer treatment may be acceptable to men who have aggressive, late-stage cancers, they are much less acceptable to men who have slow growing tumors that are

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<sup>9</sup> *Ibid.*

<sup>10</sup> American Urological Association. 2009. AUA New Guidelines on Prostate Cancer Screening. Available at: <http://www.psa-rising.com/mednews/component/content/article/38-screening/78-uaa-new-guidelines-on-prca-screening>. Accessed on December 14, 2010.

<sup>11</sup> Smith R, Cokkinides V, Brawley O. 2009. Cancer screening in the United States, 2009, A review of current American Cancer Society guidelines and issues in cancer screening. *CA Cancer J Clin* 59;27-41.

<sup>12</sup> U.S. National Institutes of Health, National Cancer Institute. 2010. Prostate Cancer. Available at: <http://www.cancer.gov/cancertopics/types/prostate>. Accessed on December 14, 2010.

<sup>13</sup> American Urological Association. 2009. AUA New Guidelines on Prostate Cancer Screening. Available at: <http://www.psa-rising.com/mednews/component/content/article/38-screening/78-uaa-new-guidelines-on-prca-screening>. Accessed on December 14, 2010.

unlikely to progress to clinical significance.<sup>14</sup>

**American Cancer Society.** The American Cancer Society (ACS) currently recommends that doctors discuss the potential benefits and limitations of prostate cancer early detection testing with men and that they offer PSA and DRE examination annually beginning at age 50 to men who are at average risk of prostate cancer and have a life expectancy of at least 10 years. Men at high risk of prostate cancer (African American men or men who have a close relative diagnosed with prostate cancer before age 65) should be offered testing at age 45. Men at very high risk of prostate cancer because they have several relatives diagnosed with prostate cancer at an early age should be offered the test at age 40. The ACS recommends joint decision-making between the patient and physician as to whether to undergo prostate cancer screening.<sup>15</sup>

**U.S. Preventive Services Task Force.** The USPSTF found that, while PSA testing can detect some cases of prostate cancer, there is inadequate evidence to determine whether treatment for prostate cancer detected by screening improves health outcomes compared with treatment after clinical detection. According to the USPSTF, a substantial proportion of prostate cancer cases detected with current screening methods will never cause symptoms during the patients' lifetime. USPSTF also suggests that over-diagnosis rates range from 29 percent to 44 percent of all prostate cancer cases detected by PSA screening.<sup>16</sup> Because these patients receive no benefit from, and may be harmed by, prostate cancer screening and treatment, prostate cancer detection in this population constitutes an important burden. USPSTF recommends that clinicians discuss with the patient the potential but uncertain benefits and the known harms of prostate cancer screening and treatment. The potential harms of treatment are discussed above. The potential harms of screening are the psychological harm of false-positive results and the discomfort and inconvenience of prostate biopsy.

The USPSTF makes no PSA screening recommendation for men younger than 75 and suggests that a screening interval of every 4 years is as beneficial as annual screening.

For men age 75 or older and men with a life expectancy of less than 10 years, it recommends that no PSA screening be performed. Most prostate cancers develop slowly and the likelihood is that men in this group who actually have early-stage prostate cancer will die of other causes before their prostate cancer reaches a life-threatening stage.

**American Urological Association.** The American Urological Association (AUA) acknowledges that the use of PSA testing for the early detection of prostate cancer remains controversial, owing to the biological variability and high prevalence of prostate cancer, and the strong evidence for its over-diagnosis and over-treatment. The AUA advises that the PSA test should be offered as a baseline test to well-informed men aged 40 years or older who have a life expectancy of at least 10 years.<sup>17</sup> Men receiving the PSA test should also have a DRE. The AUA no longer specifies a minimum threshold value for PSA results in order to recommend a prostate biopsy for possible prostate cancer. The decision to proceed to prostate biopsy should be based primarily on PSA and Digital Rectal Examination (DRE) results, but should take into account multiple factors including free and total PSA, patient age, PSA velocity, PSA density, family history, ethnicity, prior biopsy history and co-morbidities. In lieu of recent studies which suggest that PSA testing leads to over-diagnosis of prostate cancer, the AUA strongly supports that men be informed of the risks and

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<sup>14</sup> *Ibid.*

<sup>15</sup> Smith R, Cokkinides V, Brawley O. 2009. Cancer screening in the United States, 2009, A review of current American Cancer Society guidelines and issues in cancer screening. *CA Cancer J Clin* 59;27-41.

<sup>16</sup> U.S. Preventive Services Task Force. 2008. Screening for Prostate Cancer: U.S. Preventive Services Task Force Recommendation Statement. *Ann. Int. Med.* 149(3);185.

<sup>17</sup> American Urological Association. 2009. AUA New Guidelines on Prostate Cancer Screening. Available at: <http://www.psa-rising.com/mednews/component/content/article/38-screening/78-uaa-new-guidelines-on-prca-screening>. Accessed on December 14, 2010.

benefits of prostate cancer screening before biopsy and the option of active surveillance in lieu of immediate treatment for certain men newly diagnosed with prostate cancer.

### 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 under search terms including: prostate cancer screening, costs, analysis and cost analysis, clinical trial, meta-analysis, randomized controlled trial, review, controlled clinical trial, evaluation studies, multicenter study, technical report, and twin study. The search excluded papers published before 2000.

Multiple publications exist on the Prostate, Lung, Colorectal and Ovarian (PLCO) and the European Randomized Study of Screening for Prostate Cancer (ERSPC). These two multi-site studies have published reports on outcomes at different sites, on their different facets and interim reports. This evaluation included only the most recent and most comprehensive reports.

The search returned 4 cost-effectiveness reports. One study used primary data, one was modeled on a randomized trial, one was a meta-analysis of PSA studies (1980-2001) and one literature review. Only one study took a broader perspective and included indirect or patient time costs in addition to medical treatment costs.

Resources searched include:

- PubMed
- Agency for Health Care Research and Quality Medical Expenditure Panel Survey (MEPS)
- U.S. Preventive Task Force
- Cochrane Reviews
- CDC SEER Cancer Statistics
- Prostate Cancer Foundation <http://www.pcf.org/site/c.leJRIRORepH/b.5699537/k.BEF4/Home.htm>
- Council for Affordable Health Insurance [http://www.cahi.org/cahi\\_contents/resources/](http://www.cahi.org/cahi_contents/resources/)

CPHHP staff conducted independent literature searches using the Cochrane Review, Pubmed, 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 Medicine and University of Connecticut School of Pharmacy on matters pertaining to medical standards of care, current and traditional 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, 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 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.***

For 2010, the Census projects there will be 467,779 men between the ages of 50 and 75 in Connecticut. Of these, about 376,122 have private health insurance.<sup>18</sup> These individuals represent the portion of the population most likely to utilize the services specified by this mandate based on current recommendations.

Recent results from a major clinical trial have raised questions about the usefulness of routine PSA testing.<sup>19</sup> Despite this, the American Cancer Society recommends that men at average risk be offered PSA screening for prostate cancer at 50, men at high risk at age 45 and men at very high risk at age 40.<sup>20</sup> The American Urological Association recommends that baseline PSA testing be done at age 40.<sup>21</sup> The U.S. Preventive Services Task Force makes no recommendation for routine PSA screening of men younger than 65 unless they are at risk of developing prostate cancer, and recommends stopping PSA testing at age 75 or when life expectancy is less than 10 years<sup>22</sup>. PSA testing protocols range from every year<sup>23</sup> to every 3 years.<sup>24</sup>

The extent to which individuals comply with these recommendations is variable. The IC data found 42 percent of men 50 and over in Connecticut receive a PSA test in a given year. The 2007 Medical Expenditure Panel Survey (MEPS) also tracks men who receive PSA tests.<sup>25</sup> MEPS data for men aged 50-75 living in the northeast with private health insurance is as follows: 75 percent reported having a PSA test within the past 3 years, 4 percent with within the past four years or more and 22 percent had never had a PSA test. The numbers were slightly higher for African-American men who appear to be at slightly higher risk of dying from prostate cancer. Among African-American men, 80 percent had a PSA test within the past three years, 2 percent within four years or more and 18 percent had never had a PSA test.

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<sup>18</sup> US Census Bureau. Current Population Survey. Available at: [http://www.census.gov/hhes/www/cpstc/cps\\_table\\_creator.html](http://www.census.gov/hhes/www/cpstc/cps_table_creator.html). Accessed on Sept. 1, 2010.

<sup>19</sup> Andriole GL, Crawford ED, Grubb RL, et al. 2009. Mortality Results from a Randomized Prostate-Cancer Screening Trial. *New England Journal of Medicine* 360(13): 1310 – 1319.

<sup>20</sup> American Cancer Society. Cancer Screening Guidelines. Available at: <http://www.cancer.org/Healthy/FindCancerEarly/CancerScreeningGuidelines/american-cancer-society-guidelines-for-the-early-detection-of-cancer> Accessed on Sept. 1, 2010.

<sup>21</sup> U.S. Preventive Services Task Force. 2008. Screening for Prostate Cancer: U.S. Preventive Services Task Force Recommendation Statement. *Annals of Internal Medicine* 149 (3): 185-191.

<sup>22</sup> American Urological Association. 2009. Prostate-Specific Antigen Best Practice Statement: 2009 Update. Available at: <http://www.auanet.org/content/guidelines-and-quality-care/clinical-guidelines/main-reports/psa09.pdf>. Accessed on March 15, 2010.

<sup>23</sup> Andriole GL, Crawford ED, Grubb RL, et al. 2009. Mortality Results from a Randomized Prostate-Cancer Screening Trial. *New England Journal of Medicine* 360(13): 1310 – 1319.

<sup>24</sup> Schroder FH, Hugosson J, Roobol MJ et al. 2009. Screening and Prostate-Cancer Mortality in a Randomized European Study. *New England Journal of Medicine* 360(13): 1320-1328.

<sup>25</sup> AHRQ. 2007. Medical Expenditure Panel Survey Household Survey. Available at: <http://www.meps.ahrq.gov/mepsweb/>. Accessed on Sept. 2, 2010.

***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***

Individuals who are over 65 years of age or who have a qualifying disability for two years or more are eligible for Medicare. For this population, Medicare covers prostate cancer screening tests and procedures for all men age 50 and over once every twelve months.<sup>26</sup> This coverage includes digital rectal exams, for which the patient must pay 20 percent of the Medicare-approved amount, and a Prostate Specific Antigen (PSA) test, for which there is no coinsurance or Part B deductible.

### ***Medicaid***

Medicaid covers prostate cancer screening tests and procedures, including the digital rectal exam and the PSA test.<sup>27</sup> Medicaid only covers the cost of the digital rectal exam as part of an office visit; there is no separate reimbursement for the digital rectal exam.<sup>28</sup> Currently, Connecticut's SAGA program is in the process of integrating with Medicaid based on the new Patient Protection and Affordable Care Act. This change is retroactive to April 1, 2010. Consequently, SAGA coverage can be considered identical to Medicaid coverage for the purposes of this report.

### ***Public Programs Administered by Charities***

In Connecticut, several hospitals offer free prostate cancer screening clinics as part of their community outreach programs. To name but a few, Milford Hospital, Charlotte Hungerford Hospital, and St. Raphael's Hospital have offered free prostate screening clinics. In some cases, pre-registration is required.

### ***Public Programs Administered by Public Schools***

No information was found that would indicate public schools would be a source of screening for prostate cancer or funding for prostate cancer screening for employees.

### ***The Department of Public Health (DPH)***

No information was found regarding the availability of prostate cancer screening or funding for prostate cancer screening through the Connecticut Department of Public Health.

### ***Municipal Health Departments***

No information was found regarding the availability of prostate cancer screening or funding prostate cancer screening through local and municipal health departments in Connecticut.

***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 has required coverage for prostate cancer screening in group and individual health insurance plans since 2000.<sup>29</sup> All of the seven insurers domiciled in Connecticut, covering 90 percent of the population in fully-insured group and individual policies in Connecticut (1.25 million persons), cover these mandated services. In addition, 95 percent of members in the self-funded plans that were reported included

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<sup>26</sup> Medicare Coverage Guidelines for Prostate Cancer Screening (State of Connecticut)

<sup>27</sup> Connecticut DSS Provider Laboratory Fee Schedule, Codes 84152-84154

<sup>28</sup> Personal correspondence with Nina Holmes, DSS Medical Policy Unit, 4/16/2010

<sup>29</sup> CONNECTICUT GENERAL STATUTES ANNOTATED § 38A-492H (individual insurance policies); § 38A-518H (group insurance policies).

coverage for PSA screening.

**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.**

This mandate has been in effect since January 1, 2000. As such, fully insured private health insurance plans must cover prostate cancer screening for men who are symptomatic, have a family history of prostate cancer or over 50 years old.

Connecticut’s public insurance programs also cover prostate cancer screening. In many instances, early detection improves cancer outcomes and potentially reduces treatment costs. For this reason, many insurers not only cover screenings and preventives services, but they encourage it through wellness and other programs. Several Connecticut hospitals offer free prostate cancer screening clinics periodically.

For those without coverage, the cost of prostate screening is low. The Ingenix Consulting analysis reports an average paid cost per patient was \$31 for a PSA test among the group insurance plans and \$21 among individually insured plans. No cost was reported for trans-rectal ultrasonography (TRUS) or digital rectal exam (DRE). In some instances, the DRE is included in the cost of the annual patient physical exam.

There may be other reasons individuals do not access this care. For instance, those without a usual source of care were more likely to never get screened. Ongoing physician-patient relationships can be important in meeting routine care guidelines. Otherwise, an individual may only seek care when they are sick. Reviewing data from MEPS, as many as 22 percent of men aged 50-75 with private insurance have never had a PSA test.<sup>30</sup>

**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 average cost of a PSA test is \$31 according to the Ingenix analysis. The table below illustrates the percentage of family income needed to cover the cost of treatment for different income levels and different levels of cost sharing. Families with incomes of \$50,000 with no insurance would pay 0.06 percent of their income to get a PSA test. With a 10 percent co-payment, families in these three categories would pay no more than 0.01 percent of their family income for a PSA test.

	BENEFIT ►					
INCOME ▼		Member Share 10%	Member Share 20%	Member Share 30%	HD Plan	Uninsured
	50,000	0.01%	0.01%	0.02%	0.06%	0.06%
	80,000	0.00%	0.01%	0.01%	0.04%	0.04%
	160,000	0.00%	0.00%	0.01%	0.02%	0.02%

While the cost of an initial screening is low, there may be costs that flow from this test that create more of a burden. Follow-up treatment may include repeated testing, trans-rectal ultrasonography (TRUS), and/or biopsy. These follow-up tests can confirm the presence of cancer and help determine the most appropriate treatment path. These are not screening costs; however they add to the cost of the mandate.

<sup>30</sup> AHRQ. 2007. Medical Expenditure Panel Survey Household Survey. Available at: <http://www.meps.ahrq.gov/mepsweb/>. Accessed on Sept. 2, 2010.

When PSA levels are suspicious or the presence of prostate cancer is confirmed, men have two choices: they may pursue follow-up treatment or, in the case of indolent or low-risk cancers, they may choose watchful waiting or active surveillance with hormone treatment. Some men, when learning that they have prostate cancer, will choose the more radical surgical approach, prostatectomy or radiation or both, rather than watchful waiting or active surveillance. These treatment options are not without potential side effects. Both biopsies and surgeries can cause urinary and erectile problems.

**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 Urological Association recommends that all men over the age of 40 have a baseline PSA screening. The American Cancer Society recommends that men over the age of 50 be offered a PSA screening test. Both groups recommend earlier screening for men at risk of developing prostate cancer based on ethnic or family risk factors or prior history of prostate cancer. Ingenix Consulting found that 42 percent of fully-insured men in Connecticut receive a PSA test in any given year.

For PSA testing, one survey of 137 men, aged 40-50, reported a willingness-to-pay for PSA testing of \$22.<sup>31</sup> Willingness-to-pay is the maximum amount an individual theoretically would be willing to exchange for a good. Economists measure it through survey techniques rather than observing markets. This study informed some subjects that PSA testing could lead to over-detection and overtreatment and other subjects the test basics only. There was no difference in willingness-to-pay between the two groups. This finding suggests that men may want PSA testing despite the controversy surrounding its use. Men derive value and reassurance from knowing their results.

**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 2005 survey found that people with private insurance were more likely than people insured through Medicaid to undergo cancer screening tests, including PSA screening, but both groups were much more likely to be screened than people who were uninsured at the time of the survey.<sup>32</sup>

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

According to the Council for Affordable Health Insurance, 36 states have prostate screening mandates.<sup>33</sup> Prostate screening is among the top 15 most common health insurance benefit mandates among the states. Of the New England states, only Vermont does not have a prostate screening mandate. Three other states conducted cost analyses on the mandate as shown below.

The Massachusetts Division of Health Care Finance and Policy analyzed the cost and impact of proposed legislation to mandate prostate cancer screening in the state (including PSA and DRE testing).<sup>34</sup> The Report estimated the expected increase in health care costs to be \$0.10-\$0.40 per member per year.<sup>35</sup>

<sup>31</sup> Yasunga, H Ide H, Imamura T et al. 2006. Benefit Evaluation of Mass Screening for Prostate Cancer: Willingness-to-Pay Measurement Using Contingent Valuation. *Urology* 68: 1046-1050. \$2006 converted using US Medical CPI.

<sup>32</sup> U.S. National Institutes of Health, National Cancer Institute. 2008. *J Natl Cancer Inst* 100(11):772.

<sup>33</sup> Council for Affordable Health Insurance (CAHI). 2009. Health Insurance Mandates in the States 2009. Available at: [http://www.cahi.org/cahi\\_contents/resources/pdf/HealthInsuranceMandates2009.pdf](http://www.cahi.org/cahi_contents/resources/pdf/HealthInsuranceMandates2009.pdf). Accessed on Aug 15, 2010.

<sup>34</sup> Comprehensive Review of Mandated Benefits in Massachusetts. Division of Health Care Finance and Policy. August 9, 2004. <http://www.mass.gov/Eeohhs2/docs/dhcfp/r/pubs/mandates/prostate.pdf>

<sup>35</sup> *Ibid.*, p. 3

The Maryland Health Care Commission (MHCC) conducted a review of the impact of Maryland’s prostate cancer screening mandate<sup>36</sup>, which requires coverage of prostate cancer screening for men between ages 40-75, or who are considered high-risk. The Report concluded that the full cost of the mandate amounts to 0.3 percent of the premium for groups, and 0.4 percent for individuals.<sup>37</sup> Additionally, the Report concluded that “almost all” insurers in the self-funded market were in compliance with the mandate.<sup>38</sup>

Maine, which mandates annual coverage of early detection prostate cancer screening for men between the ages of 50-72,<sup>39</sup> published a report on the “Cumulative Impact of Mandates in Maine.”<sup>40</sup> The Report concluded that, “No increase in premiums should be expected for the HMOs that provide the [prostate cancer] screening benefits currently as part of their routine physical exam benefits. Their report estimated additional claims cost for non-HMO plans would approximate \$0.10 per member per month. With the inclusion of administrative expenses, we would expect a total cost of approximately \$0.11 per member per month, or about 0.07 percent of total premiums.”<sup>41</sup>

These cost estimates are in keeping with the estimate of \$0.19 per member per month premium increase in Connecticut. In each case, the prostate cancer screening mandate by itself is a relatively affordable mandate. The cumulative cost of all mandates may be less affordable.

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

Our review did not find any studies on the mandate’s social impact by any Connecticut state agencies or appropriate public organizations.

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

Currently, screening is the most important method to detect prostate cancer. PSA blood tests and physical exams (DRE) are the two main screening methods. Changes in PSA levels track many prostate changes; including benign conditions and indolent cancers as well as more serious cancers that require treatment. DRE tends to detect only more advanced cancers, which may be less amenable to treatment. Prevention and targeted screening strategies may offer alternatives to population-based screening, but there is no consensus on their effectiveness.

Androgen deprivation therapy (ADT) with androgen-antagonists such as finasteride<sup>42</sup> or dutasteride<sup>43</sup> may reduce the risk of moderate or low-grade prostate cancers. Studies found the number of aggressive cancers increased slightly with ADT.<sup>44, 45</sup> Used most commonly to treat benign prostatic hyperplasia, these drugs

<sup>36</sup> MD. CODE ANN., INS. § 15-825

<sup>37</sup> Maryland Health Care Commission. 2008. Study of Mandated Health Insurance Services: A Comparative Evaluation. [http://mhcc.maryland.gov/health\\_insurance/mandated\\_1207.pdf](http://mhcc.maryland.gov/health_insurance/mandated_1207.pdf). p. 3

<sup>38</sup> *Ibid.*, p. 8

<sup>39</sup> ME. REV. STAT. ANN. tit. 24 § 2323-C; tit. 24-A §§ 2745-E; 2837-F; 4243

<sup>40</sup> “Cumulative Impact of Mandates in Maine.” December, 2009. Maine Department of Professional and Financial Regulation, Bureau of Insurance.

<sup>41</sup> *Ibid.*, p. 3

<sup>42</sup> Kaplan SA, Roehrborn CG, Meehan AG, et al. 2009: PCPT: Evidence that finasteride reduces risk of most frequently detected intermediate- and high-grade (Gleason score 6 and 7) cancer. *Urology* 73 (5): 935-9.

<sup>43</sup> Andriole GL, Bostwick DG, Brawley OW, et al. 2010: Effect of dutasteride on the risk of prostate cancer. *New England Journal of Medicine* 362 (13): 1192-202.

<sup>44</sup> Kaplan SA, Roehrborn CG, Meehan AG, et al. 2009.

<sup>45</sup> Andriole GL, Bostwick DG, Brawley OW, et al. 2010

have significant sexual side-effects and are not recommended for broad-based prevention strategies. Investigators have assessed dietary changes with inconclusive results. Small and in vitro studies suggest that diets low in fat and rich in lycopene, isoflavonoids, vitamin E and selenium may reduce the risk of prostate cancer.<sup>46, 47, 48, 49, 50</sup> The effect of these strategies on the general population has yet to be consistently established.<sup>51</sup> For instance, the SELECT trial, a well-funded, broad-based, long-term study of vitamin E and selenium intake failed to confirm the in vitro findings.<sup>52</sup> Consequently, the existing science does not provide solid evidence for prevention as an alternative to screening.

Screening more selectively may improve the effectiveness of prostate cancer screening. For instance, the U.S. Preventative Task Force recently recommended reduced screening in the general population by increasing the screening age (to 50) and reducing screening frequency (annual to biennial).<sup>53</sup> As science progresses, it may be possible to better identify a population that will benefit from screening. For instance, one cost-effectiveness study recommended personalized screening intervals based on baseline PSA values rather than broad-based and routine screening.<sup>54</sup>

**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 prostate cancer screening fulfills a medical need that might not otherwise be met. Health insurers and managed care organizations increasingly emphasize prevention and wellness strategies. Under the assumption that an ounce of prevention is worth a pound of cure, health insurance organizations hope to avoid or minimize long term health expenditures. In the case of population-based prostate cancer screening, the cost-savings have yet to be demonstrated.

**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 prostate cancer screening mandate is similar to other screening mandates for cancer or other conditions. Based on current state health insurance mandates, there is demand for a variety of screening mandates. In Connecticut, we have mandates that address colorectal cancer screening, mammography and cervical cancer screening.<sup>55</sup> In addition, 7 other states have mandates addressing ovarian cancer screening. Outside of Connecticut, 9 states have screening mandates for AIDS/HIV and 16 states have screening mandates for

<sup>46</sup> Duffield-Lillico AJ, Dalkin BL, Reid ME, et al., 2003. Nutritional Prevention of Cancer Study Group. Selenium Supplementation, Baseline Plasma Selenium Status and Incidence of Prostate Cancer. *British Journal of Urology International* 2003;91(7):608-612.

<sup>47</sup> Heinonen OP, Albanes D, Virtmo J, et al. 1998. Prostate Cancer and Supplementation with Alpha-tocopherol and Beta-carotene. *Journal of the National Cancer Institute* 90(6): 440-446.

<sup>48</sup> Kristal AR, Arnold KB, Neuhauser ML, et al. 2010. Diet, Supplement Use, and Prostate Cancer Risk. *American Journal of Epidemiology* 172(5): 566-77.

<sup>49</sup> Vaishampayan U, Hussain M, Banerjee M, et al. 2007. Lycopene and Soy Isoflavones in the Treatment of Prostate Cancer. *Nutrition and Cancer* 59(1): 1-7.

<sup>50</sup> Kunkel EJS, Meyer B, Daskalakis C et al. 2004. Behaviors Used by Men to Protect Themselves Against Prostate Cancer. *Cancer, Epidemiology, Biomarkers and Prevention* 13: 78-86.

<sup>51</sup> National Cancer Institute. 2010. Prostate Cancer – Opportunities for Prevention. Available at: <http://www.cancer.gov/cancertopics/pdq/prevention/prostate/HealthProfessional/page4#Reference4.6> Accessed on Sept 15, 2010.

<sup>52</sup> Lippman SM, Klein EA, Goodman PJ et al. 2009. Effect of Selenium and Vitamin E on the Risk of Prostate Cancer and other Cancers. *Journal of the American Medical Association* 301(1): 39-51.

<sup>53</sup> U.S. Preventive Services Task Force. 2009. Screening for Breast Cancer Recommendations Statement. Available at: <http://www.uspreventiveservicestaskforce.org/uspstf09/breastcancer/brcanrs.htm>. Accessed on Sept 20, 2010.

<sup>54</sup> Kobayashi T, Goto R, Ito K, et al. 2007. Prostate Cancer Screening Strategies with Re-Screening Interval Determined by Individual Baseline Prostate-Specific Antigen Values Are Cost-Effective. *European Journal of Surgical Oncology* 33: 783-789.

<sup>55</sup> Council for Affordable Health Care (CAHI). 2009. Health Insurance Mandates in the States. Available at: [http://www.cahi.org/cahi\\_contents/resources/pdf/HealthInsuranceMandates2009.pdf](http://www.cahi.org/cahi_contents/resources/pdf/HealthInsuranceMandates2009.pdf). Accessed on Sept 26, 2010.

bone mass screening.<sup>56</sup> The prostate cancer screening mandate creates a precedent for other types screening mandates; including those implemented in other states.

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

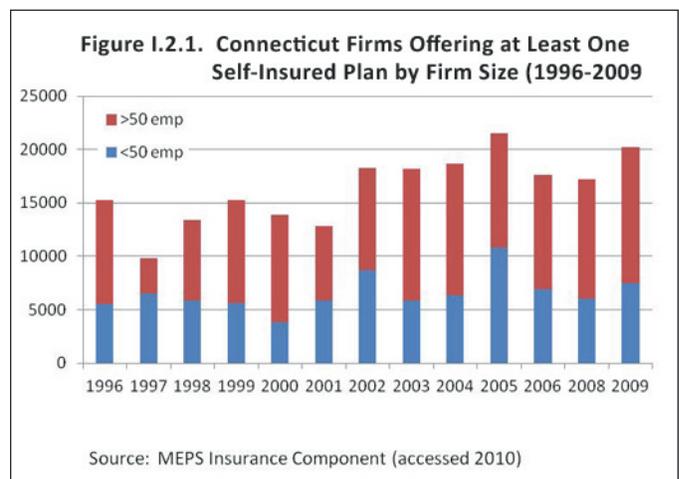
In general, insurance companies offer richer benefits to the extent that doing so maximizes revenue. Richer benefit plans may be more attractive to portions of the market while other market sectors may opt to purchase insurance based on lower prices or premiums. In the first sector, increasing benefits will increase demand for insurance and, therefore increase revenues. In the other sector, increasing premiums decreases the demand for insurance and insurers must trade-off rising revenues from increased premiums with falling revenues from decreased demand. The rate of this trade-off is determined by how sensitive consumers (individuals or companies) are to price, known as price elasticity.

Insurers use several methods to attract consumers who are most interested in lower premiums. Individuals may pay a larger portion of the health care cost through higher deductibles or co-payments. Insurers may use utilization review and pre-authorization protocols to decrease the use of unnecessary care. In smaller groups, individually written plans and high-deductible plans, insurers may reduce coverage for other types of care. Typically, essential or preventive services remain covered by plans that may carve out high cost services. The rising popularity of high-deductible, basic benefit plans indicates that there is a demand for less comprehensive plans. The extent to which mandating prostate cancer screening coverage engenders this behavior is unknown.

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

Connecticut firms, particularly firms with more than 50 employees, have increasingly offered at least one self-funded plan to their employees over the past 10 years (see figure below).<sup>57</sup> In 1999, 8.4 percent of firms with less than 50 employees and 55.2 percent of firms more than 50 employees offered at least one self-funded plan. In 2009, this percent changed to 12.6 percent and 60.4 percent respectively. For all firms, there was no significant (p=0.48) change in the percent of self-funded firms. It seems unlikely that this mandate alone has caused firms to self-fund, but the cumulative cost of multiple mandates may underlie the shift toward self-funding.

Figure I.2.1. Connecticut Firms Offering at Least One Self-insured Plan by Firm Size (1996-2009) Five Connecticut carriers provided data on their self-funded plans for this mandate, representing 47 percent of the Connecticut population covered by the self-funded plans. For these five carriers, 95 percent of members in their self-funded plans have benefits at least equal to this mandate.



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

<sup>56</sup> Council for Affordable Health Care (CAHI). 2009. Health Insurance Mandates in the States. Available at: [http://www.cahi.org/cahi\\_contents/resources/pdf/HealthInsuranceMandates2009.pdf](http://www.cahi.org/cahi_contents/resources/pdf/HealthInsuranceMandates2009.pdf). Accessed on Sept 26, 2010.  
<sup>57</sup> MEPS Insurance Component [http://www.meps.ahrq.gov/mepsweb/survey\\_comp/Insurance.jsp](http://www.meps.ahrq.gov/mepsweb/survey_comp/Insurance.jsp) Accessed on August 1, 2010.

Because the State plans were fully insured in 2007 and 2008, the claims data from the carriers and the cost projections which 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 medical cost for this mandate in 2010 is estimated to be \$374,682. 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.)<sup>58</sup>

**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.).

***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.***

This study found no available evidence suggesting that screening was unsafe. However, biopsy and subsequent treatment does have potential side effects, some serious. Men may experience urinary problems (23-48 percent), bowel problems (5-14 percent) and sexual problems (40-74 percent) 5-10 years after treatment.<sup>59</sup>

## **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 prostate screening mandate has been in effect since 2000. One meta-analysis reported that the price of PSA testing in cost analyses fell about \$26 between 1993 and 2002.<sup>60</sup> During this period, PSA testing became widespread; increasing the efficiency and lowering the price of providing the test. It is unclear how much more the unit cost of PSA tests can continue to fall 10 years later. As Connecticut's population ages, the number of men aged 50-75 may increase resulting in higher overall costs even if the per unit test costs remain unchanged. For further information, please see the Ingenix Consulting Actuarial and Economic Report.

***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 results of the ERSPC trial estimated that over-treatment occurred in 27-56 percent of the cases found. Another study reported over-treatment rates up to 84 percent.<sup>61</sup>

***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.***

<sup>58</sup> Conversation with Scott Anderson, State Comptroller's office, September 14, 2010

<sup>59</sup> Heijnsdijk EAM, der Kinderen A, Wever, EM et al. 2009. Overdetection, Overtreatment and Costs in Prostate-Specific Antigen Screening for Prostate Cancer. *British Journal of Cancer* 101: 1833-1838.

<sup>60</sup> Ekwueme DU, Stroud LA, Chen Y. 2007. Cost Analysis of Screening for, Diagnosing and Staging Prostate Cancer Based on a Systematic Review of Published Studies. *Preventing Chronic Disease* 4(4): 1-17.

<sup>61</sup> Sennfält K, Sandblom G, Carlsson P et al. 2004. Costs and Effects of Prostate Cancer Screening in Sweden. *Scandinavian Journal of Urology and Nephrology* 38; 291-298.

The American Cancer Society recommends offering prostate cancer screening to the populations identified in the legislation. Screening can lead to early detection of prostate cancer, which may or may not lead to less expensive treatment. However, prostate cancer treatment has risks as well, and many prostate cancers are slow-growing and unlikely to become clinically significant before the patient dies of other causes. PSA screening cannot currently discriminate among the various forms of prostate cancer. Positive screenings which result in treatment of an “indolent” cancer can increase costs.

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

The legislation does not prohibit insurers and MCOs from employing utilization management, prior authorization, or other utilization tools at their discretion. Cancer screening guidelines from organizations like the U.S. Preventive Task Force<sup>62</sup> and the American Cancer Society<sup>63</sup> encourage personal choice over routine screens. To contain costs, insurers may try to encourage ‘watchful waiting’ treatment instead of radical prostatectomy for low-grade cancers rather than limit screening itself.

***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 medical cost of the mandate is spread to all insureds in group plans, medical costs are estimated to be \$0.19 PMPM and retention costs are estimated to be \$0.04 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$0.23 PMPM in 2010, which is 0.1 percent of premium.

**Individual policies:** When the medical cost of the mandate is spread to all insureds in individual policies, medical costs are estimated to be \$0.11 PMPM and retention costs are estimated to be \$0.03 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$0.14 PMPM in 2010, which is 0.1 percent of premium.

It is unclear how much of this cost would be covered by employers and insurance carriers even without the mandate since it is included in nearly all self-funded plans in Connecticut.

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

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<sup>62</sup> U.S. Preventive Services Task Force. 2008. Screening for Prostate Cancer: U.S. Preventive Services Task Force Recommendation Statement. *Annals of Internal Medicine* 149 (3): 185-191.

<sup>63</sup> American Cancer Society. 2010. American Cancer Society Guidelines for the Early Detection of Cancer. Available at: <http://www.cancer.org/Healthy/FindCancerEarly/CancerScreeningGuidelines/american-cancer-society-guidelines-for-the-early-detection-of-cancer>. Accessed on Sept. 26, 2010.

**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.***

As discussed in Section IV, Question 10, there are currently no alternatives to prostate cancer screening in order to detect prostate cancer. The two main screening methods, PSA blood tests and physical exams (DRE), are low cost but both have short-comings. PSA tests are very sensitive to changes in the prostate but do not specifically detect cancer. DRE exams are not particularly sensitive to small changes in the prostate, but are more likely to find advanced cancer.

Several attempts have been made to modify the PSA test to make it more specific to finding cancer as opposed to other conditions like benign prostate hyperplasia (BPH). Lower levels of free (as opposed to complex) PSA are associated with prostate cancer compared to BPH.<sup>64</sup> The ERSPC trial used multiple cut-off values from 2.5, 3.0, and 4.0 ng/ml to refer men for additional testing or biopsy. Many physicians use ‘PSA velocity’, or the rate of increase in PSA levels over time, to assess prostate cancer risks. One study found that up to 21 percent of PSA values over 4.0 ng/ml, a standard cut-off level, return to normal over time.<sup>65</sup> However, differences in laboratory techniques can lead to a difference in PSA levels of up to 25 percent on a given test.<sup>66</sup> These alternatives provide supplementary data and uses rather than replacements for the standard tests listed above.

**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. Actuarial analysis of claims data received from insurers/MCOs in Connecticut shows an expected impact in 2010 of \$3,549,247 for prostate screening for Connecticut residents covered by fully-insured group and individual health insurance plans.

Economic benefits of the mandate may accrue to employers in terms of worker productivity. The economic benefits to business of employees with prostate cancer returning to work or on-the-job productivity may offset or be higher than the costs of cancer screening 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 section 38a-564 of the general statutes, and for employers other than small employers.***

This mandate costs about \$0.19 per member per month. 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, not mandated, may be dropped. Alternatively, firms may increase employee cost-sharing at

<sup>64</sup> Catalona WJ, Partin AW Slawin KM et. al. 1998. Use of the Percentage of Free Prostate-Specific Antigen to Enhance Differentiation of Prostate Cancer from Benign Prostatic Diseases. *Journal of the American Medical Association* 279: 1542-1547.

<sup>65</sup> Eastham JA, Riedel E, Scardino PT et. al. 2003. Variation of Serum Prostate-Specific Antigen Levels. *Journal of the American Medical Association* 289: 2695-2700.

<sup>66</sup> Slev PR, La’ulu SL Roberts WL. 2008. Intermethod Differences in Results for Total PSA, Free PSA and Percentage of Free PSA. *American Journal of Clinical Pathology* 129: 952-958.

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 businesses tend to be more sensitive to price changes than large businesses. Also, small businesses 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. Any increase in mandates constitutes a higher percentage rise for small business compared to large businesses. While this particular benefit represents a minimal increase in premiums (<1 percent PMPM), the combined expense of all mandates may cause small businesses 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.***

At a cost of \$0.19 PMPM, this mandate is unlikely to affect a firm's or individual's decision to insure. The cumulative cost of all the mandates, however, may cause some firms or individuals to drop insurance. These individuals may be eligible for state health insurance programs if their income meets program guidelines. For instance, families with children are eligible for HUSKY A insurance if family income is no more than 185 percent of the federal poverty line. People who meet these criteria may move from private to public insurance and, consequently, increase public health insurance expenses.

The Ingenix Consulting report estimates the impact of this mandate on the overall cost of the health care delivery system in the state to be \$4,173,989. This includes the medical cost included in premiums and cost sharing by insured individuals.

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-insured.

# Volume I

## Chapter 3

### Ostomy-Related Supplies

Review and Evaluation of Connecticut Statute  
Chapter 700, § 38a-518j and § a-492j

Mandatory Coverage for Ostomy-Related Supplies

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## 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 group and individual health insurance policies. The review was conducted following the requirements stipulated under Public Act 09-179. This review is 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-518j and 38a-492j state that each group and individual health insurance policy...

...that provides coverage for ostomy surgery shall include coverage, up to one thousand dollars annually, for medically necessary appliances and supplies relating to an ostomy including, but not limited to, collection devices, irrigation equipment and supplies, skin barriers and skin protectors. As used in this section, «ostomy» includes colostomy, ileostomy and urostomy. Payments under this section shall not be applied to any policy maximums for durable medical equipment. Nothing in this section shall be deemed to decrease policy benefits in excess of the limits in this section.

In March 2010, CPHHP and Ingenix Consulting (IC) requested and received ostomy claims data for 2007 and 2008 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).

### *Current coverage*

This mandate went into effect on October 1, 2000 (P.A. 00-63). Many group plans do not limit coverage to mandated benefit levels.

### *Premium impact*

**Group plans:** On a 2010 basis, medical cost is estimated to be \$0.06 per member per month (PMPM).<sup>67</sup> Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services in 2010 in group plans is \$0.07 PMPM, which is 0.02 percent of estimated total costs in group plans. Estimated cost sharing in 2010 in group plans is \$0.01 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 \$0.02 PMPM. Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services in 2010 in individual policies is \$0.03 PMPM, which is approximately 0.01 percent of estimated total costs in individual policies. Estimated cost sharing in 2010 in individual policies is \$0.00 PMPM. Individual policies data is less credible than group plans data primarily due to small sample sizes.

### *Self-funded plans*

Five insurers/MCOs domiciled in Connecticut provided information about their self-funded plans, which

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<sup>67</sup> Because some plans include coverage for ostomy supplies above the mandated level, the cost of the mandated benefit is lower than total claims costs for ostomy supplies. The cost of ostomy supplies at the mandated level (up to \$1000 annually) is \$0.04 PMPM.

represents an estimated 47 percent of the total population in self-funded plans in Connecticut. These five insurers/MCOs report that 46 percent of members in self-funded plans have coverage for the 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

An ostomy refers to a surgically created opening in the body that allows for the discharge of bodily wastes. The most common types of ostomies are colostomies, ileostomies, and urostomies. In a colostomy, a portion of the colon or the rectum is removed and the remaining colon is brought to the abdominal wall. In an ileostomy, a surgical opening is created in the small intestine, usually at the end of the ileum, and the intestine is brought to the abdominal wall. For colostomy and ileostomy, a stoma is formed when a portion of the colon or intestine protrudes through the abdominal wall.<sup>68</sup> Colostomies and ileostomies may be permanent or temporary, depending on the disease or injury that precipitated the ostomy surgery and the condition of remaining gastrointestinal tissues. For example, for cancer or diverticulitis, ostomy may be temporary; while in the case of inflammatory bowel disease and Crohn's disease, it is likely permanent since these are lifelong conditions. Ileostomies are rarely temporary; however, as many as 40 percent of colostomies are temporary and reversed after two to five months, often following a colon resection.<sup>69</sup>

Urostomy is a general term for a surgical procedure which diverts urine away from a diseased or defective bladder. Either a section at the end of the small bowel (ileum) or at the beginning of the large intestine (cecum) is surgically removed and relocated as a passageway (conduit) for urine to pass from the kidneys to the outside of the body through a stoma. A stoma is the actual end of the ureter or small or large bowel that can be seen protruding through the abdominal wall.<sup>70</sup> A urostomy is rarely temporary since the diseased bladder that necessitated both the surgery and the creation of the stoma is surgically removed.

Patients need ostomies following surgical removal of cancers and other diseases, due to birth defects, and as a result of injuries. A colostomy is indicated for cancer, diverticulitis, Hirschsprung's disease, imperforate anus, and trauma. An ileostomy or ileoanal reservoir is indicated for Crohn's disease, familial adenomatous polyposis, and ulcerative colitis. A urostomy is indicated for birth defects such as spina bifida, bladder cancer, malfunction of the bladder, and spinal cord injuries.

Studies reveal a fairly equal distribution between the major types of ostomy surgeries (colostomy, ileostomy, and urostomy).<sup>71</sup> In 2008, there were 9,662 discharges in U.S. hospitals with colostomy procedures noted as the principle procedure.<sup>72</sup> Forty-six percent of claims were paid by Medicare, 32 percent were paid by private insurance, and 15 percent were paid by Medicaid.<sup>73</sup> In 2008, there were 8,084 discharges in U.S. hospitals with ileostomy/enterostomy procedures noted as the principle procedure.<sup>74</sup> Forty-four percent of claims were paid by Medicare, 37 percent were paid by private insurance, and 13 percent were paid by

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<sup>68</sup> United Ostomy Associations of America. Available at: [www.uoaa.org](http://www.uoaa.org). Accessed on September 21, 2010.

<sup>69</sup> See Ingenix Consulting Actuarial and Economic Report. Appendix II, page 14.

<sup>70</sup> *Ibid.*

<sup>71</sup> Turnbull GB. 2003. Ostomy statistics: The \$64,000 question. *Ostomy Wound Management* 49(6). Available at: <http://www.o-wm.com/article/1756>. Accessed on September 21, 2010.

<sup>72</sup> United States Department of Health and Human Services. Agency for Healthcare Research and Quality. Healthcare Cost and Utilization Project (HCUP). Available at: <http://hcupnet.ahrq.gov/>. Accessed on September 21, 2010.

<sup>73</sup> *Ibid.*

<sup>74</sup> *Ibid.*

Medicaid.<sup>75</sup> (Note: Researchers were unable to locate urostomy estimates for the U.S.) An aging population may lead to an increase in the number of people with prostate, bladder, colorectal, and gynecologic cancers, diseases that can lead to ostomy surgery.

Ostomy appliances and supplies are required following surgery to collect and dispose of body waste, thus improving functioning and coping abilities of patients. Supplies also are required to keep the stoma healthy and functioning properly and the surrounding skin healthy. Typical supplies include a barrier (wafer) or faceplate, which acts as an interface between the patient's skin and the pouching system; pouches, for collecting stoma output (some are single use and some are designed to be emptied and re-used several times); pastes, which are used as a protective layer and sealant beneath ostomy appliances, and are applied directly on the skin; and various other supplies that allow proper use and hygiene including tapes, clamps, flanges, and absorbent materials. Irrigation equipment uses water to flush out the bodily waste collected in the ostomy. It is rarely used or prescribed currently.

Appliances and supplies allow ostomy patients to function at levels comparable to their healthy peers and enjoy a higher quality of life than would otherwise be experienced. Many people adapt well, although it is not uncommon for persons with ostomies to withdraw socially to some degree. Cost of supplies can be an obstacle to their proper use and inhibit functioning and quality of life. A study of veterans with ostomies found that those individuals who had difficulty paying for ostomy supplies scored lower on a quality of life questionnaire.<sup>76</sup> Research shows a correlation between distress over obtaining ostomy supplies and poor long-term adjustment.<sup>77</sup> Ostomy pouches can fall off when improperly attached or when the adhesive wears down, which often occurs as a result of extending use of supplies beyond their functional capacity.

The amount of supplies required varies with the type of ostomy. Persons with an ileostomy require the most frequent changes, while those with a colostomy require less frequent changes than those with an ileostomy or urostomy. It is possible that some people may require a relatively large number of supplies. For example, in severe cases of cancer requiring extensive surgery, such a person may have a colostomy or ileostomy and a urostomy and require ostomy supplies for both following the surgery.

### 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 under search terms including Ostomy, Ostomy/Statistics, Ostomy+Insurance, Ostomy/AND Equipment and Supplies, Ostomy AND Equipment Safety OR Consumer Product Safety.

Resources searched include:

- PubMed
- CINAHL
- SCOPUS
- Cochrane

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<sup>75</sup> *Ibid.*

<sup>76</sup> Coons SJ. 2007. Overall quality of life and difficulty paying for ostomy supplies in the Veterans Affairs ostomy health-related quality of life study: an exploratory analysis. *Medical Care* 45(9): 891-5.

<sup>77</sup> Haugen V, Bliss DZ, Savik K. 2006. Perioperative factors that affect long-term adjustment to an incontinent ostomy. *Journal of Wound, Ostomy and Continence Nursing* 33(5): 525-535.

- MarketResearch
- ICD-9 code — <http://icd9.chrisendres.com/ Procedure/Tabular>  
(V46.1 for Colostomy; V46.2 for Ileostomy; 56.2 for ureterostomy and 56.5 for ileal conduit.  
Note=urostomy is divided into ureterostomy and ileal conduit)
- HCUPnet — <http://hcupnet.ahrq.gov/>
- Health Care Common Procedure Coding System (HCPCS)
- Council for Affordable Health Insurance — [http://www.cahi.org/cahi\\_contents/resources/](http://www.cahi.org/cahi_contents/resources/)
- U.S. Government Accounting Office — <http://www.gao.gov/>
- Web Search Engines (Bing; Google)

CPHHP staff conducted independent literature searches using the Cochrane Review, Pubmed, Scopus, 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 Medicine on matters pertaining to medical standards of care; traditional, current and emerging practices; and evidence-based medicine related to the proposed 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 insurers/MCOs provided ostomy supplies claims data for their group and individual plan participants. Five insurers/MCOs also provided information about ostomy supplies coverage in the self-funded plans they administer.

CPHHP, CID, Ingenix Consulting, and the Connecticut Center for Economic Analysis (CCEA) at the University of Connecticut developed and administered a survey of insurance companies and MCOs domiciled in Connecticut in November 2009. Seven insurers/MCOs completed the survey, which included questions about benefit levels for ostomy supplies.

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

## IV. Social Impact

### ***1. The extent to which ostomy supplies are utilized by a significant portion of the population.***

The United Ostomy Associations of America estimates that slightly more than 500,000 Americans have some type of stoma.<sup>78</sup> Based on total population only, an estimated 5,758 people in Connecticut have some type of stoma.<sup>79</sup> This estimate includes persons enrolled in Medicare and Medicaid, as well as persons with private health insurance and the uninsured.

Ingenix Consulting actuarial analysis of a national sample of claims data provides an estimated prevalence of persons with an ostomy of 0.08 percent.<sup>80</sup> Applying this prevalence rate to Connecticut's insured population results in an estimate of 1,115 persons in fully-insured group or individual health insurance plans in Connecticut and with mandated coverage of \$1,000 annually for ostomy supplies.

For further information, please see Appendix II: Ingenix Consulting Actuarial and Economic Report, page 7-8.

### ***2. The extent to which ostomy supplies 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***<sup>81,82</sup>

Medicare covers ostomy supplies as durable medical equipment (DME) under Medicare Part B for patients who have a colostomy, ileostomy, or urinary ostomy. Medicare covers the amount of supplies as determined by the patient's physician, based on the patient's medical condition. There is no annual maximum benefit. Patients are responsible for a \$135 annual deductible and 20 percent co-payment of the Medicare-approved amounts (Medicare pays the remaining 80 percent). Medicare-approved amounts are determined annually as the maximum permissible cost reimbursement ("ceiling") per specific supply item, as well as the maximum quantity of the item that is covered in a given monthly or annual period. A prescription signed by the treating physician must be on file with the supplier, and the supplier must accept Medicare assignment and have a Medicare supplier number. The patient may also have Medicare gap insurance that covers all or part of the patient's deductible and co-payments.

#### ***Public Programs Administered by Charities***

The Crohn's and Colitis Foundation of America may have samples from manufacturers and distributors of ostomy supplies available for ostomates who are uninsured, experiencing financial difficulties, and for those whose insurance coverage for ostomy supplies has been exhausted. The American Cancer Society can be a resource for acquiring ostomy supplies at reduced prices or free of charge. The charities' resources are limited due to their own financial constraints and those of the suppliers and manufacturers.

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<sup>78</sup> United Ostomy Associations of America. Available at: <http://www.uoaa.org>.

<sup>79</sup> US Census. 2008 Population estimates for the USA and Connecticut. Available at: <http://www.census.gov/popest/states/NST-ann-est.html>. Accessed on September 21, 2010.

<sup>80</sup> 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>.

<sup>81</sup> Medicare Coverage of Durable Medical Equipment and Other Devices – Medicare Publication # 11045.

<sup>82</sup> Medicare Coverage Guidelines for Ostomy Supplies (Connecticut).

### ***Public Programs Administered by Public Schools***<sup>83</sup>

School nurses provide a number of services to students within the public and private school settings. Based on a 2009-2010 survey by the Connecticut Department of Education, ostomy care is provided in 23 percent of public school districts and in 4 percent of public schools. School nurses and other paraprofessionals help students care for their stomas and change ostomy bags that are provided by the student's parents or guardians. Public schools are not a regular source of ostomy supplies and do provide funding for ostomy supplies.

### ***The Department of Public Health (DPH)***

No information was found regarding the availability of ostomy appliances and supplies or funding for the required benefit through the Connecticut Department of Public Health. There is no information about the availability of ostomy appliances and supplies on the DPH website.

### ***Municipal Health Departments***

No information was found regarding the availability of ostomy appliances and supplies or funding for the required benefit through local and municipal health departments in Connecticut.

### ***The Department of Social Services (DSS)***

Medicaid covers a wide range of ostomy supplies, including collection devices, irrigation equipment and supplies, skin barriers, and skin protectors.<sup>84</sup> DSS produces an annual list<sup>85</sup> that specifies the maximum permissible cost reimbursements per specific supply item, as well the maximum quantity of the item that is typically coverable in a given monthly or annual period. However, DSS “does not impose an annual limit for medically necessary ostomy supplies.”<sup>86</sup>

A prescription signed by the treating doctor must be on file with the supplier, which must be registered with DSS; Medicaid will not pay any claims from unauthorized suppliers. Medicaid clients are not subject to any co-pays or coinsurance for medically necessary ostomy supplies as long as they obtain the supplies from an enrolled provider.<sup>87</sup>

### ***3. The extent to which insurance coverage is already available for ostomy supplies.***

Connecticut law requires coverage up to \$1,000 annually for ostomy appliances and supplies in fully-insured group and individual health insurance plans.<sup>88</sup> 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 in 2010 from five insurers/MCOs domiciled in Connecticut shows 46 percent of members in self-funded plans have coverage for the benefit.

As part of a previous review of a proposed mandate for increasing the dollar value of the ostomy supplies benefit in Connecticut, insurers/MCOs were surveyed in November 2009 regarding their coverage for ostomy supplies in fully-insured group and individual insurance plans and self-funded plans under

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<sup>83</sup> Personal communication. Stephanie Knutson. Connecticut Department of Education. November 8, 2010.

<sup>84</sup> DSS Provider Fee Schedule: Medical/Surgical Fee Schedule 2009, specifically Procedure Codes A4310-A4434.

<sup>85</sup> DSS Provider Fee Schedule: Medical/Surgical Fee Schedule.

<sup>86</sup> Personal Communication. Ginny Mahoney, DSS Medical Policy Consultant, 10/26/2009.

<sup>87</sup> *Ibid.*

<sup>88</sup> CONNECTICUT GENERAL STATUTES ANNOTATED § 38A-492j (individual insurance policies); § 38A-518j (group insurance policies).

their administration.<sup>89</sup> The survey results show that coverage for ostomy supplies and appliances across companies/plans ranges from the mandated minimum to unlimited coverage.

In fully-insured group plans, benefit levels higher than statutory minimums are common, while in individual policies, statutory minimums are the norm.<sup>90</sup> Three insurers provided information about annual ostomy supplies coverage for self-funded plans; two insurers provide unlimited coverage to all enrollees in self-funded plans while the third provides unlimited coverage to 46.5 percent of enrollees in self-funded plans.<sup>91</sup>

	Fully-insured Group Plans	Individual policies	Self-funded Plans
Insurer 1	Unlimited	\$1,000	Unlimited
Insurer 2	Unlimited	N/A	Unable to determine
Insurer 3	\$2,500	N/A	Unable to determine
Insurer 4	Unlimited	Unlimited	Unlimited
Insurer 5	Unlimited	\$1,000	Unlimited
Insurer 6	\$1,000	N/A	N/A
Insurer 7	\$1,000	\$1,000	Unavailable

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

Coverage is generally available to at least \$1,000 annually for persons covered by fully-insured group and individual health insurance plans. As noted above, unlimited coverage of ostomy appliances and supplies is not uncommon for policies held in Connecticut, particularly for fully-insured and self-funded group plans, which represent the vast majority of covered lives. Cost sharing varies among plans and insurers/MCOs and could be at levels that are difficult for some people to afford.

Medicare and Medicaid coverage is also unlimited, provided suppliers accept assignment and are available in the communities where persons with ostomies live and work.

***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 of ostomy appliances and supplies is included in fully-insured group and individual health insurance plans purchased in Connecticut and several plans include higher coverage limits than the currently mandated benefit level of \$1,000. The range of available benefit levels suggests that coverage may or may not be sufficient for a person with an ostomy to avoid unreasonable financial hardship depending on the plan in which he or she is enrolled and the dollar value of ostomy supplies they require, and personal financial resources available. The benefit level of the current mandate was established in October 2000 and inflation in the intervening years has reduced the spending power of \$1,000.

<sup>89</sup> 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>.

<sup>90</sup> *Ibid.*

<sup>91</sup> *Ibid.*

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

**6. *The level of public demand and the level of demand from providers for ostomy supplies.***

Medical librarians and CPHHP staff found no published literature regarding the level of public demand or level of demand from providers for ostomy appliances and supplies. As there are no alternatives to ostomy supplies for persons who have undergone ostomy surgery and lack of ostomy supplies would prohibit most activities of daily living and functioning, it is expected that the level of public demand and the level of demand from providers for ostomy supplies is high, at least for those persons aware of the issue.

**7. *The level of public demand and the level of demand from providers for insurance coverage for ostomy supplies.***

Medical librarians and CPHHP staff found no published literature regarding the level of demand from the public or from providers for insurance coverage of ostomy appliances and supplies. Expert opinion suggests providers witness the difficulties some people experience in accessing adequate quantities of ostomy supplies and the accompanying impacts on quality of life for persons with ostomies, not only among the uninsured but also among the insured population. In light of witnessing such difficulties, it is one provider's opinion that many providers support insurance coverage of ostomy supplies.<sup>92</sup>

Several members of the public and providers testified in favor of insurance coverage for ostomy supplies during the time legislation for the mandated benefits was under consideration by the Connecticut General Assembly.<sup>93</sup>

**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 (NAIC), Connecticut is the only state that requires coverage of ostomy supplies/appliances for fully-insured group and individual health insurance plans.<sup>94</sup> The NAIC also notes a mandate in Montana; however, the Montana legislation is related to Medicaid. Montana Administrative Rule 37.86.5007 requires Medicaid HMO policies to provide coverage for "ostomy or incontinence supplies" as durable medical equipment, only if supplied by a participating provider. As of December 2009, there are no Medicaid HMO plans offered in Montana so the Rule is not applicable.<sup>95</sup>

**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.<sup>96</sup> Internet searches and telephone inquiries found no relevant findings from any state agency or appropriate public organization related to the social impact of mandated insurance coverage of ostomy appliances and supplies. Internet searches of and/or telephone inquiries with states that have or had an established process for studying mandated health insurance benefits, with a relatively large number

<sup>92</sup> Personal communication, Judy Conway, APRN. November 6, 2009.

<sup>93</sup> Connecticut General Assembly. Report on Bills Favorably Reported By Committee. Insurance and Real Estate Committee. HB-5120. February 17, 2000.

<sup>94</sup> NAIC Compendium of State Laws on Insurance Topics. National Association of Insurance Commissioners.

<sup>95</sup> Personal communication, Montana Medicaid Agency. December 2, 2009.

<sup>96</sup> 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 on May 7, 2010.

of mandated health benefits, or located in the Northeast found no existing studies of mandated coverage of ostomy supplies. 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.***

Ostomy appliances and supplies are required for persons who have undergone colostomies, ileostomies, and urostomies. There are no other treatments, methods or procedures available that could be substituted for ostomy appliances and supplies.

***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.***

Ostomy supplies/appliances are a medical need because they are required following certain surgical procedures that are medically necessary for the health, well-being and survival of the patient. Ostomy supplies also meet broader social needs; they allow persons who have undergone colostomies, ileostomies, and urostomies to function at levels that permit them to maintain functioning, employment and fully participate in social activities.

Ostomy supplies are required following ostomy surgery. Coverage of required medical equipment and supplies following surgery is consistent with the role of health insurance. The statutes do not prohibit insurers/MCOs from using prior authorization, utilization review or other managed care tools at their disposal. Additionally, the mandated benefit includes an annual dollar limit for supplies. Such limits are consistent with the concept of managed care in that wasteful use is discouraged; however, restrictions may cause difficulties for individuals with legitimate needs for more ostomy supplies than can be acquired at the mandated benefit level. Despite the \$1,000 statutory benefit minimum, most fully-insured group policies provide ostomy supplies at higher benefit levels than are statutorily required.

***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.***

Ostomy appliances and supplies are a specialized type of medical equipment used as the result of a surgical intervention. It is therefore difficult to anticipate any comparable mandated benefit for similar diseases, illnesses or conditions. However, the structure of the mandated benefit (an annual dollar value limit) may be replicated; that is, mandated dollar value limits may be created to cover other types of medical equipment where current mandated coverage or dollar limits do not exist. Due to medical inflation and scientific advances, static dollar value limits associated with required benefits can prove inadequate over time.

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

Insurers and MCOs may look to cut costs by eliminating, restricting access to, or placing limits on other 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. Claims data received from Connecticut insurers/MCOs shows that ostomy supplies are a relatively low-cost benefit required by few insureds, which suggests that the impact of ostomy supplies on the availability of other benefits is minimal.

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

Due to the relatively low number of persons requiring ostomy supplies/appliances and the low aggregate total costs, it is not anticipated that employers will shift to self-funded plans as a result of this single proposed 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 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.

Five health insurers/MCOs domiciled in Connecticut provided information about self-funded plans for which they administer benefits, which represents an estimated 47 percent of the total population in self-funded plans in Connecticut. These five insurers/MCOs report that 46 percent of enrollees in their self-funded plans have coverage for the mandated services and approximately 37 percent of self-funded employer groups provide coverage for ostomy supplies and appliances that exceeds the mandated benefit level of \$1,000.

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

The ostomy supplies mandate is a current benefit that has been included in the state employee health insurance and health benefits plans at least in part 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 Medicare<sup>97</sup> 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. The November 2009 insurer survey shows that coverage limits for ostomy appliances and supplies higher than the existing mandated benefit (\$1,000/year) are common among fully-insured and self-funded group plans in Connecticut. Because some insurers offer unlimited benefits for ostomy appliances and supplies, it is likely that some percentage of state employees also had unlimited benefits for ostomy appliances and supplies while state plans were fully-insured. 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

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<sup>97</sup> Personal communication. Scott Anderson, State of Connecticut Comptroller’s Office. September 14, 2010.

health insurance plan will total \$118,320 in 2010.<sup>98</sup>

**16. *The extent to which credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community determines that use of ostomy supplies is safe and effective.***

Prior to commercial marketing, ostomy supplies must be approved as safe and effective by the U.S. Food and Drug Administration. There would seem to be few inherent risks related to the use of ostomy supplies, although adverse skin reactions to some of the materials can occur. Technological advances have improved ease of use and effectiveness of ostomy supplies, and are frequently documented in nursing and ostomy care journals.<sup>99,100</sup> However, there is a general lack of research investigating the safety and effectiveness of ostomy appliances and supplies, perhaps because they are generally composed of inert and non-toxic materials such as vinyl (bags) and pectin (wafers). Additionally, while some improvement in materials has occurred, there seems to be little medical and scientific inquiry into the development of alternatives to ostomy supplies.

#### **IV. Financial Impact**

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

The cost of ostomy supplies and appliances is likely to increase (or decrease) at the same rate as any other medical service or supply. The presence of the mandate is not expected to materially alter the availability of ostomy supplies or their cost over the next five years for several reasons, including:

- the small number of persons in fully-insured group and individual insurance plans in Connecticut who require ostomy supplies,
- the relatively low cost of ostomy supplies as compared to other health benefits and equipment,
- the inclusion of the benefit in health insurance/benefit plans not subject to state regulation, and the number of those plans that exceed the mandated benefit level, and
- the \$1,000 annual per beneficiary benefit limit.

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

The mandated health benefit may increase appropriate use of ostomy supplies if people previously extended use beyond functional capacity or if insurers did not include such coverage in the absence of the mandate. For those who acquire ostomy supplies without coverage from fully-insured group and individual health insurance benefits, a mandated benefit may not increase appropriate use. It is unlikely that inappropriate use (overutilization) is occurring due to the highly specialized nature of the supplies and lack of market for alternative use.

When this mandated health benefit was enacted in October 2000, the \$1,000 limit was not indexed or otherwise adjusted to account for the effects of inflation. Consequently, in 2010, for beneficiaries in

<sup>98</sup> See Appendix II. Ingenix Consulting Actuarial and Economic Report. This estimate has been calculated by multiplying the 2010 PMPM medical 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 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.

<sup>99</sup> Turnbull GB. 2001. The evolution, current status, and regulation of ostomy products in the United States. *Journal of Wound Ostomy Continence Nursing* 28(1): 18-24.

<sup>100</sup> Urostomy products: an update of recent developments. *British Journal of Community Nursing* 9(11): 482-6.

insurance plans that limit ostomy supplies at the mandated benefit level, \$1,000 buys fewer supplies than when the mandate was initiated, and may buy even fewer supplies over the next five years.

The insurer survey conducted in November 2009 provides evidence that many fully-insured group plans provide unlimited coverage for ostomy supplies. Should insurers and MCOs reduce current coverage to the mandated dollar limit in the statute, the mandated benefit could have the effect of reducing appropriate use of ostomy supplies for individuals currently using and covered for their ostomy supplies that cost in excess of \$1,000.

***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.***

Ostomy appliances and supplies are required for persons who have undergone colostomies, ileostomies, and urostomies. They do not serve as an alternative for any other treatment, service or equipment, supplies or drugs. Lack of adequate ostomy appliances and supplies might lead to complications with the patient's stoma and surrounding skin, resulting in added costs for treatment of such complications.

***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. Overall cost impact is limited due to the very small percentage of the insured population that requires ostomy supplies and appliances.

***5. The extent to which insurance coverage for ostomy supplies 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 14-16.)

**Group plans:** When the medical cost of the mandate is spread to all insureds in group plans, medical costs are estimated to be \$0.06 PMPM and retention costs are estimated to be \$0.01 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$0.07 PMPM in 2010. Insurance coverage for the mandated benefit may be reasonably expected to increase group health insurance premiums accordingly, that is, \$0.84 per year per insured.

**Individual policies:** When the medical cost of the mandate is spread to all insureds in individual policies, medical costs are estimated to be \$0.02 PMPM and retention costs are estimated to be \$0.01 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$0.03 PMPM in 2010. Insurance coverage for the mandated benefit may be reasonably expected to increase individual health insurance premiums accordingly, that is, \$0.36 per year per insured.

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

***6. The extent to which ostomy supplies 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. Ostomy appliances and supplies are required for persons who have undergone colostomies, ileostomies, and urostomies and there is no alternative to their use.

***7. The impact of insurance coverage for ostomy supplies 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 \$1,101,244 for ostomy supplies and appliances for Connecticut residents covered by fully-insured group and individual health insurance plans.

In terms of potential benefits or savings to insurers and employers resulting from prevention or early detection of disease or illness, insurance coverage for ostomy supplies can prevent complications that can occur when supplies are used for longer time periods than recommended. Use of ostomy supplies beyond recommended time periods can lead to pouch leakage, which precipitates peristomal skin complications that require treatment. On rare occasions, the stoma can also become infected.

Economic benefits of the mandate may also accrue to employers in terms of the available labor force. The economic benefits of persons with ostomies returning to work or participating in the workforce are likely to at least partially offset the value of the ostomy supplies they require that are 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 of ostomy supplies at \$1,000 per year 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 (\$0.06 PMPM) suggests little difference in 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 29.)

***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 to 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 is often the result of a legislative requirement.

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 October 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.

Additionally, due to the low prevalence of persons with ostomies in the insured population and associated low overall costs of the mandated benefit, 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. Actuarial analysis of claims data received from insurers/MCOs in Connecticut shows an expected cost in 2010 of \$1,290,639 for ostomy supplies and appliances 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 I

## Chapter 4

### **Hearing Aids for Children Twelve and Under**

Review and Evaluation of CGSA § 38a-516b and § 38a-490b

Mandatory Coverage for Hearing Aids for Children Age Twelve and Under

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## 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.

Connecticut General Statutes, Chapter 700, § 38a-516b and 38a-490b state that each group or individual health insurance policy...

...delivered, issued for delivery, renewed, amended or continued in this state on or after October 1, 2001, shall provide coverage for hearing aids for children twelve years of age or younger. Such hearing aids shall be considered durable medical equipment under the policy and the policy may limit the hearing aid benefit to one thousand dollars within a twenty-four-month period.  
(P.A. 01-171, S. 16.)

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 became effective October 1, 2001 (P.A. 01-171).

### *Premium impact:*

**Group plans:** On a 2010 basis, the cost of this mandate is estimated to be less than \$0.01 PMPM, which is less than .01 percent of estimated total premium costs in group plans. Estimated cost sharing on a 2010 basis in group plans is less than \$0.01 PMPM, although it can be substantial for the individual family.

**Individual policies:** Four of the six insurers/MCOs provided claims data for individual health insurance policies. On a 2010 basis, the cost is estimated to be less than \$0.01PMPM, which is less than 0.1 percent of estimated total premiums in individual policies. Estimated cost sharing on a 2010 basis in individual policies is less than \$0.01 PMPM, although the cost share can be substantial for the individual family. Individual policies data is less credible than group plans data primarily due to small sample sizes.

### *Self-funded plans:*

Information received from the six insurers/MCOs domiciled in Connecticut representing an estimated 99 percent of the total self-funded population in Connecticut shows that 58 percent of members in self-funded plans have coverage for the 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

An estimated 6.4 percent of children in the U.S. have some level of hearing loss.<sup>101</sup> Hearing loss in children has several different causes: e.g., congenital abnormalities, exposure to various viruses, bacteria or toxins either intrauterine or at birth, premature birth, ear infections, trauma, noise-induced loss, perforation of the tympanic membrane, tumors and hereditary hearing impairment.<sup>102</sup> Hearing loss can be temporary or permanent. The severity of hearing loss ranges from mild to moderate to severe to profound. Early hearing loss can cause delays in the development of speech, language and cognitive development. Hearing loss at any age can result in diminished social and emotional well-being and diminished academic performance and potential earnings capacity.<sup>103, 104</sup>

There are a variety of treatment options for hearing impairment in children, depending on the cause of the impairment.<sup>105</sup> Antibiotics or surgery are effective for some causes, such as otitis (ear infections) or tumors. Where a hearing impairment is not amenable to surgery or pharmaceuticals, a variety of hearing aids and assistive listening devices are available. Hearing aid circuitry can be analog, digital or digitally programmable. Hearing aid styles include behind-the-ear, in-the-ear, completely-in-the-canal and bone anchored implantable hearing aid systems (these attach to an anchor implanted in the bone of the skull and are used with patients who cannot benefit from conventional hearing aids). FM amplification devices, used often in educational settings, amplify the sound for the listener by effectively decreasing the distance between the listener and the speaker. They can be used alone or in addition to hearing aids. Cochlear implants are increasingly being used for people with profound hearing loss.

For the purposes of this report, it is assumed that neither FM amplification devices nor cochlear implants are included within the definition of “hearing aid” as used in CGSA sections 38a-516b and 38a-409b.

Hearing aids are fitted by an audiologist, upon a prescription by a physician.<sup>106</sup> The audiologist evaluates each patient to determine the best type of hearing aid, based on the age of the child and the level and type of hearing loss. Hearing aids must be fitted to the child’s ear, and need to be replaced as the child grows. A significant number of children (as well as adults) who are recommended for hearing aids by their physicians never fill the prescription, or do not wear them after they are fitted. A variety of reasons have been stated, including financial concerns, the stigma of being different, and physician, parent or child perception that the hearing loss is “not that bad.”<sup>107</sup>

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<sup>101</sup> Mitchell, RE. 2006. How many deaf people are there in the United States? *Journal of Deaf Studies and Deaf Education* 11(1): 112-119.

<sup>102</sup> Sanford B, Weber P. Etiology of hearing impairment in children. UpToDate, [www.uptodate.com](http://www.uptodate.com). 2008. Accessed on October 23, 2009.

<sup>103</sup> Sanford B, Weber P. Treatment of hearing impairment in children. UpToDate, [www.uptodate.com](http://www.uptodate.com). 2008. Accessed on October 23, 2009.

<sup>104</sup> O’Neill G. 1999. Profile: Hearing loss, a growing problem that affects quality of life. National Academy on an Aging Society.

<sup>105</sup> Sanford B, Weber P. Treatment of hearing impairment in children. UpToDate, [www.uptodate.com](http://www.uptodate.com). 2008. Accessed on October 23, 2009.

<sup>106</sup> *Ibid.*

<sup>107</sup> Kochkin S, Luxford W, Northern J, et al. 2007. Are 1 million dependents with hearing loss in America being left behind? *Hearing Review* 14(10): 10.

### 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
- Web
- Library Catalog

The search terms included: hearing aids, hearing loss, noise induced hearing loss, conductive hearing loss, syndrome hearing loss, deafness, epidemiology, rehabilitation, health service needs, insurance coverage trends/statistics, and hearing disorders therapy.

CPHHP staff conducted independent literature searches using Pubmed, 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 Medicine and the Connecticut Children's Medical Center on matters pertaining to medical standards of care, current and traditional practices, and evidence-based medicine related to hearing loss in children.

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 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.***

An estimated 6.4 percent of children under the age of thirteen have some level of hearing loss.<sup>108</sup> Not all children with hearing loss need or use hearing aids. For some, the hearing loss is mild or temporary, due to conditions that can be reversed by surgery or antibiotics. For others, the hearing loss is profound and they are unable to hear even with hearing aids. A 1994 study based on the 1988 National Health Interview Survey estimated that 3.46 percent of children ages 0-17 have deafness or trouble hearing.<sup>109</sup> According to the Survey of Income and Program Participation (SIPP), nationally approximately 300,000 children age 6-17 have difficulty hearing and use hearing aids.<sup>110</sup> This is roughly 0.6 percent of children age 6-17. Applying this percentage to Connecticut's population of children ages 0-14 of approximately 664,000,<sup>111</sup> an estimated 4000 children in Connecticut have difficulty hearing and use hearing aids. It is likely that more than this number could benefit from hearing aids but do not use them for a number of reasons including financial burden, stigma and perception of ability to cope without hearing aids.

### ***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***<sup>112</sup>

Medicare does not cover hearing aids.

#### ***Medicaid***

Medicaid covers hearing aids for both ears for all ages.<sup>113</sup> For children under eighteen the child must have an examination by an otolaryngologist and an examination by an audiologist, one of which has to take place within the ninety days prior to the receipt of the hearing aid.<sup>114</sup> For adults, including eighteen year olds, a medical evaluation by a doctor is required within the prior six months, to ensure that all medically treatable conditions that may affect hearing have been identified and treated first. The initial hearing aid does not require prior authorization, but prior authorization is required for replacement hearing aids. Hearing aids may be replaced every three years, unless they have been lost, stolen or damaged beyond repair. There is no co-pay or coinsurance for Medicaid clients as long as the hearing aid is obtained from an enrolled provider<sup>115</sup>

#### ***Public Programs Administered by Charities***

Quota International clubs, Sertoma clubs and Lions clubs all have programs to help low income families purchase hearing aids. They also work to repair and recycle used hearing aids.

<sup>108</sup> Mitchell, RE. How Many Deaf People Are There in the United States? *Journal of Deaf Studies and Deaf Education* 11:1; 112-119 Winter 2006

<sup>109</sup> Boyle C, DeCoufle P. Prevalence and health impact of developmental disabilities in US children. 1994. *Pediatrics* 93(3):399

<sup>110</sup> Survey of Income and Program Participation (SIPP), Panel 2001, Wave 5 public-use file.

<sup>111</sup> Backus, K, Mueller, LM (2009) State-level Bridged Race Estimates for Connecticut, 2008, Connecticut Department of Public Health, Office of Health Care Quality, Statistics, Analysis and Reporting, Hartford, Connecticut.

<sup>112</sup> Medicare.gov. Your Medicare Coverage, Connecticut. Available at: <http://www.medicare.gov/Coverage/Search/Results.asp?State=CT%7CCo nnecticut&Coverage=34%7CHearing+Exams+and+Hearing+Aids&submitState=View+Results+%3E>. Accessed on November 16, 2010.

<sup>113</sup> Personal communication. Ginny Mahoney, DSS Medical Policy Consultant, 10/26/2009.

<sup>114</sup> Connecticut Department of Social Services. Connecticut interchange MMIS: Provider Manual, Chapter 7 (MEDS), § 17-134d-45(c)(2)

<sup>115</sup> *Ibid.*

### ***Birth to Three Program***

For infants and toddlers with hearing loss that meets the eligibility requirements of the Connecticut Birth to Three program, hearing aids and audiology services are included in the early intervention services which can be provided.<sup>116</sup> (See report on Birth to Three insurance mandate for further discussion.)

The American Speech and Hearing Association has a list of additional resources for families posted on its website.<sup>117</sup>

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

Hearing aids for children twelve and under have been mandated in individual and group health insurance policies delivered, renewed or amended in Connecticut since 2001 (P.A. 01-171).

In our 2009 surveys from the seven insurance companies/MCOs domiciled in Connecticut, all provide hearing aids to children under age twelve and under, in accordance with the existing mandate. However, two companies reported that effective October 3, 2009 all their policies will provide hearing aid coverage as a standard benefit for all ages, with 24-month maximums that exceed the proposed mandate. These two companies will not include hearing aids in durable medical equipment (DME) but will apply the same level of cost sharing as DME and will have separate but consistent limits, not to exceed \$5,000 per year.

### ***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 children twelve and under enrolled in group and individual health insurance plans. In one study, approximately thirty percent of families reported financial need as a barrier to obtaining hearing aids for their children.<sup>118</sup>

### ***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 up to \$1,000 every two years for hearing aids for children twelve years of age and under is required to be included in commercial insurance plans purchased in Connecticut. This maximum applies whether a child needs a hearing aid for one or for both ears. The price of hearing aids varies considerably depending on the style and technology employed, from as little as \$750 per aid to more than \$2000 per aid. Behind-the-ear (BTE) hearing aids are most frequently recommended for children because the ear molds can be recast to accommodate growth without having to replace the entire hearing aid.

The actuarial report assumes an average price of \$2250 per hearing aid. For individuals requiring two hearing aids, their costs would be \$4500 on average.<sup>119</sup> Hearing aids typically last between three and five years.<sup>120</sup> For lower income families (those earning \$50,000 or less annually) the out-of-pocket difference between the price of two hearing aids and the \$1000 mandated insurance benefit can represent between 7.4 percent to 9 percent of income, depending on the deductible and co-pay levels of their plans. Even if they

<sup>116</sup> 34 CFR sec. 303.12

<sup>117</sup> <http://www.asha.org/public/coverage/p3AudFundingResources.htm>. Accessed on September 23, 2010.

<sup>118</sup> Kochkin S, Luxford W, Northern J, et al. 2007. Are 1 million dependents with hearing loss in America being left behind? *Hearing Review* 14(10):10.

<sup>119</sup> Ingenix Consulting report, Appendix II, p. 47.

<sup>120</sup> Kirkwood D. 2009. Despite challenging conditions, practitioners in survey remain up beat. *The Hearing Journal* 62(4): 28-29.

are purchasing lower cost devices, they may pay as much as 3 percent of their income.<sup>121</sup>

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

Children with unaddressed hearing loss have more problems with social skills, language development, emotional health, peer and family relationships and self-esteem.<sup>122</sup> The availability of hearing aids can improve their educational outcomes and future earnings capacity.

**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 demand for this mandate comes primarily from the families of children who need hearing aids. An estimated 1.75 percent of children age twelve and under would benefit from hearing aids.<sup>123</sup>

The American Speech-Language-Hearing Association also advocates for insurance coverage of hearing aids for children.<sup>124</sup>

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

Eighteen states, including Connecticut, mandate some level of insurance coverage for hearing aids for children.<sup>125</sup>

State	Effective Year	Coverage
Arkansas Ark. Code Ann. § 23-79-1401	2010	Hearing aids covered for all ages, \$1,400 per ear every 3 years
Colorado Co.R.S. sec 10-16-104	2009	Hearing aids for children under 18; replace at least every 5 years or when necessary
Connecticut CGSA 38a-490b and CGSA 38a-516b	2002	\$1000 maximum every 2 years for children under 13
Delaware House Bill 355 of 2008*	2008	\$1000 maximum every 3 years for children under 24
Kentucky KRS 304.17A-132	2002	\$1400 per ear every 3 years for children under 18
Louisiana La.R.A. 22:1038	2003	\$1400 per ear every 3 years for children under 18

<sup>121</sup> Ingenix Consulting report, Appendix II, p. 47.

<sup>122</sup> Kochkin S, Luxford W, Northern J, et al. 2007. Are 1 million dependents with hearing loss in America being left behind? *Hearing Review* 14(10):10

<sup>123</sup> Ingenix Consulting report, Appendix II, p. 21.

<sup>124</sup> American Speech-Language-Hearing Association. State Insurance Mandates for Hearing Aids. [http://www.asha.org/advocacy/state/issues/ha\\_reimbursement.htm](http://www.asha.org/advocacy/state/issues/ha_reimbursement.htm). Accessed on September 23, 2010.

<sup>125</sup> American Speech-Language-Hearing Association. State Insurance Mandates for Hearing Aids. [http://www.asha.org/advocacy/state/issues/ha\\_reimbursement.htm](http://www.asha.org/advocacy/state/issues/ha_reimbursement.htm). Accessed on September 23, 2010.

Table I.4.1 Mandated Coverage		
State	Effective Year	Coverage
Maine 24-A MRSA sec 33-2762	2008 for birth-5 2009 for 6-13 2010 for 14-18	\$1400 per ear every 3 years
Maryland Maryland Code § 15-838		\$1400 per ear every 3 years
Minnesota Minn. Stat. 62Q.675	2007	One hearing aid per ear every 3 years for children under 18 with hearing loss due to congenital malformation of the ear
Missouri § 376.1220 R.S.Mo.	1999	Infant hearing screening and initial amplification including hearing aids
New Hampshire N.H. Rev. Stat. Ann. §415-6p and §415:18-u (as created by <a href="#">H.B. 561 [2010]</a> )	2010	
New Jersey N.J. Stat. Ann. §17:48-6gg; §17:48A-7dd; §17:48E-35.31; §17B:26-2.1aa; §17B:27-46.1gg; §17B:27A-7.14; §17B:27a-19.18; §26:2J-4.32; §52:14-17.29n; §30:4J-12.2.	2009	\$1000 per ear every 24 months for children under 16
New Mexico N.M. Stat. Ann. §13-7-10; §59A-22-34.5; §59A-23-7.8; §59A-46-38.5; §59A-47-37.1.	2007	\$2200 per ear every 3 years for children under 18, or under 21 if still in high school
North Carolina, N.C. Gen. Stat. §58-3-285 (as created by <a href="#">H.B. 589 [2010]</a> )	2011	Individuals up to age 22, \$2500 per ear every 36 months
Oklahoma 36 Okl. St. sec 6060.7	1999	Hearing aids for children up to 18 every 4 years, no dollar limit
Oregon Or. Rev. Stat. sec 743A.141	2009	\$4000 every 48 months for children under 18, or over 18 if still a dependent and enrolled at an institution of higher education
Rhode Island R.I. Gen. Laws sec 27-18-60		\$1500 per ear every 3 years for children under 19, \$700 per ear for those 19 and over
Wisconsin Wis. Stat. sec 609.86	2009	One hearing aid per ear every 3 years, no dollar limit

Source: American Speech-Language-Hearing Association, [http://www.asha.org/advocacy/state/issues/ha\\_reimbursement.htm](http://www.asha.org/advocacy/state/issues/ha_reimbursement.htm)

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

For the estimated 30 percent who report that financial need prevents them from obtaining hearing aids for their children who need them, required insurance coverage may make a difference.<sup>126</sup> However, financial need is not the only reason that parents and children give for not using hearing aids. The study<sup>127</sup> found that 70 percent of those who might have profited from hearing aids did not use them because of the perceived stigma of wearing them, minimization by parents or children of the level of hearing loss, or professional recommendations that hearing aids were not needed or would not help. It is difficult to determine what role lack of insurance coverage may have played in these perceptions or recommendations.

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

Children with mild hearing loss can benefit from FM amplification devices, which effectively decrease the distance between the speaker and the child by sending the sound to an FM receptor worn around the child's neck. This is used in many educational settings to help a child hear classroom instruction. It can also be used in addition to hearing aids, which improve hearing by only about one-half of the loss.<sup>128</sup> FM amplification is not sufficient for those with more serious levels of hearing impairment. Cochlear implants may be appropriate for individuals with profound hearing loss. These involve implanting a device in the brain of the child.

**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.***

Hearing aids compensate for an impaired organ (the ear), and therefore meet a medical need of the wearer. Hearing aids also contribute to achievement of social benefits.

**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 potential social implications of this mandate lie primarily in the potential demand to extend the benefit to additional groups of beneficiaries, e.g., children over age twelve, adults from 19-21 or 19-26, all adults, etc.

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

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

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

Since this required benefit has been in effect since 2001, it is not possible to determine the extent to which required coverage for hearing aids contributed to employer decisions to shift to a self-funded plan. It is not anticipated that any more employers will shift to self-funded plans as a result of this single proposed

<sup>126</sup> Mitchell, RE. 2006. How many deaf people are there in the United States? *Journal of Deaf Studies and Deaf Education* 11(1): 112-119.

<sup>127</sup> *Ibid.*

<sup>128</sup> Sanford B, Weber P. Etiology of hearing impairment in children. UpToDate, [www.uptodate.com](http://www.uptodate.com). 2008. Accessed on October 23, 2009.

mandate. Conversely, it is also not anticipated that repeal of this single mandate would lead to a shift from self-funded plans to insured plans among employers.

Information received from the six insurers/MCOs domiciled in Connecticut representing an estimated 99 percent of the total self-funded population in Connecticut shows that 58 percent of members in self-funded plans have coverage for the 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, the claims data from the carriers and the cost projections which 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 medical cost for this mandate in 2010 is estimated to be \$19,720. 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.)<sup>129</sup>

**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.***

Hearing aids are generally considered safe and efficacious for those who can benefit from them.

## **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 assisted hearing devices 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.***

Since hearing aids cost from \$1000 to \$4000 per ear, the current mandated benefit acts as a subsidy, rather than a comprehensive benefit. For those children whose insurance plans would not otherwise cover hearing aids, the mandated health benefit may increase appropriate use of the devices. However, the co-pay levels

<sup>129</sup> Personal communication with Scott Anderson, State Comptroller's office, September 14, 2010

may act as an impediment to the appropriate use of hearing aids, if the family cannot afford to pay the remaining cost. The co-pay levels also act to restrain any inappropriate use of the equipment.

***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.***

FM amplification is a less expensive method for improving a child's hearing that is often used in classroom settings. However, some children still need hearing aids in addition to the FM amplification in order to hear classroom instruction adequately. FM amplification is not a practical alternative outside the classroom in the larger community, since it requires the speaker to use a microphone tuned to the recipient's amplifier. FM amplification alone is not an alternative for children who need hearing aids.

Cochlear implants are a more expensive treatment for profound hearing loss or deafness. They are not appropriate for children with moderate-to-severe hearing loss.

***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 will employ 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 mandate for hearing aids for children twelve and under may also have contributed to payers (insurers and MCOs) negotiating with hearing aid providers for lower prices.

***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 medical cost of the mandate is spread to all insureds in group plans, medical costs are estimated to be \$0.01 PMPM<sup>130</sup> 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, which is less than 0.1 percent of premium.

**Individual policies:** When the medical cost of the mandate is spread to all insureds in individual policies, 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, which is less than 0.1 percent of premium.

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

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

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<sup>130</sup> Ingenix Consulting report, Appendix II, p. 8

*community.*

FM amplification is a less expensive method for improving a child's hearing that is often used in classroom settings. However, some children still need hearing aids in addition to the FM amplification in order to hear classroom instruction adequately. FM amplification is not a practical alternative outside the classroom in the larger community, since it requires the speaker to use a microphone tuned to the recipient's amplifier. FM amplification alone is not an alternative for children who need hearing aids, since it requires the speaker to be in relatively close proximity to the child.

Cochlear implants are a more expensive treatment for profound hearing loss or deafness. They are not appropriate for children with moderate-to-severe hearing loss.

***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. Actuarial analysis of claims data received from insurers/MCOs in Connecticut shows an expected impact in 2010 of approximately \$176,635 to individual and group health insurance expenditures annually.

Hearing aids may lower educational costs for special accommodations for these children. Economic benefits may accrue to society through increased academic achievement, improved social and psychological functioning, and lifelong productivity.

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

According to the Ingenix Consulting report, this mandate is expected to have roughly the same effect on the medical cost of small group plans as on large group plans, approximately \$0.01 PMPM.

***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 is not expected to materially increase the demand or price for assisted hearing devices. Even with the mandated benefit, families bear a significant percent of the cost of purchasing hearing aids for their children age twelve and under.<sup>131</sup> We estimate that 1.75 percent of insured children in Connecticut age twelve and under purchase hearing aids each year,<sup>132</sup> adding approximately \$212,745 to the total medical cost. This equates to \$0.01 PMPM.<sup>133</sup>

For those able to take advantage of it, this mandate may result in better educational outcomes, social development and quality of life, and increased productivity.<sup>134</sup>

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<sup>131</sup> Ingenix Consulting report, Appendix II, p 24

<sup>132</sup> Ingenix Consulting report, Appendix II, p 24

<sup>133</sup> Ingenix Consulting report, Appendix II, p 8

<sup>134</sup> Ingenix Consulting report, Appendix II, p 48



# Volume I

## Chapter 5

### Coverage for Craniofacial Disorders

Review and Evaluation of Connecticut Statute  
Chapter 700, § 38a-516cj and § 38a-490c

Coverage for Medically Necessary Orthodontic Processes and Appliances for the  
Treatment of Craniofacial Disorders.

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## 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 (CID) and the University of Connecticut Center for Public Health and Health Policy (CPHHP).

Connecticut General Statutes, Chapter 700, § 38a-516c and § 38a-490c mandate that group and individual health insurance policies issued, renewed or continued in this state provide coverage for medically necessary orthodontic processes and appliances for the treatment of craniofacial disorders for individuals eighteen years of age or younger.

Specifically, Connecticut General Statutes, Chapter 700, § 38a-516c provides that group health insurance...

...shall provide coverage for medically necessary orthodontic processes and appliances for the treatment of craniofacial disorders for individuals eighteen years of age or younger if such processes and appliances are prescribed by a craniofacial team recognized by the American Cleft Palate-Craniofacial Association, except that no coverage shall be required for cosmetic surgery.

§ 38a-490c mandates similar provisions 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 October 1, 2003 (P.A. 03-37, S. 2.).

### *Premium impact*

**Group plans:** On a 2010 basis, medical cost of this mandate is estimated to be \$0.02 per member per month (PMPM). Estimated total cost to insurers (insurance premium, administrative fees, and profit) of the mandated services on a 2010 in group plans is \$0.02 PMPM which is less than 0.01 percent of estimated total premium costs in group plans. Estimated cost sharing on a 2010 basis in group plans is \$0.00.

**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 \$0.03 PMPM. Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services in 2010 in individual policies is \$0.04 PMPM which is less than 0.01 percent of estimated total premiums in individual policies. Estimated cost sharing in 2010 in individual policies is \$0.00. Individual policies data is less credible than group plans data primarily due to small sample sizes.

### *Self-funded plans*

Six insurers/MCOs provided information about their self-funded plans, which represents an estimated 98 percent of the total population in self-funded plans in Connecticut. These six insurers/MCOs report that 68.5 percent of members 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**

The human face and cranium are developed by a complex series of processes that occur between the third and eighth week of gestation.<sup>135</sup> Craniofacial disorders arise when there are anomalies in one or more of these developmental processes. The most common craniofacial malformation is the orofacial cleft (OFC) which consists of cleft lip with or without cleft palate (CL/P) or isolated cleft palate (CP). A cleft lip occurs when the two sides of the lip do not fuse properly and often includes the bones of the upper jaw and/or upper gum. A cleft palate is an opening in the roof of the mouth caused when the two sides of the palate do not join. Severity of the disorder may range from a bifid uvula (submucous cleft) to a complete bilateral cleft of the lip and palate.<sup>136</sup> This disorder can be a part of a syndrome involving multiple other organs or an isolated malformation. Diagnosis of orofacial cleft may be made during a routine ultrasound in utero but is typically made in the delivery room shortly after birth.

There are many short- and long-term difficulties associated with craniofacial disorders. The initial concern for newborns and babies with craniofacial disorders are feeding problems. Feeding problems are caused primarily by difficulties in creating a seal around the nipple or generating the negative pressure needed for sucking.<sup>137</sup> Children with cleft lip/palate often have recurrent middle ear infections which are believed to be due to a split in the muscles in the back of the throat prohibiting proper drainage of the Eustachian tube.<sup>138</sup> Patients with craniofacial disorders typically have a need for orthodontic treatment due to malformations of the jaw, and gum. Teeth also are adversely affected and there may be extra, missing, abnormally shaped, or out of position teeth.<sup>139</sup> Other common concerns in children with craniofacial disorders include speech development and appearance.<sup>140</sup>

The most common craniofacial disorder is the orofacial cleft (e.g. cleft lip, cleft palate, or cleft lip with cleft palate). Nationally, approximately 1 in 1,000 babies are born each year with CL and 1 in 2000 babies are born with CP.<sup>141</sup> CL is more likely to occur in boys than girls, and CP is more likely to occur in girls than in

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<sup>135</sup> Stal S, Hollier LH, Cole P, et al. Facial clefts and holoprosencephaly. UpToDate. August 11, 2009. Available at: <http://www.uptodate.com/patients/content/topic.do?topicKey=-jh2/QtFgWTVunF2>. Accessed on March 4, 2010.

<sup>136</sup> Cunningham S, Horrocks E, Hunt N, et al. 2000. ABC of oral health: Improving occlusion and orofacial aesthetics: Orthodontics. *British Medical Journal* 321: 288-290.

<sup>137</sup> Zarate YA, Martin LJ, Hopkin RJ, et al. 2010. Evaluation of growth in patients with isolated cleft lip and/or cleft palate. *Pediatrics* 125(3): 543-549.

<sup>138</sup> Gillette Children's Specialty Healthcare. 2003. A Pediatric Perspective. Volume 12, Number 1. Available at: [www.gillettechildrens.org/fileUpload/Vol12No1.pdf](http://www.gillettechildrens.org/fileUpload/Vol12No1.pdf). Accessed on March 4, 2010.

<sup>139</sup> *Ibid.*

<sup>140</sup> Flint PW, Haughey BH, Lund VJ, et al. 2010. Cummings *Otolaryngology: Head and Neck Surgery*, 5<sup>th</sup> ed. Mosby Elsevier: Philadelphia.

<sup>141</sup> Canfield MA, Honein MA, Yuskiv N, et al. 2006. National estimates and race/ethnic-specific variation of selected birth defects in the United States, 1999-2001. Birth Defects Research Part A, *Clinical Molecular Teratology* 76: 747-56.

boys.<sup>142</sup> Craniofacial disorders are significantly more likely to occur in a multiple birth than in a singleton.<sup>143</sup> The prevalence of CL varies by race and is highest among Native Americans and Asians and lowest among African Americans. In Connecticut, the rate of cleft lip and/or cleft palate is approximately 1 in 2,200.<sup>144</sup> This ranks cleft lip/palate fourth among birth defects in Connecticut. However, cleft lip/palate prevalence rates in Connecticut are considerably lower than national rates. Consistent with national data, more cleft palate birth defects occurred in boys (62 percent) than girls (38 percent) born in Connecticut. However, no significant differences were found when examining the data by race or ethnicity.

The study of craniofacial anomalies has found several genetic and environmental factors that influence facial development in-utero.<sup>145</sup> The categories of genes associated with craniofacial disorders include those involving control cell patterning, cell proliferation, extracellular communication, and differentiation. However, genetics are not the sole determinant. Numerous environmental factors have been identified that increase the risk of craniofacial malformation due to in-utero exposure. Medications such as anti-seizure drugs and folic acid antagonist, smoking while pregnant (due primarily to hypoxia and cadmium, an ingredient in tobacco), maternal alcohol consumption particularly weekly binge drinking (consuming more than five alcoholic beverages at one time), and folate deficiency have been linked to a variety of birth defects including craniofacial disorders.

The treatment of craniofacial disorders can be complex and, depending upon the medical need, can involve many multistage procedures. The orthodontic component is necessary for the effective treatment of children with craniofacial disorders.<sup>146</sup> The role of the orthodontist is “to provide presurgical orthopedics, to monitor facial growth and dental eruption for appropriate timing of surgical procedures, to position tooth bearing bony segments as a frame work for surgery, and to correct debilitating occlusal abnormalities.”<sup>147</sup> Inadequate orthodontic care can lead to “unstable or malpositioned oral structures, premature tooth loss, functional deficiencies in chewing, swallowing, respiration, speech and poor esthetics.”<sup>148</sup>

The American Cleft Palate Association’s report entitled *Parameters for Evaluation and Treatment of Patients with Cleft Lip/Palate and Other Craniofacial Anomalies* suggests a team approach to provide coordinated care for the diverse services a child with a craniofacial disorder may need over several years.<sup>149</sup> An interdisciplinary cleft palate or craniofacial team typically includes professionals from a variety of health care disciplines such as audiology, radiology, genetics and genetic counseling, nursing, pediatrics, oral and maxillofacial surgery, orthodontics, dentistry, otolaryngology, psychology, social work, and speech pathology among others. The primary benefits of a team approach are to provide comprehensive evaluations and coordinated care.<sup>150</sup>

<sup>142</sup> Dyleski RA, Crockett DM, Seibert RW. 2001. *Head and Neck Surgery-Otolaryngology*, 3<sup>rd</sup> ed. Cleft lip and palate. Eds. Mailey BJ, Calhoun KH, Derkay CS, et al. Philadelphia: Lippincott Williams and Wilkins, 961-977.

<sup>143</sup> Tang Y, Ma CX, Cui W, et al. 2006. The risk of birth defects in multiple births: a population-based study. *Maternal and Child Health Journal* 10(1): 75-81.

<sup>144</sup> Galvin JR, Gyle N. 2007. Oral Health in Connecticut. Connecticut Department of Public Health. Available at: [http://www.ct.gov/dph/lib/dph/oral\\_health/pdf/oral\\_health\\_in\\_ct.pdf](http://www.ct.gov/dph/lib/dph/oral_health/pdf/oral_health_in_ct.pdf). Accessed on July 20, 2010.

<sup>145</sup> Wilkins-Haug L. Prenatal diagnosis of orofacial clefts. Available at: <http://www.uptodate.com/patients/content/topic.do?topicKey=-N/N/muJF8KLznJN>. Accessed on March 4, 2010.

<sup>146</sup> Lewis CW, Ose M, Aspinall C, et al. 2005. Community orthodontists and craniofacial care: results of a Washington State survey. *Cleft Palate-Craniofacial Journal* 42(5): 521-525.

<sup>147</sup> *Ibid.*

<sup>148</sup> *Ibid.*

<sup>149</sup> American Cleft Palate-Craniofacial Association. Rev 2004. Parameters for Evaluation and Treatment of Patients with Cleft Lip/Palate or Other Craniofacial Anomalies. American Cleft Palate-Craniofacial Association. Available at: [www.acpa-cpf.org/teamcare/Parameters04rev.pdf](http://www.acpa-cpf.org/teamcare/Parameters04rev.pdf). Accessed on July 20, 2010.

<sup>150</sup> Strauss RP. 1999. The organization and delivery of craniofacial health services: the state of the art. *Cleft Palate-Craniofacial Journal* 36(3): 189-95.

The interventions used and timing of the interventions vary considerably based on the nature of the disorder, severity of the condition and the maturation rate of the individual. Medically necessary orthodontic procedures to treat craniofacial disorders may include:

- Pre-surgical orthodontics occurs during the first few months of life
- Early bone grafting occurs during infancy
- Secondary bone grafting occurs between the ages of 6 and 10
- Maxillary expansion and braces occurs between the ages of 6 and 10
- Bone graft surgery occurs after the completion of orthodontic treatment
- Bone graft splint occurs after surgery to protect the graft site
- Maxillary distraction may occur at any age to preserve vision
- Mandibular osteogenesis may be necessary to clear airway

Orthodontics processes and appliances have been found to be effective in correcting teeth misalignment, malocclusion, etc.<sup>151,152</sup> Not surprisingly, the benefit of the treatment increases with the experience of the orthodontist and patient co-operation. There are few inherent risks related to orthodontics treatment of craniofacial disorders. However, some patients may experience root resorption, loss of periodontal support, decalcification, and soft tissue damage.<sup>153</sup>

Barriers to orthodontic care for children with craniofacial disorders are frequently reported anecdotally and include concerns such as costs, difficulties in identifying a provider, or inconvenient office location, etc. Researchers surveyed 138 orthodontists in Washington State to investigate potential barriers to care from the provider perspective.<sup>154</sup> Type of insurance played a primary role in obtaining treatment. The investigators found that 90 percent of the respondents' patients relied on private insurance and/or paid cash for treatment. Only two percent of the orthodontists routinely accepted Medicaid patients although 30 percent indicated they would accept a limited number of Medicaid patients under special circumstances or with specific diagnoses.

Training specific to treating craniofacial disorders may also influence care since the vast majority (76 percent) of the respondents reported that their training to treat children with craniofacial disorders was adequate to poor. Lack of experience treating patients with OFC may function as a barrier. Almost two-thirds of the orthodontists (59 percent) had cared for three or fewer patients with cleft lip and/or palate (CLP) in the previous three years and only 20 percent had seen more than three patients with CLP during that same time period. On average interested respondents reported they could accommodate six craniofacial patients at a time. Only 11 percent of the respondents reported that they were affiliated with a craniofacial team. Referrals tended to come from a craniofacial team (27 percent), or a community dentist (32 percent).

Connecticut's mandate for craniofacial abnormalities is unique in that it mandates coverage of orthodontic processes as recognized by the American Cleft Palate-Craniofacial Association for the treatment of craniofacial disorders without explicitly mandating coverage of corrective surgery for cleft lip and palate. Most of the other state craniofacial abnormality mandates do not specifically mandate coverage for the treatment.

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<sup>151</sup> O'Brien K, et al. 2003. Effectiveness of early orthodontic treatment with the Twin-block appliance: A multicenter, randomized, controlled trial. Part 1: Dental and skeletal effects. *American Journal of Orthodontics and Dentofacial Orthopedics* 124: 234-43.

<sup>152</sup> Bernas AJ, Banting DW, Short LL. 2007. Effectiveness of Phase I orthodontic treatment in an undergraduate teaching clinic. *Journal of Dental Education* 71(9): 1179-1186.

<sup>153</sup> Mitchell, L. 2007. *An Introduction to Orthodontics*. Oxford University Press: London.

<sup>154</sup> Lewis CW, Ose M, Aspinall C, et al. 2005. Community orthodontists and craniofacial care: results of a Washington State survey. *Cleft Palate-Craniofacial Journal* 42(5): 521-525.

### 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 using PubMed. Search terms included: Dental care for children utilization, cleft lip, cleft palate, orthodontics, orthodontics-corrective, orthodontics-interceptive, economics, mouth rehabilitation, cleft lip surgery, cleft palate surgery, dental pediatric, oral surgical procedures, reconstructive procedure, statistics, numerical date, and adverse effects.

CPHHP staff conducted independent literature searches using Pubmed, Google, and Google Scholar using similar search terms as 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 orthodontists in private practice who provide orthodontic treatment to children with craniofacial disorders on matters pertaining to medical standards of care; traditional, current and emerging practices; insurance plan reimbursement; 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, 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 and individual plan participants. Six insurers/MCOs also provided information 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 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 most common craniofacial malformation is the orofacial cleft (e.g. cleft lip, cleft palate, or cleft lip with cleft palate). Nationally, approximately 1 in 1,000 babies are born each year with cleft lip and 1 in 2,000 babies are born with cleft palate.<sup>155</sup> In Connecticut, the rate of cleft lip and/or cleft palate is approximately 1 in 2,200.<sup>156</sup> This ranks cleft lip/palate fourth among birth defects in Connecticut. However, cleft lip/palate prevalence rates in Connecticut are considerably lower than national rates.

In its national database, Ingenix Consulting found no members in Connecticut who received the mandated

<sup>155</sup> Canfield MA, Honein MA, Yuskiv N, et al. 2006. National estimates and race/ethnic-specific variation of selected birth defects in the United States, 1999-2001. Birth Defects Research Part A *Clinical Molecular Teratology* 76: 747-56.

<sup>156</sup> Galvin JR, Gyle N. 2007. Oral Health in Connecticut. Connecticut Department of Public Health. Available at: [http://www.ct.gov/dph/lib/dph/oral\\_health/pdf/oral\\_health\\_in\\_ct.pdf](http://www.ct.gov/dph/lib/dph/oral_health/pdf/oral_health_in_ct.pdf). Accessed on July 20, 2010.

benefit. The five members with craniofacial disorders located in the database had orthodontic treatment at an average cost of \$1,664 per year.<sup>157</sup>

***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***

This mandate covers only individuals 18 and under. There may be rare occurrences when an individual is “dually-eligible.”

***Public Programs Administered by Charities***

The Cleft Palate Foundation provides a variety of services for parents of children born with craniofacial abnormalities, including a toll-free phone line for parents seeking basic information, referrals to medical professionals and support groups, as well as scholarships for “Students With Craniofacial Differences.”<sup>158</sup> Additionally, the Foundation recommends several non-profit organizations to parents seeking financial assistance for treatment of craniofacial abnormalities, including the Easter Seal Society and the March of Dimes.<sup>159</sup> However, the Cleft Palate Foundation does not provide direct treatment or funding for treatment of craniofacial disorders. Other charitable programs such as Smile Train and Thousand Smiles Foundation provide craniofacial surgeries but focus on offering services to children in developing countries.<sup>160,161</sup>

***Public Programs Administered by Public Schools***

No information was found that would indicate public schools would provide funding for orthodontics related to craniofacial disorders.

***The Department of Public Health (DPH)***

No information was found regarding the availability of funding or other resources for orthodontics related to craniofacial disorders through the Connecticut Department of Public Health. There is general information and data related to cleft lip, cleft palate and other birth defects on the DPH website.<sup>162</sup>

***Municipal Health Departments***

No information was found regarding the availability of funding for orthodontics related to craniofacial disorders through local and municipal health departments in Connecticut.

***The Department of Social Services (DSS)***

Medicaid covers many different medically necessary (not cosmetic) orthodontic procedures for the treatment of craniofacial disorders as recognized by the American Cleft Palate-Craniofacial Association (ACPA), an organization which serves children and adults with cleft lip, cleft palate, and craniofacial anomalies.<sup>163</sup> The amount covered by Medicaid varies based upon the exact procedure or service. DSS produces an annual list

<sup>157</sup> See Appendix II: Ingenix Consulting Actuarial and Economic Report, page 24.

<sup>158</sup> The Cleft Palate Foundation. 2010. Quick Links. Available at: <http://www.cleftline.org/>. Accessed on July 20, 2010.

<sup>159</sup> *Ibid.*

<sup>160</sup> The Smile Train. 2010. Available at: [www.smiletrain.org](http://www.smiletrain.org). Accessed on July 20, 2010.

<sup>161</sup> Thousand Smiles Foundation. 2010. Available at: <http://www.thousandmiles.org/>. Accessed on July 20, 2010.

<sup>162</sup> Galvin JR, Gyle N. 2007. Oral Health in Connecticut. Connecticut Department of Public Health. Available at: [http://www.ct.gov/dph/lib/dph/oral\\_health/pdf/oral\\_health\\_in\\_ct.pdf](http://www.ct.gov/dph/lib/dph/oral_health/pdf/oral_health_in_ct.pdf). Accessed on July 20, 2010.

<sup>163</sup> American Cleft Palate-Craniofacial Association (ACPA). 2010 Available at: <http://www.acpa-cpf.org/whoware/>. Accessed on July 20, 2010.

that specifies the maximum permissible cost reimbursements (“ceiling”) per specific craniofacial procedure.<sup>164</sup> Medicaid clients are not subject to any co-pays or coinsurance for medically necessary craniofacial procedures performed by Medicaid-participating physicians.

***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 of orthodontics related to craniofacial disorders in fully-insured group and individual health insurance plans as of October 1, 2003.<sup>165</sup> 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 six insurers/MCOs domiciled in Connecticut shows that 69 percent of members in their self-funded plans have benefits at least equal to the coverage required in fully-insured plans.

***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 children enrolled in fully-insured group and individual health insurance plans. Sixty-nine percent of members in self-funded plans have coverage for the benefit. Medicaid also covers orthodontics for children with craniofacial disorders. The cost of orthodontic treatment for those with craniofacial disorders can range from roughly \$1,500 to \$8,000 depending on the amount of work required which is a substantial financial burden for most families.<sup>166</sup>

***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 of orthodontics related to craniofacial disorders is required to be included in fully-insured group and individual insurance plans purchased 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. Due to the high cost of the mandated services, in the absence of an insurance mandate, it is likely that there would be substantial cost burdens for affected patients and families.

***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 level of demand for appropriate care for craniofacial disorders from the general public and providers has been well established. The American Cleft Palate Craniofacial Association developed a protocol for the treatment of persons with oral cleft.<sup>167</sup> The protocol endorsed a team approach to coordinated care including orthodontists. The Cleft Palate Foundation (CPF) which was founded in 1973 by the American Cleft Palate Craniofacial Association has become the public service arm of the professional association and provides assistance including support and referrals.

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<sup>164</sup> DSS Provider Fee Schedule: Dental Fee Schedule, Specifically Procedure Codes 21193, 21194, 21210, 21215, 21230, 21260, 21270, 21275, 21280, 21431-21435, 40700-40761, 42200-42225, 42810 and 42815. Available at: <https://www.ctdssmap.com/CTPortal/Provider/Provider%20Fee%20Schedule%20Download/tabId/52/Default.aspx>. Accessed on March 23, 2010.

<sup>165</sup> CONNECTICUT GENERAL STATUTES. Revised January 1, 2010. § 38A-490C (individual insurance policies); § 38A-516C (group insurance policies).

<sup>166</sup> See Appendix II, Ingenix Consulting Actuarial and Economic Report

<sup>167</sup> American Cleft Palate-Craniofacial Association (ACPA). 2000. Parameters for evaluation and treatment of patients with cleft lip/palate or other craniofacial anomalies. Available at: <http://www.acpa-cpf.org/teamcare/parameters00rev.pdf>. Accessed on July 14, 2010.

**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.***

Organizations such as Cleft Advocate and the Association of Independent Craniofacial Advocates provide information on a variety of ways to advocate for insurance coverage related to craniofacial disorders. These organizations host websites and other forums to disseminate information on pending federal and state legislation, ways to contact U.S. and State elected officials (including sample letters), and guidance on navigating through the healthcare system.

One health professional associated with treatment of craniofacial disorders, one representative of an advocacy organization for children with craniofacial disorders and one parent of a child with craniofacial disorder provided comments 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 February 2003.<sup>168</sup>

**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 (NAIC), as of August 2008, eleven states other than Connecticut had mandates regarding treatment of craniofacial abnormalities in children.<sup>169</sup> The language of these mandates varies widely, ranging from mandatory coverage of orthodontic treatments<sup>170</sup> or speech therapy<sup>171</sup> to broadly mandating the provision of medically necessary care for individuals with cleft lip or palate.

Supplemental research discovered three other mandates: (a) Delaware, which mandates that managed care organizations provide access to specialty pediatric outpatient centers for treatment of cleft lip and palate as determined to be medically necessary,<sup>172</sup> (b) Pennsylvania, which mandates coverage for the necessary care and treatment of medically diagnosed congenital defects and birth abnormalities,<sup>173</sup> and (c) California, which mandates health benefits for oral cleft repair.<sup>174</sup>

Table I.5.1 lists the states with health insurance mandates that address craniofacial disorders.<sup>175</sup>

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<sup>168</sup> Connecticut General Assembly. Report on Bills Favorably Reported By Committee. Public Health Committee. SB-1. February 25, 2003.

<sup>169</sup> National Association of Insurance Commissioners. Compendium of State Laws on Insurance Topics. 2010. "Craniofacial Abnormalities."

<sup>170</sup> Maryland Insurance Code §15-818; Louisiana Revised Statutes §22:215.8; Virginia Code § 38.2-3411

<sup>171</sup> Florida Statutes. §§ 627.64193; 627.66911; 641.31

<sup>172</sup> Delaware Division of Public Health, Regulation 69.4; Moon M, Cowdry RW. 2008. Study of Mandated Health Insurance Services: A comparative evaluation. Maryland Health Care Commission. Available at: [http://mhcc.maryland.gov/health\\_insurance/mandated\\_1207.pdf](http://mhcc.maryland.gov/health_insurance/mandated_1207.pdf). Accessed on July 16, 2010.

<sup>173</sup> Pennsylvania Statutes 40 P.S. 772; Moon M, Cowdry RW. 2008. Study of Mandated Health Insurance Services: A comparative evaluation. Maryland Health Care Commission. Available at: [http://mhcc.maryland.gov/health\\_insurance/mandated\\_1207.pdf](http://mhcc.maryland.gov/health_insurance/mandated_1207.pdf). Accessed on July 16, 2010.

<sup>174</sup> California Insurance Code § §10128.3; 10123.88

<sup>175</sup> National Association of Insurance Commissioners. Compendium of State Laws on Insurance Topics. 2010. "Craniofacial Abnormalities.;" Council for Affordable Health Insurance. Available at: [www.cahi.org](http://www.cahi.org); Maryland Health Care Commission. 2008. Study of Mandated Health Insurance Services: A Comparative Evaluation; California Insurance Code § §10128.3; 10123.88; Delaware Division of Public Health Reg. 69.4; Pennsylvania Statutes 40 P.S. 772

<b>Table I.5.1: Craniofacial Abnormality Mandates in the States</b>	
<b>State</b>	<b>Summary</b>
California	Health benefits for oral cleft repair.
Colorado	There shall be no age limit on benefits for cleft lip and cleft palate and other birth abnormalities. Care and treatment shall include medically necessary procedures.
Connecticut	Cover medically necessary orthodontic processes and appliance for the treatment of craniofacial abnormalities of individuals 18 years of age and younger, if the processes are recognized by the American Cleft Palate-Craniofacial Association; covers group and individual policies.
Delaware	Managed care organizations must have a policy assuring access to specialty pediatric outpatient centers for treatment of cleft lip and palate as determined to be medically necessary.
Florida	A health insurance policy that covers a child under the age of 18 must provide coverage for treatment of cleft lip and cleft palate for the child, including medical, dental, speech therapy, etc. prescribed by a physician.
Indiana	Must include benefits for inpatient and outpatient expenses arising from medical and dental treatment of cleft palate and cleft lip.
Louisiana	Cleft lip and cleft palate covered, including related needs such as orthodontics, speech therapy, etc.
Maryland	Cleft palate and cleft lip inpatient and outpatient benefits arising from orthodontics, oral surgery, etc. shall be covered.
Minnesota	Cleft palate and cleft lip coverage required for expenses arising from medical and dental expenses up to limiting age for coverage of dependents.
North Carolina	Must cover all necessary treatment and care for individuals with cleft lip and cleft palate.
Pennsylvania	Mandatory coverage for the necessary care and treatment of medically diagnosed congenital defects and birth abnormalities.
South Carolina	Must provide medically necessary care and treatment for cleft lip and cleft palate.
Texas	Must cover reconstructive surgery for craniofacial abnormalities caused by congenital defect, trauma, disease, etc. Applies to children under the age of 18.
Vermont	Must cover surgical and nonsurgical treatments for musculoskeletal disorders affecting the face and neck caused by congenital defect, trauma, disease, etc.
Virginia	Must cover inpatient and outpatient dental, oral surgical, and orthodontic services that are medically necessary for cleft lip, cleft palate and ectodermal dysplasia.

***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.<sup>176</sup> 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 orthodontic processes

<sup>176</sup> 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 on May 7, 2010.

and appliances for the treatment of craniofacial disorders.

One major analysis of the financial impact of mandated coverage of orthodontics related to craniofacial disorders was found. The Maryland Health Care Commission conducted a review of the impact of Maryland's craniofacial abnormality mandate, which includes orthodontics.<sup>177</sup> The report does not include information related to social impact. In terms of financial implications, it concludes that the full cost of mandated craniofacial abnormality coverage equaled 0.0 percent of the insurance premium.<sup>178</sup> Additionally, the report found voluntary compliance in "Almost All" self-funded plans in Maryland.<sup>179</sup>

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.***

Medically necessary orthodontic processes and appliances are generally recommended for children who have undergone surgery to correct craniofacial disorders. There are no other treatments, methods or procedures available that could substitute for orthodontics.

***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.***

Medically necessary orthodontic processes and appliances for the treatment of craniofacial disorders fulfill a medical need. In addition to having improperly fused lip and/or palate, children with orofacial cleft typically have some degree of malformation of the jaw, gum, and teeth requiring orthodontic care.<sup>180</sup> Orthodontists may provide presurgical orthopedics, monitor facial growth and dental eruption, position toothbearing bony segments as a framework for surgery, and correct occlusal abnormalities.<sup>181</sup> Inadequate orthodontic care can lead to "unstable or malpositioned oral structures, premature tooth loss, functional deficiencies in chewing, swallowing, respiration, speech and poor esthetics."<sup>182</sup>

Orthodontic procedures and appliances may also contribute to meeting broader social needs. Several studies have investigated the relationship of craniofacial disorders on the psychosocial status of individuals with this disorder. Speech problems and concerns about aesthetics, issues that can be addressed through proper orthodontic treatment, are thought to contribute to psychological challenges among children, adolescents, and young adults with craniofacial disorders.<sup>183</sup> An investigation of maternal perceptions of quality of life of their children (2-12 years old) with craniofacial disorders found that quality of life decreased significantly with the presence of severe speech problems.<sup>184</sup> However the study did not have a control group

<sup>177</sup> Maryland Insurance Code § 15-818

<sup>178</sup> Moon M, Cowdry RW. 2008. Study of Mandated Health Insurance Services: A comparative evaluation. Maryland Health Care Commission. Available at: [http://mhcc.maryland.gov/health\\_insurance/mandated\\_1207.pdf](http://mhcc.maryland.gov/health_insurance/mandated_1207.pdf). Accessed on July 16, 2010.

<sup>179</sup> *Ibid.*

<sup>180</sup> Gillette Children's Specialty Healthcare. 2003. A Pediatric Perspective. Volume 12, Number 1. Available at: [www.gillettechildrens.org/fileUpload/Vol12No1.pdf](http://www.gillettechildrens.org/fileUpload/Vol12No1.pdf). Accessed on March 4, 2010.

<sup>181</sup> Lewis CW, Ose M, Aspinall C, et al. 2005. Community orthodontists and craniofacial care: results of a Washington State survey. *Cleft Palate-Craniofacial Journal* 42(5): 521-525.

<sup>182</sup> *Ibid.*

<sup>183</sup> Wehby, GL, Cassell CH. 2009. The impact of orofacial clefts on quality of life and health care use and costs. *Oral Diseases* 16: 3-10.

<sup>184</sup> Damiano P, Tyler M, Romitti P, et al. 2007. Health-related quality of life among preadolescent children with oral cleft. *Pediatrics* 120: 283-290.

of unaffected children. A comparison of health related quality of life (HRQL) of a small sample of adults with bilateral CLP and unaffected adults found higher HRQL among adults who were satisfied with their appearance.<sup>185</sup> Researchers surveyed 126 Norwegian adults with repaired orofacial cleft to investigate social and psychological adjustment. The researchers found no significant differences in employment or education when compared to a control group.<sup>186</sup> However, the individuals with orofacial cleft reported lower income, lower marriage rates, and older age at marriage.

Orthodontics for craniofacial disorders is generally a high-cost medical expense that few individuals could afford on an out-of-pocket basis, thus the benefit is consistent with the role of health insurance and the concept of managed care.

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

The orthodontic processes and appliances related to craniofacial disorders as defined in the statute are narrow in scope. It is therefore difficult to anticipate any comparable mandated benefit for similar diseases, illnesses or conditions.

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

Insurers and MCOs may cut costs by eliminating or restricting access to, or placing limits on other non-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. The extremely low volume of delivery of the benefit in Connecticut would suggest little to no impact on the availability of other benefits currently offered.

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

Due to the relatively low number of children requiring orthodontics related to craniofacial disorders, it is not anticipated that employers will shift to self-funded plans as a result of this single proposed 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”). 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.

Six insurers/MCOs provided information about their self-funded plans, which represents an estimated 98 percent of the total population in self-funded plans in Connecticut. These six insurers/MCOs report that

<sup>185</sup> Oosterkamp BC, Dijkstra PU, Rimmelink HJ, et al. 2007. Satisfaction with treatment outcome in bilateral cleft lip and palate patients. *International Journal of Oral and Maxillofacial Surgery* 36: 890-895.

<sup>186</sup> Ramstad T, Ottem E, Shaw WC. 1995. Psychosocial adjustment in Norwegian adults who had undergone standardized treatment of complete cleft lip and palate. *Scandinavian Journal of Plastic and Reconstructive Surgery and Hand Surgery* 29: 251-257.

68.5 percent of members in their self-funded plans have coverage for the mandated services.

A mandated benefits review conducted in Maryland found that “almost all” employers with self-funded plans provide benefits that comply fully with the mandate requirement for benefits for treatment of cleft lip and cleft palate (which includes orthodontics).<sup>187</sup>

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

The orthodontic treatment associated with craniofacial disorders is a current benefit that has been included in the state employee health insurance and health benefits plans since October 2003. 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<sup>188</sup> 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 employees 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 health insurance plans will total \$39,440 in 2010.<sup>189</sup>

***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.***

Orthodontics processes and appliances have been found to be effective in correcting teeth misalignment, malocclusion, etc.<sup>190,191</sup> Not surprisingly, the benefit of the treatment increases with the experience of the orthodontist and patient cooperation. There are few inherent risks related to orthodontic treatment of craniofacial disorders. However, some patients may experience root resorption, loss of periodontal support, decalcification, and soft tissue damage.<sup>192</sup>

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<sup>187</sup> Moon M, Cowdry RW. 2008. Study of Mandated Health Insurance Services: A comparative evaluation. Maryland Health Care Commission. Available at: [http://mhcc.maryland.gov/health\\_insurance/mandated\\_1207.pdf](http://mhcc.maryland.gov/health_insurance/mandated_1207.pdf). Accessed on July 16, 2010.

<sup>188</sup> Personal communication. Scott Anderson, State of Connecticut Comptroller's Office. September 14, 2010.

<sup>189</sup> 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.

<sup>190</sup> O'Brien, K. et al. 2003. Effectiveness of early orthodontic treatment with the Twin-block appliance: A multicenter, randomized, controlled trial. Part 1: Dental and skeletal effects. *American Journal of Orthodontics and Dentofacial Orthopedics* 124: 234-43.

<sup>191</sup> Bernas AJ, Banting DW, Short LL. 2007. Effectiveness of Phase I orthodontic treatment in an undergraduate teaching clinic. *Journal of Dental Education* 71(9): 1179-1186.

<sup>192</sup> Mitchell, L. 2007. *An Introduction to Orthodontics*. Oxford University Press: London.

## 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.***

Due to the very low incidence of craniofacial disorders among children in Connecticut this mandate is not expected to materially alter the availability of orthodontics or its cost 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. For further information, please see Appendix II: Ingenix Consulting Actuarial and Economic Report, page 24.

***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.***

Medically necessary orthodontic processes and appliances related to craniofacial disorders would seem to increase their appropriate use if insurers did not include such coverage in the absence of the mandate. As noted, it is not uncommon for mandated benefits to be included in self-funded plans that are not subject to state benefit mandates. For those who use out-of-pocket funds to cover orthodontics related to craniofacial disorders or access funds from other sources, a mandated benefit may not increase appropriate use. Due to the low incidence of craniofacial disorders it is highly unlikely that inappropriate use (overutilization) is occurring.

***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.***

Medically necessary orthodontics related to craniofacial disorders is required for treatment to be effective for children who have undergone surgeries for craniofacial disorders. Such orthodontics does not serve as an alternative for any other treatment, service or equipment, supplies or drugs. Lack of any medically necessary care often leads to complications and more extensive treatment that is more expensive than the care forgone at the earlier treatment opportunity.

***4. The methods that will be implemented to manage the utilization and costs of the 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. Overall cost impact is limited due to the low incidence of craniofacial disorders in Connecticut.

***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 medical cost of the mandate is spread to all insureds in group plans, medical costs

are estimated to be \$0.02 PMPM and retention costs are estimated to be \$0.00 in 2010. Thus the total effect on insurance premiums is estimated at \$0.02 PMPM in 2010. Insurance coverage for the mandated benefit may be reasonably expected to increase group health insurance premiums accordingly, that is, \$0.24 per year per insured.

**Individual policies:** When the medical cost of the mandate is spread to all insureds in individual policies, medical costs are estimated to be \$0.03 PMPM and retention costs are estimated to be \$0.01 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$0.04 PMPM in 2010. Insurance coverage for the mandated benefit may be reasonably expected to increase individual health insurance premiums accordingly, that is, \$0.48 per year per insured.

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

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

Medically necessary orthodontic processes and appliances are required for the treatment plan to be effective for children who have undergone surgery for craniofacial disorders and there is no alternative to the treatment.

***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 of insurance premiums and cost sharing. Actuarial analysis of claims data received from insurers/MCOs in Connecticut shows an expected cost in 2010 of \$381,009 for orthodontics related to craniofacial disorders for Connecticut residents covered by fully-insured group and individual health insurance plans.

Medically necessary orthodontic processes and appliances for the treatment of craniofacial disorders may provide potential benefits or savings to insurers and employers. In addition to having improperly fused lip and/or palate, children with craniofacial disorders typically have some degree of malformation of the jaw, gum, and teeth requiring orthodontic care.<sup>193</sup> Teeth may be missing, abnormally shaped, or out of position around the cleft.<sup>194</sup> The role of the orthodontist in the treatment of orocleft is to provide presurgical orthopedics, to monitor facial growth and dental eruption for appropriate timing of surgical procedures, to position toothbearing bony segments as a frame work for surgery, and to correct debilitating occlusal abnormalities.<sup>195</sup> Orthodontic treatment can improve a patient's bite and jaw growth allowing for more efficient dental occlusion for chewing and reducing future problems such as temporomandibular joint disorder (TMJD). In addition, orthodontics can improve teeth alignment allowing for proper teeth cleaning

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<sup>193</sup> Gillette Children's Specialty Healthcare. 2003. A Pediatric Perspective. Volume 12, Number 1. Available at: [www.gillettechildrens.org/fileUpload/Vol12No1.pdf](http://www.gillettechildrens.org/fileUpload/Vol12No1.pdf). Accessed on March 4, 2010.

<sup>194</sup> *Ibid.*

<sup>195</sup> Lewis CW, Ose M, Aspinall C, et al. 2005. Community orthodontists and craniofacial care: results of a Washington State survey. *Cleft Palate-Craniofacial Journal* 42(5): 521-525.

and reducing cavities and gingivitis. Feeding, speech development and appearance are also improved with orthodontics.<sup>196</sup>

***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 orthodontics related to craniofacial disorders on the cost of health care for small employers. Although small employers may be more sensitive to premium increases than other employers, the estimated low impact of the mandate on insurance premiums in fully-insured group plans (\$0.02 PMPM) suggests little difference in effects among different sized employers.

For further discussion of the differential effect of health insurance 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 became effective in 2003, 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 incidence of orthodontics related to craniofacial disorders 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. Actuarial analysis of claims data received from insurers/MCOs in Connecticut shows an expected cost in 2010 of \$460,045 for orthodontics related to craniofacial disorders 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.

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<sup>196</sup> Flint PW, Haughey BH, Lund VJ, et al. 2010. Cummings *Otolaryngology: Head and Neck Surgery*, 5<sup>th</sup> Ed. Mosby Elsevier: Philadelphia.



# Volume I

## Chapter 6

### **In-patient, Outpatient, or One-Day Dental Services**

Review and Evaluation of Connecticut Statute  
Chapter 700, § 38a-517a and § 38a-491a

Coverage of In-patient, Outpatient or One-Day Dental Services in Certain Instances

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## 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 group and individual health insurance policies. The review 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-517a and 38a-491a state that each group or individual health insurance policy...

...shall provide coverage for general anesthesia, nursing and related hospital services provided in conjunction with in-patient, outpatient or one-day dental services if the following conditions are met:

(1) The anesthesia, nursing and related hospital services are deemed medically necessary by the treating dentist or oral surgeon and the patient's primary care physician in accordance with the health insurance policy's requirements for prior authorization of services; and

(2) The patient is either (A) determined by a licensed dentist, in conjunction with a licensed physician who specializes in primary care, to have a dental condition of significant dental complexity that it requires certain dental procedures to be performed in a hospital, or (B) a person who has a developmental disability, as determined by a licensed physician who specializes in primary care, that places the person at risk.

(b) The expense of such anesthesia, nursing and related hospital services shall be deemed a medical expense under such health policy and shall not be subject to any limits on dental benefits under such policy.

The mandate requires health insurers to cover the facility, nursing, and anesthesia costs for those who need to have dental procedures performed in a hospital inpatient or outpatient setting under general anesthesia. Dental charges are covered for under a separate dental policy or rider or out of pocket. Only the facility costs apply to the medical insurance.

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). Claims data shows that very few individuals covered undergo the treatment and it is reserved for those who cannot tolerate dental treatment without general anesthesia.

### *Current coverage*

This mandate went into effect on January 1, 2000 (P.A. 99-284). Most adults who receive general anesthesia for dental care in Connecticut are covered by Medicaid; the majority of children are covered by private insurance.

### *Premium impact*

**Group plans:** On a 2010 basis, medical cost is estimated to be \$0.05 per member per month (PMPM). Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services in 2010 in group plans is \$0.06 PMPM, which is 0.02 percent of estimated total costs in group plans. Estimated cost sharing in 2010 in group plans is \$0.01 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 \$0.19 PMPM. Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services in 2010 in individual policies is \$0.24 PMPM, which is approximately 0.1 percent of estimated total costs in individual policies. Estimated cost sharing in 2010 in individual policies is \$0.02 PMPM. Individual policies data is less credible than group plans data primarily due to small sample sizes.

### *Self-funded plans*

Five 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 59 percent of members in their self-funded plans have coverage for the mandated 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**

Untreated dental disease frequently affects quality of life. It causes pain; difficulty eating, speaking and sleeping; and affects social behavior. In most cases dental treatment improves quality of life.<sup>197</sup> Most children and adults are able to undergo dental treatment in conventional settings; however some patients are too young, have underlying medical conditions that would make standard outpatient dental care unsafe, or fail to respond to the usual behavior management techniques, including sedation. Dental treatment under general anesthesia is a common approach in these situations. In excess of five million persons annually in the United States receive general anesthesia for dental care and 16 percent of all general anesthetics administered in the U.S. annually are related to dental care.<sup>198</sup> Many children with acquired or developmental disabilities who receive dental care under general anesthesia are privately insured; almost all of the adults with acquired or developmental disabilities who receive such care are covered by Medicaid.<sup>199</sup>

Common indications for dental care under general anesthesia are the extensive need of dental treatments, dental fear, problems related to general health, conditions following extensive orofacial or dental trauma, and noncooperation due to the age of the patient or presence of a serious mental disease, dementia, or acquired or developmental disability.<sup>200</sup> Treatment under general anesthesia for these types of patients is recommended because treatment can be completed during a single visit and under minimal duress to the patient, parent, and dentist.

The majority of pediatric dental procedures completed under general anesthesia are surgical or restorative

<sup>197</sup> Low W. Tan S. Schwartz S. 1999. The effect of severe caries on the quality of life in young children. *Pediatric Dentistry* 21(6): 325-6.

<sup>198</sup> Malamed SF. 2003. *Sedation: A Guide to Patient Management*. Mosby: St. Louis, MO.

<sup>199</sup> Personal communication. Steven M. Lepowsky, DDS. April 29, 2010.

<sup>200</sup> Savanheimo N, Vehkalahti MM. 2008. Preventive aspects in children's caries treatments preceding dental care under general anesthesia. *International Journal of Paediatric Dentistry* 18: 117-123.

in nature. British research found that 88.7 percent of procedures completed under general anesthesia involved removal of impacted, carious and supernumerary teeth or exposure of impacted teeth and soft tissue surgery.<sup>201</sup> In the adult population with acquired or developmental disabilities, all types of procedures are completed; however, the vast majority are surgical or restorative.<sup>202</sup> Multi-step procedures, such as orthodontia and prosthodontics are rare.<sup>203</sup>

The risks associated with general anesthesia are well-known, including overdose, allergic reaction, hypotension, hypertensive episode, cardiac dysrhythmias, myocardial infarction, airway obstruction, laryngospasm, aspiration of foreign material, hyperventilation, respiratory depression, seizures, hypoglycemia, and syncope.<sup>204</sup> The risks of general anesthesia are generally less than the risks of continued neglect of dental care and when general anesthesia is recommended other less invasive alternatives have been attempted unsuccessfully.<sup>205</sup> Both the Association of Pediatric Dentistry and the Special Care Dentistry organization publish guidelines related to the practice of general anesthesia for dental and oral health care.

Children undergoing dental rehabilitation under general anesthesia commonly experience postoperative symptoms such as pain, agitation, need for analgesics, and sleepiness.<sup>206</sup> However, children's oral health-related quality of life improved after treatment under general anesthesia.<sup>207</sup> Parents and guardians of children who receive dental care under general anesthesia also report observed improvement in their child's quality of life, including improvement in pain and abilities to eat and sleep.<sup>208</sup>

Typical costs for general anesthesia include anesthesiologist professional fees and a facilities charge that includes pre-operative nursing, use of the operating room, and post-anesthesia care unit (PACU) services. For a Medicaid patient in Connecticut, these services cost approximately \$8,000 per occurrence.<sup>209</sup> Dental charges vary depending on the procedures completed. Other invasive medical procedures are often scheduled concurrently for efficient use of resources, the most common being gynecological in the Medicaid population.<sup>210</sup>

Early assessment of high-carries risk and primary prevention are keys in reducing the number of patients requiring dental rehabilitation under general anesthesia. The practice of dental care under general anesthesia for such patients is currently effective in managing such needs.

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<sup>201</sup> Foley J. 2008. Paediatric minor oral surgery procedures under inhalation sedation and general anesthetic: a comparison of variety and duration of treatment. *European Archives of Paediatric Dentistry* 9(1): 46-50.

<sup>202</sup> Personal communication. Steven M. Lepowsky, DDS. April 29, 2010.

<sup>203</sup> *Ibid.*

<sup>204</sup> Malamed SF. 2003.

<sup>205</sup> Personal communication. Steven M. Lepowsky, DDS.

<sup>206</sup> Needleman HL, Harpavat S, Wu S, et al. 2008. Postoperative pain and other sequelae of dental rehabilitations performed on children under general anesthesia. *Pediatric Dentistry* 30: 111-121.

<sup>207</sup> Klaasen MA, Veerkamp JSJ, Hoogstraten J. 2009. Young children's oral health-related quality of life and dental fear after treatment under general anaesthesia: a randomized controlled trial. *European Journal of Oral Sciences* 117: 273-278.

<sup>208</sup> Acs G, Pretzer S, Foley M, et al. 2001. Perceived outcomes and parental satisfaction following dental rehabilitation under general anesthesia. *Pediatric Dentistry* 23(5): 419-423.

<sup>209</sup> Personal communication. Steven M. Lepowsky, DDS.

<sup>210</sup> *Ibid.*

### 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:

- Decision making
- Dental care
  - Psychology
  - Methods
  - For children
  - Legislation and jurisprudence
- Delayed diagnosis
- Attitude towards health
- Cost of illness
- Cost savings
- Cost- benefit analysis
- Health services accessibility
- Anesthesia
  - General
  - Dental
  - Dental methods
- Sedation
- Tooth diseases
- Mouth diseases
- Insurance coverage
- Dental procedures

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

CPHHP staff consulted with clinical faculty from the University of Connecticut School of Dental 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 and received 2007 and 2008 claims data from insurance companies and MCOs domiciled in Connecticut. Six insurers/MCOs provided inpatient dental claims data for their fully-insured group and individual plan participants. Five insurers/MCOs that cover approximately 47 percent of the population in

self-funded plans in Connecticut provided information about inpatient dental 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 service is utilized by a significant portion of the population.*

Approximately 360 adults and 480 children receive general anesthesia for dental care in Connecticut hospitals each year.<sup>211</sup> (Very little dental care under general anesthesia takes place in out-patient settings or same day surgery centers in Connecticut).<sup>212</sup> Most of the adults are covered by Medicaid; the majority of children are covered by private insurance. The estimated percentage of Connecticut residents under age 65 in fully insured group and individual health insurance plans is 46.6 percent.<sup>213</sup> Thus, the estimated number of children who receive general anesthesia for dental care covered by insurance plans subject to the state mandate is 224. Because most adults who receive dental care under general anesthesia are covered by Medicaid, an estimate of the number of adults receiving the mandated benefit is not available.

For further information, please see Appendix II: Ingenix Consulting Actuarial and Economic Report, page 9.

### *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**

Medicare generally does not cover routine dental care.<sup>214</sup> However, in 1980, Congress authorized an amendment to the Social Security Act,<sup>215</sup> which authorized coverage under Medicare Part A for “inpatient hospital services in connection with the provision of such dental services if the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services.”<sup>216</sup>

In practice, the amendment authorized Medicare Part A to pay for certain dental services performed in a hospital, such as post-accident jaw reconstruction and oral examinations in advance of kidney or heart operations. Additionally, Medicare Part A may cover hospital stays for emergency or complicated dental

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<sup>211</sup> Personal Communication. Steven M. Lepowsky, DDS. April 29, 2010. Based on scheduling capacity at hospitals in Connecticut that perform dental care under general anesthesia.

<sup>212</sup> *Ibid.*

<sup>213</sup> 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 on October 8, 2010.

<sup>214</sup> Medicare Coverage Guidelines for Dental Service (Connecticut).

<sup>215</sup> 42 U.S.C.A. § 1395y.

<sup>216</sup> Centers for Medicare and Medicaid Services (CMS) Overview of Medicare Dental Coverage. Available at: <http://www.cms.hhs.gov/MedicareDentalCoverage>

procedures even when the dental care itself is not covered.<sup>217</sup>

### ***Public Programs Administered by Charities***

No information was found that would indicate public programs administered by charities provide the mandated benefit or funding for general anesthesia, nursing and related hospital services in conjunction with inpatient, outpatient and one-day dental services. The Connecticut State Dental Society organizes the “Connecticut Mission of Mercy” annually which serves the dental needs of many residents during the two-day event. The CSDA also organizes the “Give Kids a Smile” program—a one-day event that provides dental care to underserved children. There is no indication that dental care under general anesthesia is provided at these events. Inquiries to several Federally Qualified Health Centers (FQHCs) in Connecticut showed that they do not provide dental services under general anesthesia.

### ***Public Programs Administered by Public Schools***

School-based and school-linked dental clinics provide oral health services to school-aged children; however, no information was found that would indicate public schools provide the mandated benefit or funding for general anesthesia, nursing and related hospital services in conjunction with inpatient, outpatient and one-day dental services.

### ***The Department of Public Health (DPH)***

No information was found regarding the availability of funding or other resources for general anesthesia, nursing and related hospital services in conjunction with inpatient, outpatient and one-day dental services through the Connecticut Department of Public Health. There is general information and data related to oral health on the DPH website.

### ***Municipal Health Departments***

No information was found regarding the availability of funding for or provision of general anesthesia, nursing and related hospital services in conjunction with inpatient, outpatient and one-day dental services through local and municipal health departments in Connecticut.

### ***The Department of Social Services (DSS)***

Medicaid provides coverage for a wide-range of dental services, from routine oral health procedures including x-rays and topical fluoride applications to more complicated procedures requiring hospitalization.<sup>218</sup> Coverage for the services of a dental anesthesiologist is also covered for most procedures otherwise covered by Medicaid.<sup>219</sup> Authorization by the Connecticut Dental Health Partnership<sup>220</sup> is often required either before or after services are rendered, depending upon the procedure.<sup>221</sup> The majority of adult patients with acquired or developmental disabilities who require dental care under general anesthesia are covered by Medicaid.<sup>222</sup>

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<sup>217</sup> *Ibid.*

<sup>218</sup> DSS Provider Fee Schedule: Dental Fee Schedule.

<sup>219</sup> *Ibid.*

<sup>220</sup> The Connecticut Dental Health Partnership (CTDHP) manages Connecticut’s publicly funded dental health care programs for HUSKY A, HUSKY B, Medicaid (Title XIX Fee-for-Service), and SAGA. [http://www.ctdhp.com/clients/client\\_faq.html](http://www.ctdhp.com/clients/client_faq.html).

<sup>221</sup> DSS Provider Fee Schedule: Dental Fee Schedule.

<sup>222</sup> Personal communication. Steven M. Lepowsky, DDS. April 29, 2010.

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

State of Connecticut law requires coverage for general anesthesia, nursing and related hospital services in conjunction with inpatient, outpatient and one-day dental services in fully-insured group and individual health insurance plans as of January 1, 2000.<sup>223</sup> 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 which represents an estimated 47 percent of the total population in self-funded plans in Connecticut shows that 59 percent of members in 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.***

Coverage is required and generally available for persons enrolled in fully-insured group and individual health insurance plans. Coverage is available to an estimated 59 percent of persons enrolled in self-funded plans; persons enrolled in fully-insured and self-funded group plans represent the majority of the insured population under age 65 in Connecticut.

Lack of dental insurance may be a barrier to some individuals who have insurance coverage for the mandated benefit but cannot afford to pay the costs of the dental procedures, which for a dental rehabilitation involving multiple restorations and/or extractions are not insignificant. In North Carolina, analysis of dental visits pre- and post-general anesthesia legislation showed a statistically significant increase in access to care for children needing dental care<sup>224</sup>

**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 general anesthesia, nursing and related hospital services in conjunction with inpatient, outpatient and one-day dental services is required to be included in fully insured group and individual policies 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. Due to the high cost of the mandated services, in the absence of an insurance mandate, it is likely that there would be substantial cost burdens on affected patients and families.

Further discussion of financial and socioeconomic effects of the mandated benefit may be found in Appendix II: Ingenix Consulting Actuarial and Economic Report, page 50.

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

Medical librarians and CPHHP staff found no published literature regarding the level of public demand or level of demand from providers for general anesthesia, nursing and related hospital services in conjunction with inpatient, outpatient and one-day dental services. There is evidence that parents and caregivers support general anesthesia for dental procedures as a means of improving oral-health quality of life for young children.<sup>225</sup> Dentists and facilities that provide the mandated services receive referrals from other dentists,

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<sup>223</sup> CONNECTICUT GENERAL STATUTES ANNOTATED § 38A-491A (individual insurance policies); § 38A-517A (group insurance policies).

<sup>224</sup> White HR, Lee JY, Rozier RG. 2008. The effects of general anesthesia legislation on operating room visits by preschool children undergoing dental treatment. *Pediatric Dentistry* 30(1): 70-75.

<sup>225</sup> Malden PE, Thomson WM, Jokovic A, et al. 2008. Changes in parent-assessed oral health-related quality of life among young children following dental treatment under general anaesthetic. *Community Dentistry and Oral Epidemiology* 36: 108-117.

therefore it follows that the provider demand exists at some level.

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

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 and when the statute was amended to remove an age restriction.<sup>226</sup>

There is evidence of demand for insurance coverage for general anesthesia dental care for persons covered under federal health insurance plans. For example, the federal health insurance program for U.S. military members and dependents includes coverage of general anesthesia for dental care for children age 5 or under and for patients with development, mental, or physical disabilities.<sup>227</sup>

Due to the high costs of the mandated services and the populations served (children and persons with acquired or developmental disabilities), in the absence of a mandate it would be expected that public demand and demand from providers for insurance coverage for the services would be high, at least among those aware of the need. 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 general anesthesia for dental services for children and persons with disabilities as described below.

**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, 24 states (including Connecticut) require policies in fully insured plans to cover general anesthesia and associated hospital charges related to dental care for certain populations.<sup>228</sup> The Council for Affordable Health Insurance reports that 30 states have coverage mandates for general anesthesia for dental care.<sup>229</sup> CPHHP researchers found evidence of the mandated benefit in 26 states in addition to Connecticut. For details, please see Table 1.6.1.

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<sup>226</sup> Connecticut General Assembly. Report on Bills Favorably Reported By Committee. Public Health Committee. HB-6704. April 1, 1999; Insurance and Real Estate Committee. SB-918. March 13, 2003.

<sup>227</sup> Office of the Secretary, Department of Defense. 2007. TRICARE: Changes included in the John Warner National Defense Authorization Act for fiscal year 2007; authorization of anesthesia and other costs for dental care for children and certain other patients. Final rule. *Federal Register* 72(185): 54353-54355.

<sup>228</sup> NAIC Compendium of State Laws on Insurance Topics. National Association of Insurance Commissioners. August 2008.

<sup>229</sup> 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](http://www.cahi.org/cahi_contents/resources/pdf/HealthInsuranceMandates2009.pdf). Accessed on May 6, 2010.

**Table I.6.1: States with Mandated Coverage of General Anesthesia and Hospital Charges Related to Dental Care**

State	Coverage
Arkansas	Anesthesia, nursing and related hospital procedures for dental services for a child under age 7 or developmentally disabled person.
California	General anesthesia and associated facility charges for dental procedures rendered in a hospital or surgery center when insured is under seven years of age, is developmentally disabled, or any person whose health is compromised and for whom general anesthesia is medically necessary, regardless of age.
Colorado	General anesthesia and associated hospital or facility charges when rendered in a hospital or outpatient surgical facility to a dependent child who has a physical, mental, or medically compromising position.
Florida	Policy which provides coverage for general anesthesia and hospitalization services shall not preclude such coverage in the safe delivery of necessary dental care provided to a covered person who is under 8 years of age and is determined to require necessary dental treatment in a hospital due to a significantly complex dental condition or a developmental disability.
Georgia	General anesthesia and associated hospital or ambulatory surgical facility charges in conjunction with dental care if such person is seven years of age or younger or is developmentally disabled.
Illinois	Charges incurred and anesthetics provided in connection with dental care provided in a hospital or ambulatory surgical center if the individual is a child under age 6, has a medical condition that requires such treatment, or is disabled.
Indiana	Coverage for anesthesia and hospital charges for dental care for an insured if the mental or physical condition of the insured requires dental treatment to be rendered in a hospital or an ambulatory outpatient surgical center.
Iowa	Coverage for general anesthesia and hospital or ambulatory surgical center charges related to dental care services provided to a child under five years of age when child requires necessary dental treatment in a hospital or ambulatory surgical center due to a dental condition or a developmental disability.
Kansas	General anesthesia and medical care facility charges for dental care provided to a child five years of age and under, or a person who is severely disabled, or a person has a medical or behavioral condition which requires hospitalization or general anesthesia when dental care is provided.
Kentucky	General anesthesia and hospitalization services in connection with dental procedures for children below the age of 9 years, persons with serious mental or physical problems, and persons with significant behavior problems.
Louisiana	Anesthesia and associated hospital charges when the mental or physical condition of the insured requires dental treatment to be rendered in a hospital setting.
Maine	General anesthesia for dental procedures rendered in a hospital when the clinical status or underlying medical condition requires it.
Maryland	General anesthesia and associated hospital or ambulatory facility charges in conjunction with dental care if the insured is 7 years of age or younger or is developmentally disabled.

**Table I.6.1: States with Mandated Coverage of General Anesthesia and Hospital Charges Related to Dental Care**

State	Coverage
Minnesota	Anesthesia and hospital charges for dental care to a child under age 5 or one who is severely disabled or one who has a medical condition and requires general anesthesia for dental care.
Mississippi	Anesthesia and associated facility charges when the mental or physical condition of the child or mentally handicapped adult requires dental treatment to be rendered under physician-supervised general anesthesia in a hospital setting, surgical center or dental office.
Missouri	General anesthesia and hospital charges for dental care provided to a child under the age of five, a person who is severely disabled, or a person who has a medical or behavioral condition which requires hospitalization or general anesthesia when dental care is provided.
Nebraska	Reasonable cost of hospitalization and general anesthesia in order for a covered person to safely receive dental care if he or she is under 8 years old or is developmentally disabled.
Nevada	General anesthesia and associated care if the child has a physical, mental or medically compromising condition.
New Hampshire	Dental procedures for child under the age of 6 who has dental condition of sufficient complexity to require certain procedures to be conducted in surgical facility or hospital.
New Jersey	General anesthesia and hospitalization charges associated with dental services for any person who is severely disabled or a child five years or younger.
North Carolina	Anesthesia and hospital or facility charges for services performed in a hospital or ambulatory surgical facility in connection with dental procedures for children below the age of nine years, persons with serious mental or physical conditions, and persons with significant behavioral problems.
Oklahoma	Anesthesia expenses and hospital and ambulatory surgical center expenses associated with any medically necessary dental procedure when provided to a covered person who is severely disabled or a minor eight years of age or under, and who has a medical or emotional condition which requires hospitalization or general anesthesia for dental care.
South Dakota	Anesthesia and hospital charges for dental care provided to a covered person who: (1) Is a child under age five; or (2) Is severely disabled or otherwise suffers from a developmental disability as determined by a licensed physician which places such person at serious risk.
Virginia	Medically necessary general anesthesia and hospitalization or facility charges for dental care provided to a covered person who is under the age of five, or is severely disabled, or has a medical condition and requires admission to a hospital or outpatient surgery facility and general anesthesia for dental care treatment.
Washington	Anesthesia in conjunction with dental procedures performed in a hospital or ambulatory service center when medically necessary.
Wisconsin	Hospital or ambulatory surgery center charges incurred, and anesthetics provided, in conjunction with dental care that is provided to a child under the age of 5, or to an individual who has a chronic disability or a medical condition that requires hospitalization or general anesthesia for dental care.

## ***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.<sup>230</sup> Internet searches and telephone inquiries found several studies from state agencies and public organizations related to the social impact of mandated insurance coverage for general anesthesia, nursing and related hospital services in conjunction with inpatient, outpatient and one-day dental services.

**Maine:** In May 2001, the Maine Bureau of Insurance reviewed LD 403, *An Act to Provide Health Insurance Coverage for General Anesthesia and Associated Facility Charges for Dental Procedures for Certain Vulnerable Persons*. Major findings include that fewer than 500 Maine residents would require the service annually and that similar legislation had been passed in twenty four states at that time. The report also notes that two of six major insurers in Maine covered general anesthesia for dental care even in the absence of legislation requiring the benefit; the costs of general anesthesia could be a hardship for some individuals, and the lack of needed dental services may lead to serious medical problems if unattended dental conditions interfere with proper nutrition or lead to severe infection.<sup>231</sup>

**Pennsylvania:** In September 2000, the Pennsylvania Health Care Cost Containment Council (PHC4) published a review of a proposed mandated health benefit for dental anesthesia.<sup>232</sup> PHC4 did not find sufficient evidence to support the proposed legislation as it was written at that time because of concerns that enactment of the legislation would not ultimately help those most in need in accessing dental care services. Additionally, PHC4 did not support the legislation because it did not contain any measures to address the underlying cause of dental disease; the majority of those in need were already covered through Medicaid or the State Children's Health Insurance Program (SCHIP); concerns about the safety of general anesthesia; and it would have allowed parents to require that general anesthesia for dental treatment be administered in a hospital regardless of the opinion of the dentist.<sup>233</sup>

**Washington:** In 1999 the Washington State Department of Health reviewed a proposed mandate to require medical and dental plans to cover general anesthesia and associated hospital charges for children under age six, severely disabled persons, and persons with medical conditions that require dental treatment under general anesthesia as recommended by the patient's physician. The review noted that for some small children and persons with disabilities, traditional office approaches to delivering necessary dental care are ineffective and may be unsafe for patients and providers; medical insurance plans often deny benefits/claims for general anesthesia for medically necessary dental care; and treatment is delayed or forgone because of inability to pay, resulting in serious health consequences. The review estimated the cost of adding the benefit to health plans at \$0.02 per member per month and recommended passage of the bill requiring the mandated coverage.<sup>234</sup>

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<sup>230</sup> 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 on May 7, 2010.

<sup>231</sup> Maine Bureau of Insurance. 2001. A Report to the Joint Standing Committee on Banking and Insurance of the 120<sup>th</sup> Maine Legislature: Review and Evaluation of LD 403, An Act to Provide Health Insurance Coverage for General Anesthesia and Associated Facility Charges for Dental Procedures for Certain Vulnerable Populations. Available at: [http://www.maine.gov/pfr/legislative/documents/ld403boi\\_1.pdf](http://www.maine.gov/pfr/legislative/documents/ld403boi_1.pdf). Accessed on May 10, 2010.

<sup>232</sup> Pennsylvania Senate Bill 1291, Access to Dental Care Act. 2000.

<sup>233</sup> Pennsylvania Health Care Cost Containment Council. 2000. Mandated benefits review, Senate Bill 1291, Dental Anesthesia. Available at: <http://www.phc4.org/reports/mandates/>. Accessed on May 10, 2010.

<sup>234</sup> Washington State Department of Health. 1999. Information summary and recommendations: dental anesthesia mandated benefits sunrise review. Office of Health Services Development, Olympia, WA.

States searched for which no evidence of a review was found include Arkansas, California, Colorado, Louisiana, Maryland, Massachusetts, Minnesota, New Jersey, New York, Ohio, Oregon, Rhode Island, Texas, Virginia, and Wisconsin.

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

General anesthesia, nursing and related hospital services in conjunction with inpatient, outpatient and one-day dental services for the designated populations developed as a result of the difficulties in delivering necessary treatment related to standard practice and frequently occurring poor outcomes. There are no other treatments, methods or procedures currently available that provide similar efficacy for the population receiving dental care under general anesthesia. Recommendations for the appropriate use of general anesthesia for dental care developed by professional organizations such as the American Association of Pediatric Dentistry and Special Care Dentistry organization are generally followed by the majority of dentists involved with treating these populations.

***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.***

General anesthesia, nursing and related hospital services in conjunction with inpatient, outpatient and one-day dental services for the designated populations fulfill a medical need. Specifically, oral health needs are met for some children and persons of all ages with acquired or developmental disabilities that might otherwise not be met due to the difficulties of treatment without the use of general anesthesia for these populations. Provision of the mandated services may positively impact broader social needs as well, through such things as academic achievement and vocational outcomes.

One of the roles of health insurance is to cover low utilization, high cost health services. The mandated benefit under review falls under such a category. The statutes are also consistent with the concept of managed care as they do not prohibit insurers/MCOs from using prior authorization, 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.***

General anesthesia, nursing and related hospital services in conjunction with inpatient, outpatient and one-day dental services developed due to difficulties in delivering necessary treatment related to standard practice and frequently occurring poor outcomes for the designated populations. It is conceivable that a comparable mandated benefit could be enacted for other medically necessary procedures, treatments or services that are unavoidably invasive and difficult for certain populations to endure.

***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. Claims data shows that the mandated benefit accounts for a very small percentage of overall health costs in Connecticut. This data, coupled with the extremely low volume of delivery of the benefit in Connecticut, suggests the benefit has little to no impact on the availability of other benefits currently offered.

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

Due to the relatively small number of persons requiring general anesthesia, nursing and related hospital services in conjunction with inpatient, outpatient and one-day dental services and the expected small overall financial impact of the mandate, 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.

Five insurers/MCOs domiciled in Connecticut provided information about self-funded plans for which they administer benefits, which represents an estimated 47 percent of the total population in self-funded plans in Connecticut. These five insurers/MCOs report that 59 percent of members in their self-funded plans have coverage for the mandated services. A mandated benefits review conducted in Maryland found that “significantly more than half but not all employers with self-funded plans provide benefits that comply fully with the mandate requirement” for general anesthesia for dental care provided under certain conditions.<sup>235</sup>

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

The inpatient, out-patient, and one-day dental mandate is a current benefit that has been included in the state employee health insurance and health benefits plans at least in part since 1999. 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<sup>236</sup> is expected to be the same or similar<sup>237</sup> 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 health insurance plan will total \$98,600 in 2010.<sup>237</sup>

<sup>235</sup> Moon M, Cowdry RW. 2008. Study of Mandated Health Insurance Services: A comparative evaluation. Maryland Health Care Commission. Available at: [http://mhcc.maryland.gov/health\\_insurance/mandated\\_1207.pdf](http://mhcc.maryland.gov/health_insurance/mandated_1207.pdf). Accessed on July 16, 2010.

<sup>236</sup> Personal communication. Scott Anderson, State of Connecticut Comptroller’s Office. September 14, 2010.

<sup>237</sup> 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.

**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.***

Administration of general anesthesia is not without risks. Damage to teeth can occur during administration of general anesthesia as well as risks associated with the anesthesia itself.<sup>238</sup> Rigorous safety measures are generally in place when general anesthesia is administered. A survey of practitioners in Illinois found that 90 percent had obtained advanced cardiovascular life support training and 80 percent reported that the training was current (within 2 years).<sup>239</sup>

General anesthesia is an effective means of facilitating tolerance of the dental procedures for the designated populations. A review of dental anesthesia and sedation over a ten-year period in Illinois reported two mortalities and two cases of long-term morbidity.<sup>240</sup> Thirty patients required transfer to a hospital but suffered no long-term morbidity. The total number of sedations and general anesthetics administered for the ten-year period is estimated at over one million, resulting in an estimated mortality rate of one death for every 500,000 patients who received anesthetics. The two mortalities were related to undisclosed medical conditions.

An outcomes study of dental rehabilitation under general anesthesia for special needs patients found that such practices are safe and effective. In a five-year period of study that included 363 patients there were two complications.<sup>241</sup> Both led to unplanned inpatient admissions and were treated successfully with no residual morbidity.

## **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 affect the availability of general anesthesia, nursing and related hospital services in conjunction with inpatient, outpatient and one-day dental services or its cost over the next five years. 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. 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.***

General anesthesia, nursing and related hospital services in conjunction with inpatient, outpatient and one-day dental services for the designated populations would seem to increase their appropriate use if insurers did not include such coverage in the absence of the mandate. However, it is not uncommon for the mandated benefit to be included in self-funded plans that are not subject to state benefit mandates. For those who use out-of-pocket funds to cover general anesthesia, nursing and related hospital services for dental procedures or get them from other sources such as Medicaid, a mandated benefit may not increase appropriate use. In addition, for those without dental insurance (to cover the costs of the dental procedures), mandated coverage

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<sup>238</sup> Chadwick RG, Lindsay SM. 1996. Dental injuries during general anesthesia. *British Dental Journal* 180(7): 255-8.

<sup>239</sup> Flick WG, Katsnelson A, Alstrom H. 2007. Illinois dental anesthesia and sedation survey for 2006. *Anesthesia Progress* 54: 52-58.

<sup>240</sup> *Ibid.*

<sup>241</sup> Messieha Z, Ananda RC, Hoffman I, et al. 2007. Five year outcomes study of dental rehabilitation conducted under general anesthesia for special needs patients. *Anesthesia Progress* 54: 170-174.

of general anesthesia, nursing and related hospital services may not increase appropriate use of the service.

Due to the invasive nature of general anesthesia and limited availability of operating rooms for dental services it is unlikely that a significant amount of inappropriate use or overutilization is occurring.

***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).***

General anesthesia, nursing and related hospital services in conjunction with inpatient, outpatient and one-day dental services for populations for which it is appropriate does not serve as an alternative for any other treatment, service or equipment, supplies or drugs. Sedation may be the service most similar to general anesthesia. It carries a lower unit cost, but is not a true alternative to general anesthesia. For a patient with severe dental disease, care under sedation requires multiple appointments, which can negate the cost differential between it and general anesthesia.<sup>242</sup> More often than not, dental care under sedation has been tried unsuccessfully in patients who receive dental care under general anesthesia. Behavior management techniques help some patients tolerate dental care, but are generally not effective for the populations currently receiving care under general anesthesia due to patient characteristics (very young children or developmentally disabled).

***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. Utilization and cost impact is limited due to the small number of members in fully-insured group and individual policies requiring the services and limited availability of operating rooms for dental services.

***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). (For further discussion, please see Appendix II, Ingenix Consulting Actuarial and Economic Report, page 14.)

**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. Insurance coverage for the mandated benefit may be reasonably expected to increase group health insurance premiums accordingly, that is, \$0.72 per year per insured.

**Individual policies:** When the medical cost of the mandate is spread to all insureds in individual policies, medical costs are estimated to be \$0.19 PMPM and retention costs are estimated to be \$0.06 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$0.25 PMPM in 2010. Insurance coverage for the mandated benefit may be reasonably expected to increase individual health insurance

<sup>242</sup> Lee JY, Vann WF, Roberts MW. 2000. A cost analysis of treating pediatric dental patients using general anesthesia versus conscious sedation. *Pediatric Dentistry* 22(1): 27-32.

premiums accordingly, that is, \$3.00 per year per insured.

For further information, please see 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.***

Not applicable. At present, there seem to be no equally safe and effective alternatives. The use of general anesthesia, nursing and related hospital services in conjunction with inpatient, outpatient and one-day dental services developed due to the difficulties in providing treatment and poor oral health outcomes for the designated populations. Medical librarians and CPHHP staff found no published literature documenting any equally safe and effective treatment methods.

**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. Actuarial analysis of claims data received from insurers/MCOs in Connecticut shows an expected cost in 2010 of \$1,241,285 for general anesthesia, nursing and related hospital services provided in conjunction with inpatient, outpatient, or one-day dental services for Connecticut residents covered by fully-insured group and individual health insurance plans.

In terms of potential benefits or savings to insurers and employers resulting from prevention or early detection of disease or illness, some of dental services provided under general anesthesia are preventive, such as prophylaxis and sealants; however, most are restorative or extractions. Restoration of diseased teeth allows the patient to eat and speak without pain or with more tolerable levels of pain. Restoration prevents partial or full edentulism (tooth loss), which can lead to high costs associated with dental implants and dentures or special dietary needs and food preparation. Extraction of severely diseased teeth prevents infections that can cause other diseases and complications, including cardiovascular disease and Type II diabetes.<sup>243</sup> While no formal studies of the cost-effectiveness of dental care delivered under general anesthesia were found, at least one study found that performing multiple dental or medical procedures during the same course of general anesthesia can improve health system efficiency.<sup>244</sup>

**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 general anesthesia, nursing and related hospital services in conjunction with inpatient, outpatient and one-day dental services on the cost of health care for small employers. Although small employers may be more sensitive to premium increases than other employers, the estimated low impact of the mandate on insurance premiums in fully-insured group plans (\$0.06 PMPM) suggests little difference in effects among different sized employers. For further information regarding the differential effect of the mandates on small group versus large group

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<sup>243</sup> Kim J, Amar S. 2006. Periodontal disease and systemic conditions: a bidirectional relationship. *Odontology* 94: 10-21.

<sup>244</sup> Stapleton M, Sheller B, Williams BJ, et al. 2007. Combining procedures under general anesthesia. *Pediatric Dentistry* 29(5): 397-402.

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 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.

Additionally, due to the low incidence of dental care that requires general anesthesia, nursing and related hospital services 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. Medicaid coverage currently accounts for the majority of persons with acquired or developmental disabilities accessing the mandated benefit while most children requiring the benefit are covered by private insurers.

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 \$1,503,625 for general anesthesia, nursing and related hospital services provided in conjunction with inpatient, outpatient, or one-day dental 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 I

## Chapter 7

### Diabetes Testing and Treatment

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

Mandatory coverage for diabetes testing and treatment

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## 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 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-492d and §38a-518d mandate individual and group health policies delivered, issued for delivery or renewed in Connecticut on or after October 1, 1997 to provide coverage for laboratory and diagnostic tests for all types of diabetes and to provide medically necessary coverage for the treatment of insulin-dependent diabetes, insulin-using diabetes, gestational diabetes and non-insulin-using diabetes, including medically necessary equipment, drugs and supplies.

Specifically, CGSA § 38a-518d provides that:

Each group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of § 38a-469 delivered, issued for delivery or renewed in this state on or after October 1, 1997, shall provide coverage for laboratory and diagnostic tests for all types of diabetes.

(b) Notwithstanding the provisions of § 38a-518a, each group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of § 38a-469 delivered, issued for delivery or renewed in this state on or after October 1, 1997, shall provide medically necessary coverage for the treatment of insulin-dependent diabetes, insulin-using diabetes, gestational diabetes and non-insulin-using diabetes. Such coverage shall include medically necessary equipment, in accordance with the insured person's treatment plan, drugs and supplies prescribed by a prescribing practitioner, as defined in § 20-571.

(P.A. 97-268, S. 5.)

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

In March 2010, the University of Connecticut Center for Public Health and Health Policy (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 1997 (P.A. 97-268).

### *Premium impact*

**Group plans:** On a 2010 basis, the medical cost of this mandate is estimated to be \$4.60 PMPM. Estimated total cost to insurers (insurance premium, administrative fees, and profit) of the mandated services on a 2010 basis in group plans is \$5.52 PMPM, which is approximately 1.5 percent of estimated total premium costs in group plans. Estimated cost sharing on a 2010 basis in group plans is \$0.85 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 \$0.56 PMPM. Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services in 2010 in individual policies is \$0.73 PMPM, which is less than 0.1 percent of estimated total premiums in individual policies. Estimated cost sharing on a 2010 basis in individual policies is \$0.14 PMPM. Individual policies data is less credible than group plans data primarily due to small sample sizes.

### *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 88 percent of members in self-funded plans have coverage for the 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**

Diabetes (also called diabetes mellitus) is a condition characterized by hyperglycemia (high blood glucose or high blood sugar) resulting from the body's inability to use blood glucose for energy.<sup>245</sup> In 2007, 1.6 million new cases of diabetes were diagnosed in people ages 20 and over in the United States.<sup>246</sup>

There are three major categories of diabetes: Type 1, Type 2 and gestational diabetes. The terms "juvenile" and "adult onset" diabetes are no longer used to describe Type 1 or Type 2 diabetes respectively, since Type 1 diabetes can begin in adulthood as well as in childhood and Type 2 diabetes is increasingly being diagnosed in children.

In Type 1 diabetes, which accounts for 5-10 percent of all diabetes, the person's immune system has destroyed the ability of the pancreas to make insulin, which is a hormone that helps the body use glucose for energy, helping move glucose from the blood into the body's cells for energy. Without enough insulin, glucose remains in the blood stream, depriving cells in tissues and organs of nourishment. Type 1 diabetes usually strikes children and young adults, but its onset can occur at any age.

In Type 2 diabetes, which accounts for 90-95 percent of all diabetes, either the pancreas does not make enough insulin or the body is unable to use insulin correctly. Type 2 diabetes is more common among American Indians (16.5 percent), African Americans (11.8 percent), Hispanic/Latino Americans (10.4 percent), and some Asian Americans and Pacific Islanders (7.5 percent), than among white non-Hispanic Americans (6.6 percent). The risk of developing Type 2 diabetes increases with age, obesity and physical

<sup>245</sup> US Department of Health and Human Services, NIH National Diabetes Information Clearinghouse (NDIC). Diabetes Dictionary, 2007. Available at: <http://diabetes.niddk.nih.gov/dm/pubs/dictionary/pages/e-k.htm#I>. Accessed on April 27, 2010.

<sup>246</sup> US Department of Health and Human Services, NIH National Institute of Diabetes and Digestive and Kidney Diseases. National Diabetes Statistics, 2007 fact sheet. Last updated June 2008. Bethesda, MD: U.S. DHHS. Available at: <http://diabetes.niddk.nih.gov/dm/pubs/statistics/index.htm#allages>. Accessed on June 16, 2010.

inactivity. Although still rare, it is increasingly being diagnosed in children.<sup>247</sup> Gestational diabetes develops during pregnancy and accounts for 1-5 percent of diagnosed cases of diabetes. It generally disappears after delivery, but may predispose a woman to develop diabetes later in life.<sup>248</sup> The CDC estimated in 2007 that 23.6 million people, or 7.8 percent of the overall population in the United States, have some form of diabetes.<sup>249</sup> 5.7 million of them do not know they have it. Approximately 186,300 people younger than 20 years of age have diabetes (Type 1 or Type 2). Annually, approximately 15,000 children and adolescents are diagnosed with Type 1 diabetes in the United States and 3,700 are diagnosed with Type 2 diabetes. This represents 0.2 percent of this population. Among those age 20 years or older, 23.5 million or 10.7 percent have diabetes (both Type 1 and Type 2). Among seniors age 60 and older, 12.2 million or 23.1 percent, have diabetes.

Untreated or poorly controlled diabetes can lead to serious complications or death. Complications include heart disease, stroke, kidney failure, blindness, nerve damage and limb amputation, pregnancy complications and severe periodontal disease.<sup>250</sup> People with diabetes are 2-4 times more likely to have high blood pressure, stroke or heart disease. Diabetic retinopathy causes up to 24,000 new cases of blindness annually. Diabetes accounts for 44 percent of new cases of kidney failure each year and more than 60 percent of non-traumatic lower-limb amputations annually. Poorly controlled diabetes among women with Type 1 diabetes can cause major birth defects, spontaneous abortion or excessively large babies, which pose a risk to both baby and mother.

Diabetes is the seventh leading cause of death in Connecticut.<sup>251</sup> It was listed as the primary or secondary cause of death for 2,771 Connecticut residents in 2002. The NIH estimates that direct medical care for diabetes in the US in 2007 cost \$116 billion. Indirect costs of diabetes for disability, lost time from work and premature death amounted to an additional \$58 billion.<sup>252</sup>

**Caveat:** Although the complications of diabetes contribute significantly to the costs of medical care for people with diabetes, these costs are not included in this study. We have interpreted the legislative mandate to cover only the costs of diagnosis, follow-up care and monitoring by the medical team treating the diabetes, as recommended by the American Diabetes Association (ADA) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), which is a part of the National Institutes of Health (NIH). The costs of retinal repair, treatment for stroke or heart attack, or limb amputation, for example, are not included in the cost factors in this report. Even though they add significantly to the burden of diabetes on the economy, we assumed that these treatments would be covered by most health insurance policies even without this mandate and thus those costs would not be incurred as a result of the mandate itself.

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<sup>247</sup> US Department of Health and Human Services, NIH National Institute of Diabetes and Digestive and Kidney Diseases. National Diabetes Statistics, 2007 fact sheet. Last updated June 2008. Bethesda, MD: U.S. DHHS. Available at: <http://diabetes.niddk.nih.gov/dm/pubs/statistics/index.htm#allages>. Accessed on June 16, 2010.

<sup>248</sup> Diabetes Dictionary, National Diabetes Information Clearinghouse (NDIC). Available at: <http://diabetes.niddk.nih.gov/dm/pubs/dictionary/pages/e-k.htm#I>. Accessed on: April 27, 2010.

<sup>249</sup> US Department of Health and Human Services, Centers for Disease Control and Prevention. National diabetes fact sheet, 2007. Available at: <http://www.searchfordiabetes.org/documents/CDCFact2008.pdf>. Accessed on September 9, 2010.

<sup>250</sup> US Department of Health and Human Services, NIH National Institute of Diabetes and Digestive and Kidney Diseases. National Diabetes Statistics, 2007 fact sheet. Last updated June 2008. Bethesda, MD: U.S. DHHS. Available at: <http://diabetes.niddk.nih.gov/dm/pubs/statistics/index.htm#allages>. Accessed on June 16, 2010.

<sup>251</sup> Connecticut Department of Public Health. 2006. The Burden of Diabetes in Connecticut, 2006 Surveillance Report.

<sup>252</sup> US Department of Health and Human Services, NIH National Institute of Diabetes and Digestive and Kidney Diseases. National Diabetes Statistics, 2007 fact sheet. Last updated June 2008. Available at: <http://diabetes.niddk.nih.gov/dm/pubs/statistics/index.htm#allages>. Accessed on June 16, 2010.

## Diagnosis and laboratory tests

According to the recommended protocols of the American Diabetes Association, diabetes should be diagnosed by means of either a fasting plasma glucose test or a glucose tolerance test, both of which require blood to be drawn and analyzed by a laboratory.<sup>253</sup> Unless the patient presents with clear signs of severe high blood sugar or complications of diabetes, the ADA recommends that the findings of the initial blood test be confirmed by repeat testing.<sup>254</sup>

After diagnosis, standard treatment recommendations call for hemoglobin A1c values to be determined on a regular basis. This measures the average blood glucose in the blood for the prior 60-90 days and can be done by a laboratory (or in the doctor's office if it is appropriately equipped) from a blood sample. Recommended laboratory tests also include regular testing for lipids and for protein in the urine.<sup>255</sup>

## Screening Recommendations

Type 2 diabetes is frequently not discovered until serious complications have developed. If caught early, treatment and life style changes that keep blood glucose and blood pressure in good control can significantly reduce the incidence and severity of such complications. The NIDDK estimates that as many as 57 million Americans have undiagnosed diabetes or are at risk of developing diabetes. The ADA recommends screening all adults over the age of 45 for diabetes every three years by means of either a fasting glucose test or a glucose tolerance test. Patients who are at higher risk for developing diabetes based on family history, obesity, life style or prior high blood glucose results, should be screened more frequently.<sup>256</sup> Pregnant women should be assessed for their risk of developing gestational diabetes at the first pre-natal visit. Those at high risk should be tested immediately. Those at greater than low risk should be tested at 24-28 weeks of gestation.<sup>257</sup>

## Treatment Recommendations

The American Diabetes Association recommends that health care providers monitor the following six factors for patients with diabetes.<sup>258</sup>

- Hemoglobin A1c levels
- Blood pressure
- Lipids
- Protein in urine
- Retina and cornea health
- Foot health
- Equipment, drugs and supplies
- Drugs

### Insulin

People with Type 1 diabetes produce no insulin themselves and must self-administer or receive insulin daily in order to survive. People with Type 2 diabetes sometimes require insulin in order to manage blood glucose levels. A variety of insulins have been developed, with different speeds and durations. Insulins have also been developed which can be inhaled through the nose.

<sup>253</sup> Standards of Medical Care in Diabetes - 2010. *Diabetes Care*, Vol. 33, Supp. 1, p.S11.

<sup>254</sup> Standards of Medical Care in Diabetes - 2010. *Diabetes Care*, vol. 33, Supp. 1, p.S12.

<sup>255</sup> Standards of Medical Care in Diabetes – 2010. *Diabetes Care*, vol. 33, Supp. 1, p.S18.

<sup>256</sup> Standards of Medical Care in Diabetes – 2010. *Diabetes Care*, vol. 33, Supp. 1, p.S14.

<sup>257</sup> Standards of Medical Care in Diabetes – 2010. *Diabetes Care*, vol. 33, Supp. 1, p.S16.

<sup>258</sup> Standards of Medical Care in Diabetes – 2010. *Diabetes Care*, vol. 33, Supp. 1, p.S18.

Non-insulin medications: Many people with Type 2 or gestational diabetes can control their blood sugar levels without insulin through the use of a variety of oral medications. The most common of these medications is metformin.<sup>259</sup>

## Equipment and supplies

### Insulin administration

- Equipment needs vary depending on the method of insulin administration. Insulin cannot be taken orally and must be administered subcutaneously. There are a number of ways to accomplish administration of insulin.
- Subcutaneous shots, via syringe, are perhaps the most common way to administer insulin. A variety of mechanical devices have also been developed to assist those with diabetes to self-administer such shots. These include spring-loaded holders for the syringe as well as insulin pens that use cartridges of insulin and caps with a needle in them to administer insulin.<sup>260</sup>
- Insulin can also be administered via a jet pen, which forces a dose of insulin into the skin, or via a nasal spray.
- Insulin pumps attached to infusion ports inserted under the skin allow small amounts of insulin to be administered on a continuous basis, mimicking a pancreas. These pumps also permit a “bolus,” or extra amount of insulin, to be administered when food is eaten.
- Those who use insulin pumps need infusion sets, which consist of a port with a cannula, or small tube, which is inserted under the skin and a length of tubing to connect the port with the insulin pump. These ports need to be changed every 2-3 days to avoid encapsulation by body tissue.
- Alcohol wipes and skin preparation wipes are needed to keep injection and infusion sites clean and avoid infection.

### Blood glucose monitoring

- Glycemic (blood sugar) control is the primary goal of diabetes treatment. People with any type of diabetes need to regularly monitor their blood sugar levels. Blood glucose monitors, lancets and blood or urine test strips are used to monitor blood glucose and ketone levels. People with Type 1 diabetes are recommended to test blood sugar levels at least 3-4 times per day. People with Type 2 diabetes may test less frequently, depending on their level of control of their blood sugars.
- Technology in this field is continually evolving, with the goal of developing an “artificial pancreas” in the sense of an insulin pump and a real time glucose monitoring system that will not only communicate with each other, but will also automatically direct the administration of insulin as needed by the body, just as the human pancreas and liver do.

## 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:

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<sup>259</sup> US Department of Health and Human Services, Agency for Healthcare Research and Quality, Effective Healthcare Program. Comparative effectiveness and safety of oral diabetes medications for adults with type 2 diabetes, 2007. Available at: <http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=40#tableb>. Accessed on September 9, 2010.

<sup>260</sup> US Department of Health and Human Services, Centers for Disease Control and Prevention, National Diabetes Information Clearinghouse. Taking care of your diabetes every day. Available at: <http://www.diabetes.niddk.nih.gov/dm/pubs/type1and2/daily.htm>. Accessed on September 9, 2010.

- PubMed
- Scopus
- Cochrane Systematic Review
- CINAHL
- Government Agency/Associations/Society Websites
- General Internet

Search terms used included: “Diabetes Mellitus,” “Health Services Needs and Demand,” “Health Services Accessibility,” “Healthcare Disparities,” and “Insurance.”

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

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

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

With the assistance of the Connecticut Insurance Department (CID), CPHHP and Ingenix Consulting 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.*

In a 2006 report, the Connecticut Department of Public Health reported that approximately 163,000 adults age 18 and older, or 6.2 percent of the population, have diabetes in Connecticut. Another 70,000 adults are estimated to have undiagnosed diabetes, based on 2003-2005 data. In 1995, the prevalence of diabetes in the adult population of Connecticut was 4.4 percent.<sup>261</sup>

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<sup>261</sup> State of Connecticut, Department of Public Health. 2006. The burden of diabetes in Connecticut, 2006 Surveillance Report.

**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 pays for diabetes screening tests for individuals with any of the following risk factors: high blood pressure (hypertension), a history of abnormal cholesterol and triglyceride levels (dyslipidemia), obesity (with certain conditions), or a history of high blood sugar.<sup>262</sup> For individuals without any of the above risk factors, Medicare will provide testing for patients who fall into at least two of the following categories:

- 1) age 65 or older,
- 2) overweight,
- 3) family history of diabetes including parents and/or siblings,
- 4) history of gestational diabetes, and
- 5) women who delivered a baby weighing more than 9 pounds.<sup>263</sup>

There is no coinsurance, copayment or Part B deductible associated with the screening itself, though the patient generally must pay 20 percent of the Medicare-approved amount for the office visit.<sup>264</sup> Medicare covers two diabetes screening tests in a 12-month period; the second test is covered upon a doctor's recommendation of a follow-up screening and is performed at a period as recommended by the physician.<sup>265</sup>

Medicare covers a wide range of drugs and medical services for diabetics under Parts B and D, including:

#### **Part B:**

**Supplies:** Part B covers diabetic supplies, including blood sugar testing monitors, strips, lancet devices and lancets. For these products, the patient must pay 20 percent of the Medicare-approved amount after the yearly Part B deductible. Additionally, some of these products may have annual limits.<sup>266</sup>

**Foot exams and care:** Individuals with diabetic peripheral neuropathy and loss of protective sensation are provided coverage under Part B to have a foot exam every six months, provided that they have not seen a foot care professional for another reason between visits. 20 percent of the Medicare-approved amount after the annual Part B deductible applies.<sup>267</sup>

**Glaucoma screening:** Since diabetics are a higher risk for glaucoma, Medicare Part B covers glaucoma testing once every 12 months for diabetics. 20 percent of the Medicare-approved amount after the annual Part B deductible applies.

**Pumped insulin:** External insulin pumps, as well as the insulin those devices use, may be covered for some people with diabetes as durable medical equipment (DME) of Medicare Part B. 20 percent copayment of the Medicare-approved amount after the yearly Part B deductible is required.

**Therapeutic shoes or inserts:** Diabetics with severe diabetic foot disease are eligible under Part B for coverage of therapeutic shoes or inserts. The doctor who treats the individual's diabetes must certify the patient's need for the shoes or inserts. Additionally, the shoes or inserts must be prescribed by a

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<sup>262</sup> US Department of Health and Human Services, Centers for Medicare and Medicaid Service, Publication # 11022: Medicare Coverage of Diabetes Supplies and Services. pp. 3, 15-16. Available at: <http://www.medicare.gov/Publications/Pubs/pdf/11022.pdf>. Accessed on November 29, 2010.

<sup>263</sup> *Ibid.* p. 3.

<sup>264</sup> *Ibid.* p. 3.

<sup>265</sup> *Ibid.* p. 16.

<sup>266</sup> *Ibid.* p. 4.

<sup>267</sup> *Ibid.* p. 5.

podiatrist or other qualified doctor and provided by a podiatrist, orthotist, prosthetist or pedorthist.<sup>268</sup>

#### **Part D:**

**Drugs:** Part D covers anti-diabetic drugs for maintaining blood sugar (glucose). Coinsurance, copayment and a Part D deductible may apply.<sup>269</sup>

**Non-pumped insulin:** Insulin not administered with an insulin pump is covered under Medicare Part D. Coinsurance, copayment and Part D deductibles apply.<sup>270</sup>

**Supplies:** Certain insulin administration supplies (i.e.: syringes, needles, alcohol swabs, gauze and inhaled insulin devices) are covered under Part D. Regular Part D deductibles, coinsurance and copayments may apply.<sup>271</sup>

### **Medicaid**

Medicaid coverage of testing and treatment closely parallels the coverage provided by Medicare, including blood test screenings,<sup>272</sup> glucose monitors (covered as durable medical equipment),<sup>273</sup> test strips,<sup>274</sup> and diabetic shoes.<sup>275</sup>

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

These treatments, services or equipment, supplies and drugs have been mandated in individual and group health insurance policies delivered, renewed or amended in Connecticut since 1997 (P.A. 97-268).

#### **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.**

A number of studies have shown that tight control of blood glucose levels and blood pressure significantly reduces the development of complications attributable to diabetes.<sup>276, 277</sup> To the extent that insurance coverage allows people with diabetes to get recommended follow-up care and monitoring and to comply with recommended self-monitoring, they are likely to have better long-term health outcomes and to place less burden on the cost of health care in Connecticut.

A number of studies have shown that, in low-income populations, lack of coverage for glucose test strips results in poorer glycemic control and higher A1c results.<sup>278</sup> Frequent monitoring of blood glucose levels is critical to optimal management of diabetes, and glucose test strips can be very expensive.

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<sup>268</sup> *Ibid.* p. 6.

<sup>269</sup> *Ibid.* p. 3.

<sup>270</sup> *Ibid.* p 13

<sup>271</sup> *Ibid.* p. 13

<sup>272</sup> Connecticut Department of Social Services. 2010 Laboratory Fee Schedule, Procedure Codes 82945-82963.

<sup>273</sup> Connecticut Department of Social Services. 2010 Durable Medical Equipment Fee Schedule, procedure codes E0607, E2100 and E2101.

<sup>274</sup> Connecticut Department of Social Services. 2010 Medical Surgical Supplies Fee Schedule, procedure code A4253.

<sup>275</sup> Connecticut Department of Social Services. 2010 Medical Surgical Supplies Fee Schedule, procedure codes A5500-5507.

<sup>276</sup> American Diabetes Association. 2010. Standards of Medical Care in Diabetes – 2010.

<sup>277</sup> Diabetes Control and Complications Trial Research Group. 1993. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *The New England Journal of Medicine* 329:977-986.

<sup>278</sup> Bowker SL, Mitchell CG, Majumdar SR et al. 2004. Lack of insurance coverage for testing supplies is associated with poorer glycemic control in patients with type 2 diabetes. *Canadian Medical Association Journal* 171(1): 39-43.

**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.***

People with diabetes have a wide range of glycemic control and diabetic complications, which in turn can impose a wide range of financial burden. An uninsured person earning \$50,000 who has Type 2 diabetes that is well controlled with only one or two oral medications, and who has no diabetic complications, may spend up to \$1,800 or 3 percent of income on diabetes treatment and supplies. An uninsured person with poorly-controlled diabetes and micro-vascular or macro-vascular complications could have annual treatment costs of up to \$14,000 or 25 percent income, with half of that directly related to diabetes treatment.<sup>279</sup>

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

Ten percent of people over the age of 20 in the U.S. have some form of diabetes, and 23 percent of those over age 60 have developed it.<sup>280</sup> Current standards of care are evidenced-based and are widely accepted and followed.

**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. Specifically, the ADA has taken the position that medical nutrition therapy and diabetes self-management education should also be covered by insurance and other third-party payers. It does not directly address other components of recommended care, presumably because these are generally provided by medical providers and are covered by many insurance policies.

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

***Mandated Benefit Reviews in the other states***

Massachusetts, which mandates outpatient coverage of medically necessary diabetes-related services and supplies, including “durable medical equipment, prosthetics, and prescription drugs such as blood glucose monitoring strips, insulin, and oral medications,” published a review of their mandate in 2008.<sup>281</sup> The report found the cost of the mandate equaled \$1.49 PMPM (0.50 percent of the total premium) “after administrative loading.” Further, the report noted, “Regular use of preventive and monitoring services to control diabetes is linked with ‘short-term decreases in health care utilization [among diabetics]’ and can result in cost-savings ‘within one to two years.’”<sup>282</sup>

The Maryland Health Care Commission (MHCC) conducted a review of the impact of Maryland’s diabetes mandate, which requires coverage of all medically necessary diabetes equipment and supplies, as well as outpatient self-management training and educational services (including medical nutrition therapy coverage for six visits).<sup>283</sup> Maryland’s mandate consolidates the diabetes testing/treatment and self-management

<sup>279</sup> Ingenix Consulting Report, 2010. Appendix II, p. 51.

<sup>280</sup> US Department of Health and Human Services, NIH National Institute of Diabetes and Digestive and Kidney Diseases. National Diabetes Statistics, 2007 fact sheet. Last updated June 2008. Available at: <http://diabetes.niddk.nih.gov/dm/pubs/statistics/index.htm#allages>. Accessed on June 16, 2010.

<sup>281</sup> Commonwealth of Massachusetts, Division of Health Care Finance and Policy. 2008. Report: Comprehensive Review of Mandated Benefits in Massachusetts. July 7, 2008.

<sup>282</sup> *Ibid.*

<sup>283</sup> MD. CODE ANN., INS. § 15-822.

mandates separated under Connecticut statute. The Report concluded that the full cost of the diabetes mandate amounts to 0.5 percent of the premium for groups and 0.6 percent for individuals.<sup>284</sup> Additionally, the Report concluded that “all” insurers in the self-funded market were in compliance with the mandate.<sup>285</sup>

The Ohio General Assembly contracted with Milliman USA in 2001 to study and project the expected cost of a proposed mandate<sup>286</sup> to require coverage of “diabetes equipment, supplies, medication, and self-management education to be included in health care coverage.” The report concludes that implementation of the mandate “would increase health insurance premiums in Ohio by between 0.2 percent and 0.6 percent on average, and by up to 2 percent for plans that did not provide any of the required services at that time.”<sup>287</sup> However, that report failed to account for “potential savings due to the possible avoidance of expensive complications associated with diabetes.”<sup>288</sup>

A 2003 report from the Utah Insurance Department<sup>289</sup> studied the impact of Utah’s diabetes mandate,<sup>290</sup> which requires coverage of medically necessary equipment, supplies and appliances such as blood glucose monitors and test strips, lancets and lancet devices, insulin, injection aides and syringes, as well as “self-management training and patient management, including medical nutrition therapy.” The Report concluded that the estimated cost PMPM would equal \$1.03, or 0.9 percent of the premium.<sup>291</sup>

A 2003 report<sup>292</sup> from the Wisconsin Office of the Commissioner of Insurance studied the impact of proposed legislation to amend existing state law (which subjected insulin and other prescription medicines used to treat diabetes to policy limits and deductibles) to instead require “first dollar coverage for covered expenses related to treatment of diabetes,” effectively creating an exception to the requirement that insulin and other prescription medicines be subject to the general limitations, deductibles, exclusions and coinsurance provisions of the policy. The Report estimated that the revision to the mandate could increase health care expenditures by \$46.8-\$88.4 million, representing between 0.66 percent and 1.2 percent of commercial health insurance premiums in the state.<sup>293</sup>

Maine’s 1996 mandate of coverage for “medically necessary equipment and supplies used to treat diabetes and approved self-management and education training” was estimated to have a maximum cost of 0.20 percent the premium.<sup>294</sup>

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

<sup>284</sup> Maryland Health Care Commission. 2008. Study of Mandated Health Insurance Services: A Comparative Evaluation. P. 3. Available at: [http://mhcc.maryland.gov/health\\_insurance/mandated\\_1207.pdf](http://mhcc.maryland.gov/health_insurance/mandated_1207.pdf). Accessed on November 27, 2010.

<sup>285</sup> *Ibid.* p. 8.

<sup>286</sup> Ohio. 2001. H.B. 100 Introduced on February 15, 2001.

<sup>287</sup> Ohio. Ohio Legislative Service Commission. 2007. Fiscal Note and Local Impact Statement: Pursuant to S.B. 99 of the 127<sup>th</sup> General Assembly of Ohio. Report published 11/13/2007. Available at: <http://www.lbo.state.oh.us/fiscal/fiscalnotes/127ga/SB0099IN.htm>. Accessed on November 27, 2010.

<sup>288</sup> *Ibid.*

<sup>289</sup> Utah. Utah Insurance Department. 2003. Diabetes Mandate Report. Available at: <http://www.insurance.utah.gov/docs/2003DiabetesRpt.pdf>. Accessed on November 27, 2010.

<sup>290</sup> UTAH CODE ANN. § 31A-22-626.

<sup>291</sup> Utah. Utah Insurance Department. 2003. Diabetes Mandate Report. p. 15.

<sup>292</sup> Wisconsin, Office of the Commissioner of Insurance. 2003. Social and Financial Impact Report- Assembly Bill 362. Report issued August 18, 2003. Available at: <http://oci.wi.gov/finimpct/sfiab362.pdf>. Accessed on November 27, 2010.

<sup>293</sup> *Ibid.* p. 2.

<sup>294</sup> Maine Department of Professional and Financial Regulation, Bureau of Insurance. 2009. Report: Cumulative Impact of Mandates in Maine. Report issued December, 2009. p. 6.

Connecticut Department of Public Health implemented a five-year Connecticut Diabetes Prevention and Control Plan in 2007 “to create an environment for change in which a comprehensive system of care and prevention will reduce or delay the onset of diabetes and its complications . . .” That plan states that according to the Centers for Disease Control and Prevention, diabetes cost Connecticut an estimated \$1.7 billion in 2003 in direct and indirect costs. In 2002, approximately \$77 million was billed for hospitalizations due to diabetes as a principal diagnosis. \$39 million was billed for hospitalizations related to diabetes with a lower extremity amputation.<sup>295</sup>

The plan calls for efforts to encourage insurers to cover diabetes preventive care, treatment, supplies, education and treatment by imposing co-payments that do not exceed 25 percent of the covered item’s total cost. It also calls for efforts to change Federal ERISA provisions to require self-funded employers to cover diabetes supplies, education and treatment, and to adopt the ADA Diabetes Bill of Rights to guide insurance regulation in Connecticut. It also calls for the development of report cards for insurance plans that reflect what is covered by each plan and that report on the HEDIS/NCQA measures of quality for each plan, which include rates for testing of A1c levels, administration of flu shots, foot exams and eye exams.

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

Life style changes such as increased physical activity and weight loss can help some people with Type 2 or gestational diabetes keep their blood glucose levels at optimal levels without oral medication or insulin. However, people with Type 1 diabetes require insulin and many people with Type 2 diabetes require oral medications and/or insulin to control blood glucose.

Regular follow-up by a trained diabetes care team has also been shown to be effective in managing glucose levels and avoiding the long-term complications of diabetes.<sup>296</sup> Diabetes self-management education for patients with diabetes has been shown to be effective in lowering blood glucose levels and is discussed further in Chapter 1 of this Volume.

Research is ongoing into the causes, treatments and possible cures for diabetes. New technologies, procedures and medications are continuously being developed for the management of diabetes.

***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.***

This mandate covers the diagnosis and treatment of a chronic disease and, as such, it is consistent with the role of health insurance and the concept of managed care.

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

This mandate may have implications for coverage of other chronic diseases, such as asthma.

***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

<sup>295</sup> Connecticut Dept of Public Health. 2007. The Connecticut Diabetes Prevention and Control Plan, 2007-2012.

<sup>296</sup> Standards of Medical Care in Diabetes – 2010. *Diabetes Care*, Vol. 33, Supp. 1, Jan 2010.

barrier to access, especially for low-income members. Many carriers have shifted to plans that cover certain preventive services, such as diabetes management (or other high value services) at low or no cost to the member. This is intended to discourage underutilization of important care.<sup>297</sup>

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

Information received from five insurers/MCOs domiciled in Connecticut representing an estimated 47 percent of the total self-funded population in Connecticut shows that 88 percent of members in self-funded plans have coverage for the 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 \$9,071,237. 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.)<sup>298</sup>

**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.***

The diagnosis and treatment protocols listed in the Background section are those recommended by both the American Diabetes Association and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), a part of the National Institutes of Health (NIH).<sup>299</sup> They are based on extensive research over many years.<sup>300</sup> These are the diagnosis and treatment services, equipment, drugs and supplies which are covered by the mandate.

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<sup>297</sup> Ingenix Consulting report, Appendix II, p. 31.

<sup>298</sup> Personal Communication with Scott Anderson, Connecticut State Comptroller's Office, September 14, 2010.

<sup>299</sup> American Diabetes Association. 2010. Standards of Medical Care in Diabetes-2010. *Diabetes Care* 33(Supp1); S11.

<sup>300</sup> Diabetes Control and Complications Trial Research Group. 1993. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *New England Journal of Medicine* 329:077-986.

## 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 is a broad mandate that extends to all aspects of care for diabetes. As treatment protocols for diabetes have evolved over the last 15 years, the cost of treating diabetes has also increased.<sup>301</sup> New diabetes oral medications, types of insulin, insulin delivery systems, and blood glucose monitoring equipment may be more likely to be covered than advances in other, non-diabetic therapies.<sup>302</sup> Some health plans apply no cost-sharing to diabetes treatments and supplies, which may shift cost-sharing burdens to other types of therapies.<sup>303</sup>

### ***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.***

Diabetes and public health research findings emphasize the importance of effective maintenance treatment for diabetes.<sup>304</sup> The treatment protocols of the ADA are widely recognized and used by both primary care doctors and endocrinologists who treat patients with diabetes.<sup>305</sup> As a result, frequent monitoring of blood glucose levels has increased and the development of new technologies for both the delivery of insulin and the monitoring of blood glucose levels has accelerated. Third party payment for blood glucose monitoring equipment and supplies has been shown to contribute to better management of blood glucose levels, which is the goal of diabetes management.<sup>306</sup> In this regard, the mandate has increased the appropriate use of the treatment, equipment and supplies. To the extent it has supported the development and deployment of new medicines and new technologies, the mandate has probably increased the cost of diabetes treatment and management for individual patients in return for improved management of the disease.

The mandate also allows health insurers and HMOs to reap the benefit of improved diabetes management by reducing complications and total medical costs of treatment of diabetics by lowering the rate of costly complications of diabetes, even if members do not remain with the same plan for a long period of time. Because all carriers are required to cover these services, equipment and supplies, all carriers benefit from the lower medical costs and reduced complications associated with effective diabetes management over the long term.<sup>307</sup>

### ***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 management of diabetes is focused on maintaining good glycemic control in order to avoid the complications of diabetes, which can be very expensive to treat and are often life-threatening.

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<sup>301</sup> Ingenix Consulting Report, Appendix II, p. 51.

<sup>302</sup> Ingenix Consulting Report, Appendix II, p.51.

<sup>303</sup> Ingenix Consulting Report, Appendix II, p. 51.

<sup>304</sup> US Department of Health and Human Services. 2000. Healthy People, 2010: Diabetes control and complications trial. Available at: <http://www.ahrq.gov/qual/diabqual/diabqguideref.htm/>. Accessed on November 29, 2010.

<sup>305</sup> Personal communication Dr. Carl Malchoff, Diabetes, Metabolism and Endocrinology Specialist.

<sup>306</sup> Bowker SL, Mitchell CG, Majumdar SR et al. 2004. Lack of insurance coverage for testing supplies is associated with poorer glycemic control in patients with type 2 diabetes. *Canadian Medical Association Journal* 171(1):39-43.

<sup>307</sup> Ingenix Consulting Report, Appendix II, p. 36.

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

Medicare manages the cost of diabetes treatment by limiting the number of glucose monitors and glucose test strips it will pay for in a given time frame. Some insurance carriers use similar methods. In addition, cost-sharing, deductibles and co-pay tiers for pharmaceuticals may also act as a deterrent to over-utilization and a brake on costs. Carriers can also require justification for the use of more expensive methods of blood glucose management and treatment of diabetic complications as part of their utilization control efforts.

***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 medical cost of the mandate is spread to all insureds in group plans, medical costs are estimated to be \$4.60 PMPM and retention costs are estimated to be \$0.92 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$5.52 PMPM in 2010, which is 1.5 percent of premium.

**Individual policies:** When the medical cost of the mandate is spread to all insureds in individual policies, medical costs are estimated to be \$0.56 PMPM and retention costs are estimated to be \$0.17 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$0.73 PMPM in 2010, which is 0.3 percent of premium.

It is unclear how much of this cost would be covered by employers and insurance carriers in the absence of the mandate since it is now widely accepted that improving blood glucose management reduces the likelihood and severity of diabetic complications.

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

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

This mandate covers a wide variety of services, equipment, supplies and medications, which vary significantly in cost. At one extreme, some patients with Type 2 diabetes can maintain good glycemic control with diet and exercise alone. At the other extreme, some patients need multiple insulin injections or insulin delivery via an insulin pump, coupled with multiple blood glucose checks per day to achieve good glycemic control. Some patients have no diabetic complications; some have advanced stages of one or more complications of diabetes. What is safe and effective for one group may not be for another.

**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. Actuarial analysis of claims data received from insurers/MCOs in Connecticut shows an expected impact in 2010 of \$81,281,593 for diabetes diagnosis, treatment, equipment and supplies for Connecticut residents covered by fully-insured group and individual health insurance plans.

Several studies have documented the relationship between improved glycemic control and reduced medical care costs, primarily from reduced inpatient hospital costs.<sup>308, 309</sup> It is difficult to quantify these savings, however.

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

According to the Ingenix Consulting report, this mandate is expected to have roughly the same effect on the medical cost of small group plans as on large group plans, approximately \$4.60 PMPM. However, because small employers often purchase smaller, leaner plans and require employees to pay a larger share of the premium, the cost of this mandate as a percentage of total paid medical cost may be somewhat higher than it is for large plans.

**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 to be \$95,104,374. This includes the medical and retention costs included in premiums and cost sharing by insured individuals.

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.

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<sup>308</sup> Menzin J, Korn JR, Cohen J et al. 2010. Relationship between glycemic control and diabetes-related hospital costs in patients with type 1 or type 2 diabetes. *Journal of Managed Care Pharmacy* 16(4): 264-275.

<sup>309</sup> Wagner EH, Sandhu N, Newton KM et al. 2001. Glycemic control and health care costs for patients with diabetes mellitus. *Journal of the American Medical Association* 285(2): 182-189.



# Volume I

## Chapter 8

### Birth-to-Three Program

Review and Evaluation of Connecticut Statute  
Chapter 700, § 38a-516a and § 38a-490a

Coverage for Birth-to-Three Program

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## 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 (CID) and the University of Connecticut Center for Public Health and Health Policy (CPHHP).

Connecticut General Statutes, Chapter 700, § 38a-516a and 38a-490a require group or individual health insurance policies to cover medically necessary Early Intervention services provided as part of an individualized family service plan.

Specifically, CGSA § 38a-516a 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 or renewed in this state on or after July 1, 1996, shall provide coverage for medically necessary early intervention services provided as part of an individualized family service plan pursuant to section 17a-248e. Such policy shall provide (1) coverage for such services provided by qualified personnel, as defined in section 17a-248, for a child from birth until the child's third birthday, and (2) a maximum benefit of three thousand two hundred dollars per child per year and an aggregate benefit of nine thousand six hundred dollars per child over the total three-year period. No payment made under this section shall be applied by the insurer, health care center or plan administrator against any maximum lifetime or annual limits specified in the policy or health benefits plan.

§ 38a-490a 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 July 1, 1996 (P.A. 96-185, S. 7, 16; June 30 Sp. Sess. P.A. 03-3, S. 8.).

### *Premium impact*

**Group plans:** On a 2010 basis, medical cost for Birth to Three services is estimated to be \$0.22 per member per month (PMPM). Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services on a 2010 basis in group plans is \$0.26 PMPM, which is approximately 0.1 percent of estimated total premium costs in group plans. Estimated cost sharing in 2010 in group plans is \$0.01 PMPM.

**Individual policies:** Four of the six insurers/MCOs provided claims data for individual health insurance policies. On a 2010 basis, medical cost for Birth to Three services is estimated to be \$0.25 PMPM.

Estimated total cost (insurance premium, administrative fees, and profit) of Birth to Three services in 2010 in individual policies is \$0.33 PMPM, which is approximately 0.1 percent of estimated total premium costs in individual policies. Estimated cost sharing in 2010 in individual policies is \$0.01 PMPM. Individual policies data is less credible than group plans data primarily due to small sample sizes.

### ***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 26 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**

In 1986, Congress established Part C of IDEA, the Early Intervention Program for Infants and Toddlers with Disabilities. The purpose of Part C is to: 1) enhance the development of infants and toddlers with disabilities; 2) reduce educational costs by minimizing the need for special education through Early Intervention; 3) minimize the likelihood of institutionalization, and maximize independent living; and, 4) enhance the capacity of families to meet their child's needs. Services are designed to address a child's needs in five developmental areas: physical development, cognitive development, communication, social or emotional development, and adaptive development.<sup>310</sup>

Early Intervention (Part C) is funded in part with federal grant monies provided to states to offer statewide Early Intervention services to children from birth to thirty-six months old with disabilities and their families. Under Part C, states must provide services to children under three who are experiencing developmental delays, or who have a diagnosed mental or physical condition that has a high probability of resulting in a developmental delay. Eligibility criteria are defined by each state. All 50 states and 6 jurisdictions participate in the Part C program.

In Connecticut, eligibility for Early Intervention services can be established in one of three ways. A child is eligible if he or she scores two standard deviations below the mean in one developmental area or 1.5 standard deviations below the mean in two or more developmental areas on a standardized test. Alternatively, an informed clinical opinion of at least two qualified professionals can substantiate a developmental delay. Infants and toddlers with a diagnosed mental or physical condition that has a high probability of resulting in a developmental delay are automatically eligible.<sup>311</sup> Connecticut does not provide services to children deemed "at risk", which is defined under Part C as "an individual under 3 years of age who would be at risk of experiencing a substantial developmental delay if early intervention services were not provided to the individual."<sup>312</sup>

In fiscal year 2009, Connecticut's Birth to Three system received 9,228 referrals which was an increase of 1.3 percent over the previous year. The median age at referral was 19 months. The majority of the children referred were boys (65 percent). Most (62 percent) of the families self-referred or were referred by a health care provider (29 percent). Over half of the referrals were due to concerns about delays in communication

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<sup>310</sup> Blann LE. 2005. Early intervention for children and families with special needs. *American Journal of Maternal/Child Nursing* 30(4): 263-7.

<sup>311</sup> Connecticut Birth to Three System. 2008. A Family Handbook: Guide I Referral and Eligibility Evaluation. Available at: [www.birth23.org](http://www.birth23.org). Accessed on May 12, 2010.

<sup>312</sup> IDEA 2004, § 632 (1).

(51.3 percent). 8,680 children received comprehensive multidisciplinary evaluations and 60 percent (5,194) were found eligible for Early Intervention. Ninety percent (4,711) of these children were found eligible due to developmental delays (based on standardized tests or clinical opinion). Ten percent (483) of the children were found to be automatically eligible based on a diagnosed condition likely to result in a developmental delay (e.g., low birth weight, hearing/vision loss, Down syndrome, cleft palate, autism spectrum disorder, neurological disorder).<sup>313</sup>

Early Intervention services include:

- audiology,
- family training,
- counseling and home visits,
- health services (only those necessary to enable a child to benefit from the other Early Intervention services during the time the child is receiving other Early Intervention services),
- initial evaluation,
- medical services only for diagnostic or evaluation purposes,
- nursing services,
- nutrition services,
- occupational therapy,
- physical therapy,
- psychological services,
- service coordination,
- social work services,
- special instruction, and/or
- speech-language.<sup>314</sup>

Early Interventions services are provided by qualified personnel contracted by the Connecticut Birth to Three System which is administered by the Connecticut Department of Developmental Services (DDS). Such qualified personnel include: audiologists, board certified behavior analysts and associated behavior analysts, early intervention associates with a BA in education, human services or a related area with a minimum of one year's experience in working with infants and toddlers and credentialed by DDS as an infant toddler family specialist, family therapists, nurses, nutritionists, occupational therapists and certified occupational therapy assistants, orientation and mobility specialists, pediatricians and other physicians, physical therapists and registered physical therapy assistants, professional counselors, psychologists, social workers, speech and language pathologists, special educators, early childhood educators, teachers of the hearing or visually impaired.<sup>315</sup>

As described in the regulations of Part C of IDEA, a parent or guardian of a child enrolled in Birth to Three is a key decision-maker and member of a multidisciplinary team. This team develops, agrees upon, and authorizes Early Intervention services via an Individualized Family Service Plan (IFSP). The parent or

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<sup>313</sup> Connecticut Birth to Three System. 2009. Learning Through Play. Available at: [www.birth23.org](http://www.birth23.org). Accessed on May 12, 2010.

<sup>314</sup> Health Insurance Coverage for Early Intervention Services. April 14, 2004. State of Connecticut, Department of Mental Retardation, Insurance Department. Available at: [www.ct.gov/cid/lib/cid/hmoltr.pdf](http://www.ct.gov/cid/lib/cid/hmoltr.pdf). Accessed on May 11, 2010.

<sup>315</sup> *Ibid.*

guardian and the service coordinator re-evaluate the IFSP at least every six months or as needed to verify the appropriateness of the plan.<sup>316</sup>

The research literature indicates that Early Intervention can reduce the severity of the impact of a disability and assist young children with special needs in reaching their full potential. It can also improve family adjustment and functioning.<sup>317</sup> In the case of low birth weight and premature infants, early intervention may alter the anatomy of the brain, thus enhancing developmental paths that improve health, educational and social outcomes.<sup>318</sup> Language development for children who are deaf or hard of hearing is positively and significantly affected by early identification of the hearing loss and early initiation into intervention services.<sup>319</sup> In a randomized, controlled trial to evaluate the efficacy of Early Start Denver Model (ESDM), a behavioral intervention designed to address the needs of toddlers diagnosed with autism spectrum disorder, children as young as 18 months showed significant improvements in IQ, adaptive behavior, and autism diagnosis.<sup>320</sup> It should be noted that long-term effects of early intervention on children with disabilities and their families is less consistent. There is no singular pattern for a child's development and deficits in some children remain even after early intervention services. Influences that occur after the age of three and the inherent heterogeneity of children who enroll in Early Intervention programs with a variety of impairments and varying degrees of severity influence outcomes.<sup>321,322</sup>

Several barriers to Early Intervention service utilization are cited in the literature. For example, national trends suggest that young children with disabilities who have difficulty accessing health care in general (children who are economically disadvantaged, live in rural communities, and are ethnic minorities) are less likely to utilize Early Intervention services.<sup>323,324</sup> Additionally, service pathways for identifying, evaluating and referring younger children (0 – 2 years) with disabilities and those with at-risk challenging behavior have been found to be fragmented.<sup>325</sup> In Connecticut, family fees may function as a deterrent to Birth to Three services. More Hispanic families in Connecticut access Birth to Three services than census data would indicate. By the same measure, African American families are underserved.<sup>326</sup> Cultural barriers may contribute to lower participation rates for African American families.

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<sup>316</sup> The National Early Childhood Technical Assistance Center. Available at: <http://www.nectac.org/topics/families/families.asp#ifsp>. Accessed on May 10, 2010.

<sup>317</sup> Shonkoff JP and Meisels SJ (Eds.). 2000. *Handbook of early childhood intervention*. Cambridge: Cambridge University Press.

<sup>318</sup> Vanderveen JA, Bassler D, Robertson CMT, et al. 2009. Early interventions involving parents to improve neurodevelopmental outcomes of premature infants. A meta-analysis. *Journal of Perinatology* 29: 343-51.

<sup>319</sup> Yoshinaga-Itano C. 2003. From screening to early identification and intervention: Discovering predictors to successful outcomes for children with significant hearing loss. *Journal of Deaf Studies and Deaf Education* 8(1): 11-30.

<sup>320</sup> Dawson G, Rogers S, Munson J, et al. 2010. Randomized, controlled trial of an intervention for toddlers with autism: The Early Start Denver Model. *Pediatrics* 125(1): 17-23.

<sup>321</sup> Ramey CT and Ramey SL. 1994. Which children benefit the most from early intervention? *Pediatrics* 94: 1064-6.

<sup>322</sup> Shonkoff JP and Phillips DA. 2000. *From Neurons to Neighborhoods*. Washington, DC: National Academy Press.

<sup>323</sup> Sontag JC and Schacht R. 1993. Family diversity and patterns of service utilization in early intervention. *Journal of Early Intervention* 17(4): 431-44.

<sup>324</sup> Newacheck P, Hung YY, Hochstein M et al. 2002. Access to health care for disadvantaged young children. *Journal of Early Intervention* 25(1): 1-11.

<sup>325</sup> Powell D, Fixsen D, Dunlap G, et al. 2007. A synthesis of knowledge relevant to pathways of service delivery for young children with or at risk of challenging behavior. *Journal of Early Intervention* 29(2): 81-106.

<sup>326</sup> Personal communication. Linda Goodman, Director, Connecticut Birth to Three System. December 14, 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 using search terms including child development, developmental disabilities, growth, child behavior disorders, child psychology, early intervention, preventative health services, cognition disorders, motor skills disorders, psychomotor disorders, treatment outcome, program development, public policy, child health services, community health planning, intervention studies, disabled children, hearing impaired, visually impaired, autism, autism spectrum disorders, low birth weight, premature birth, infant premature. Librarians used search resources including PubMed, SCOPUS, Cochrane Review, and the Web.

CPHHP staff conducted independent literature searches using the search resources:

- Cochrane Review,
- Pubmed,
- PsychInfo,
- Google,
- Google Scholar,

and employed search terms similar to those selected by the UCHC medical librarians. When available, articles published in peer-reviewed journals are cited to support the analysis. CPHHP staff consulted with Birth to Three experts in the community for additional and specialized information.

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 (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 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 Birth to Three Program is utilized by a significant portion of the population.***

The number of children birth to three years old in the United States receiving Early Intervention services in 1987 was about 30,000. By 2006, the number of children in this age group who received some type of Early Intervention services had grown to approximately 304,510, or about 2.43 percent of children in the United States.<sup>327</sup> The increase in the number of children served can be attributed in large part to increased awareness and identification of children with developmental delays, advances in research indicating the positive cognitive, behavioral, and social outcomes for children receiving Early Intervention services, improved survival rates of children with complex medical conditions, and greater incidence of disorders associated with developmental delays.<sup>328</sup>

In fiscal year 2009, Connecticut's Birth to Three system served approximately 3.5 percent of the state's children under the age of three. The system received 9,228 referrals which was an increase of 1.3 percent over fiscal year 2008. The median age at referral was 19 months and the average number of months of services received was 11. Boys were more likely to be referred than girls (65 percent versus 35 percent). The children were typically referred by their families (62 percent) or a health care provider (29 percent). Over half of the referrals were due to concerns about delays in communication (51.3 percent). 8,680 children received comprehensive multidisciplinary evaluations and 60 percent (5,194) were found eligible for Early Intervention. Ninety percent (4,711) of children who were found eligible had a developmental delay (based on standardized tests or clinical opinion). Ten percent (483) of the children who were found eligible had a diagnosed condition (e.g. low birth weight, hearing vision loss, Down syndrome, cleft palate, autism spectrum disorder, or neurological disorder) likely to result in a developmental delay making them automatically eligible for enrollment.<sup>329</sup>

### ***2. The extent to which the Birth to Three Program 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***

Due to Medicare eligibility requirements and waiting periods for Medicare coverage for persons with disabilities, it is unlikely that Medicare provides a significant amount of funding for birth-to-three services.

#### ***Public Programs Administered by Charities***

Many non-profit and for-profit organizations are approved providers to the Connecticut Birth to Three System. Regardless of the provider, families accessing Birth to Three services pay on a sliding scale if their income is \$45,000 or greater.

#### ***Public Programs Administered by Public Schools***

Public schools do not provide Early Intervention services to children with disabilities age birth to three. However, under Part B of IDEA public schools fund special education for eligible children age 3 to 21.

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<sup>327</sup> U.S. Department of Education, Office of Special Education Programs, Data Analysis System. 2007. Table 7-1. infants and toddlers receiving early intervention services under IDEA, Part C, by age and state: Fall 2006 (data updated July 15, 2007). Available at [https://www.ideadata.org/tables30th%5Car\\_7-1.xls](https://www.ideadata.org/tables30th%5Car_7-1.xls). Accessed on April 27, 2010.

<sup>328</sup> Blann LE. 2005.

<sup>329</sup> Connecticut Birth to Three System Annual Report (2009). Available at: <http://www.birth23.org/aboutb23/ADR/AnnualReportFY09.pdf>. Accessed on April 23, 2010.

Birth to Three service providers must provide transition services to help families move from Birth to Three services to the early childhood special education services provided by their local school systems at age three.

### ***The Department of Public Health (DPH)***

The Connecticut Department of Public Health does not provide direct Early Intervention services. However, it has operated the Early Hearing Detection and Intervention Program since 2000 which provides hearing screening to newborns as part of the standard of care. Depending on the type and degree of the hearing loss children are referred to the Birth to Three system.

### ***Municipal Health Departments***

No information was found regarding the availability of Birth to Three programs or funding for Birth to Three programs through local and municipal health departments in Connecticut.

### ***The Department of Social Services (DSS)***

Medicaid covers a wide range of medically necessary Early Intervention services provided as part of individualized family service plans, including physical therapy, occupational therapy and speech therapy.

<sup>330,331</sup>

In addition to covering a variety of therapeutic Early Intervention services, DSS covers a range of durable medical equipment (DME) for children, including wheelchairs, walkers and canes.<sup>332</sup>

### ***The Department of Developmental Services (DDS)***

The Connecticut Birth to Three System is administered by the Connecticut Department of Developmental Services. It received almost \$52 million from state and federal sources and 97 percent of funding was spent on direct services in 2009. DDS contracts with a variety of agencies (e.g. Easter Seals, Wheeler Clinic, and Child and Family Network, among others) that operate local Birth to Three programs. Each Birth to Three program must be comprehensive in nature, i.e. must be able to provide any or all of the types of direct services, including service coordination, that are listed in IDEA Part C. DDS does not contract with individual providers.

### ***3. The extent to which insurance coverage is already available for the Birth to Three Program.***

State of Connecticut law requires coverage for Birth to Three programs in group and individual health insurance plans.<sup>333</sup> 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. Five Connecticut carriers provided data on their self-funded plans for this mandate, representing an estimated 47 percent of the population covered by self-funded plans in Connecticut. For these five carriers, 26 percent of members in their self-funded plans have benefits at least equal to this mandate.

### ***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 children enrolled in group and individual health insurance plans. From the information provided, coverage is available to 26 percent of persons enrolled in self-funded plans; persons enrolled in fully-insured and self-funded group plans represent the majority of the insured

<sup>330</sup> DSS Provider Fee Schedule: Physical Therapy (July, 2009).

<sup>331</sup> Personal communication. Ginny Mahoney, DSS Medical Policy Consultant. April 7, 2010; "Connecticut Medicaid: Summary of Services." Medical Care Administration, DSS. <http://www.ct.gov/dss/lib/dss/pdfs/medicaidservicesv3kk.pdf>

<sup>332</sup> DSS Provider Fee Schedule: Durable Medical Equipment (2010)

<sup>333</sup> CONNECTICUT GENERAL STATUTES ANNOTATED § 38A-490A (individual insurance policies); § 38A-516A (group insurance policies).

population under age 65 in Connecticut.

***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 Early Intervention services are primarily covered by state and federal funding. According to state law, fully-insured group and individual health insurance policies in Connecticut are required to reimburse for Early Intervention services and these payments are not counted against a child's annual or lifetime benefit caps. The Birth to Three System absorbs the cost of all insurance copayments and deductibles. Families of children using Early Intervention services are required to cover some of the costs of services. Parent payments are based on a sliding fee scale according to family income, family size, and consent to bill insurance. Service fees can range from zero for families with an adjusted gross annual income of less than \$45,000 to as high as \$544 per month.

Depending on the level of cost-sharing and personal financial resources available, a family's contribution for Birth to Three services may present an unreasonable financial hardship. For children requiring extensive services, the coverage limit of \$6400 per year may not meet all the child's needs, which could then result in significant economic costs for the child's family, even for those with comprehensive health benefits. In addition to financial contributions to Early Intervention services, parents and caretakers may incur additional financial burdens in the course of caring for a child with special needs such as lost work time and income, and other costs associated with the program that are not covered by health insurance.

***6. The level of public demand and the level of demand from providers for the Birth to Three Program.***

For the past several decades, pressure from parents, providers, advocates, researchers and legislators have prompted the passage of federal legislation to create and advance Early Intervention services. Legislation initiating Early Intervention began with the Education for all Handicapped Children Act of 1975 which gave access to public education to children with disabilities. This Act evolved into the Education of the Handicapped Act (EHA) in 1986 which extended services to children birth to 21 years old. In 1990, the EHA was amended and renamed the Individuals with Disabilities Education Act (IDEA). When IDEA was reauthorized in 1997, Part C of this law was designated for children from birth to three years. IDEA most recently was reauthorized in 2004, with the support of families and disability advocacy organizations. Connecticut formally joined the federal program in 1993 with the Department of Education as lead agency. The Department of Developmental Services (DDS) became the lead agency for Birth to Three in 1996.

The demand for Birth to Three services has increased substantially over the past few decades. The number of children birth to three years old in the United States receiving Early Intervention services in 1987 was about 30,000. By 2006, the number of children in this age group who received some type of Early Intervention services had grown to approximately 304,510, or about 2.43 percent of children in the United States.<sup>334</sup> In fiscal year 2009, Connecticut's Birth to Three system served approximately 3.5 percent of the state's children under the age of three. The system received 9,228 referrals which was an increase of 1.3 percent over fiscal year 2008. 8,680 children received comprehensive multidisciplinary evaluations and 60 percent (5,194) were found eligible for Early Intervention.<sup>335</sup>

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<sup>334</sup> U.S. Department of Education, Office of Special Education Programs, Data Analysis System. 2007. Table 7-1. Infants and toddlers receiving early intervention services under IDEA, Part C, by age and state: Fall 2006 (data updated July 15, 2007). Available at [https://www.ideadata.org/tables30th%5Car\\_7-1.xls](https://www.ideadata.org/tables30th%5Car_7-1.xls). Accessed on April 27, 2010.

<sup>335</sup> Connecticut Birth to Three System Annual Report, 2009. Available at: <http://www.birth23.org/aboutb23/ADR/AnnualReportFY09.pdf>. Accessed on April 23, 2010.

***7. The level of public demand and the level of demand from providers for insurance coverage for the Birth to Three Program.***

The Individuals with Disabilities Education Act (IDEA) requires the state lead agency for the Early Intervention System to identify and coordinate all available resources for Early Intervention services including federal, state, local, and private resources. In Connecticut, the Birth to Three System, administered by the Department of Developmental Services, pursues reimbursement for services via third party payments including both Medicaid and commercial insurance. This procedure is supported by sections 38a-490a and 38a-516a of the Connecticut General Statutes which states that Early Intervention services must be covered in specified health insurance policies.

***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 (CAHI) defines an Early Intervention services mandate as a mandate that “provides for reimbursement up to \$5,000 per child from birth to age three for numerous therapies, including speech and language therapy, physical therapy, case management, nutrition service plan development and review, nursing services and assistive technologies.”<sup>336</sup> CAHI lists six states that meet this definition: Colorado, Indiana, Massachusetts, New Hampshire, Rhode Island, and Virginia.

While Connecticut mandates Early Intervention benefits, the reimbursement is not explicitly stated as “up to \$5,000” per child, which may explain Connecticut’s absence from the list.<sup>337</sup> The Connecticut mandate provides a maximum benefit of \$3,200 per child per year and an aggregate benefit of \$9,600 per child over the total three-year period. However, the maximum benefit was raised to \$6,400 per year (maximum aggregate benefit of \$19,200) by the Office of Policy and Management in 2009.

***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.<sup>338</sup> 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 Birth to Three Programs. States searched included Arkansas, California, Colorado, Indiana, Louisiana, Maine, Maryland, Massachusetts, Minnesota, New Jersey, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Texas, Virginia, Washington, and Wisconsin.

CPHHP researchers found reviews of proposed mandates in Colorado and Virginia that would require insurance coverage of certain services and interventions for children of various ages. Both reviews focused on the financial impact of the proposed mandated benefits.

A 2007 Colorado report studied the potential implications of a proposed program to require state registration of early childhood intervention providers and state negotiation of reimbursement rates with such providers, and state billing of appropriate funding sources, including Medicaid and private insurance for

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<sup>336</sup> Council for Affordable Health Insurance. 2009. Mandated Benefit Definition Memo.

<sup>337</sup> Council for Affordable Health Insurance. 2009. Health Insurance Mandates in the States.

<sup>338</sup> 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 on May 7, 2010.

providers' services.<sup>339</sup> The services would be identified in the individualized family service plan, including assistive technology, audiology services, developmental intervention, health services, nutrition services, occupational therapy, physical therapy, psychological services, respite care, service coordination, social work, speech-language pathology, transportation, and vision services. The report found that if all of the proposed policies were implemented, the estimated maximum annual additional cost to health plans would be \$3,589,450. This calculates to an additional annual benefit payment of \$2,310 for each of the estimated 1,554 eligible children covered by Colorado regulated insurance above what carriers are already covering.<sup>340</sup> Additionally, the Colorado Department of Personnel and Administration estimated that implementation would cost the 50,748 state employee health plan members an estimated \$4 per member per year.<sup>341</sup>

A 2006 Joint Legislative Audit and Review Commission of the Virginia General Assembly report evaluated a proposal to mandate coverage of habilitative services for children 18 and under with developmental delays. The coverage would include speech and language therapy, occupational therapy and physical therapy. Estimated PMPM cost for individual policyholders was estimated between \$0.31 and \$2.00. Estimated PMPM cost for group policyholders ranged from \$0 to \$2.94.<sup>342</sup>

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

The reauthorization of IDEA was signed into law in 2004 and Congress allocated close to \$5 million of Part C funding to Connecticut. The Connecticut Birth to Three System has a current Memorandum of Understanding and has been allotted almost \$48 million in state funds by the legislature. There are no indications to suggest that there will be an alternative to the Part C services offered to children birth to three with disabilities and their families in Connecticut.

There is four decades worth of research literature indicating positive outcomes for infants and toddlers with disabilities who receive Early Intervention services. Early Intervention has been associated with improved scores on developmental outcomes, enhanced parent-child interactions and increased collaboration among providers.<sup>343</sup>

***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 Birth to Three programs fulfills a medical need that might not otherwise be met. The research literature indicates that Early Intervention can reduce the severity of a disability, or development delay and thus, assist young children with special needs reach their full potential, and improve family adjustment and functioning.<sup>344</sup> Birth to Three programs also provide social benefits by improving child development and functioning resulting in subsequent increased academic achievement, improved social and psychological functioning, and lifelong productivity.

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<sup>339</sup>Commission on Mandated Health Insurance Benefits Report On SB07-04. February 9, 2007. State of Colorado Department of Regulatory Agencies, Division of Insurance, Commission on Mandated Health Benefits . <http://www.dora.state.co.us/insurance/meet/MHBC/SB07-04.pdf>

<sup>340</sup> *Ibid.*

<sup>341</sup> *Ibid.*

<sup>342</sup> Evaluation of House Bill 657: Mandated Coverage of Habilitative Services for Children With Developmental Delays. Joint Legislative Audit and Review Commission of the Virginia General Assembly. October, 2006. Available at: <http://jlarc.state.va.us/reports/Rpt340.pdf>. Accessed on December 23, 2010.

<sup>343</sup> Gromby DS, Larner MB, Stevenson CS, et al. 1995. Long term outcomes of early childhood programs: Analysis and recommendations. *The Future of Children* 5: 6-24.

<sup>344</sup> Shonkoff JP and Meisels SJ (Eds.). 2000.

One of the roles of health insurance is to cover low utilization, high cost health services. The mandated benefit under review falls under such a category. The statutes are also consistent with the concept of managed care as they do not prohibit insurers/MCOs from using prior authorization, 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.***

It is possible that the basic structure of the mandate could be replicated for other types of diseases, conditions, or services. If denials of insurance coverage for certain treatable diseases and conditions were viewed as withholding a medically necessary treatment, restricting access for a particular constituency or 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. Claims data shows that the mandated benefit accounts for a lower than average percentage of overall health costs in Connecticut. This data, coupled with the low volume of delivery of the benefit in Connecticut, suggests the benefit has little to no impact on the availability of other benefits currently offered.

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

In fiscal year 2009, Connecticut's Birth to Three system served approximately 3.5 percent of the state's children under the age of three.<sup>345</sup> Due to the relatively low number of persons requiring Birth to Three services and the expected small overall financial impact of the mandate it is not anticipated that employers shifted or 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 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.

Five Connecticut carriers provided information on their self-funded plans for this mandate, which represents an estimated 47 percent of Connecticut residents covered by self-funded plans. For these five carriers, 26 percent of members in their self funded plans have benefits at least equal to this mandate.

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<sup>345</sup> Connecticut Birth to Three System Annual Report, 2009. Available at: <http://www.birth23.org/aboutb23/ADR/AnnualReportFY09.pdf>. Accessed on April 23, 2010.

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

The Birth to Three program mandate is a current benefit that has been included in the state employee health insurance and health benefits plans at least in part since 1996. 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.<sup>346</sup>

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 health insurance plan will total \$433,842 in 2010.<sup>347</sup>

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

The research literature indicates that Early Intervention can reduce the severity of the impact of a disability, and thus, assist young children with special needs in reaching their full potential, and improve family adjustment and functioning.<sup>348</sup> In the case of low birth weight and premature infants, Early Intervention may alter the anatomy of the brain, thus enhancing developmental paths that improve health, educational and social outcomes.<sup>349</sup> Language development for children who are deaf or hard of hearing is positively and significantly affected by early identification of the hearing loss and early initiation into intervention services.<sup>350</sup> In a randomized, controlled trial to evaluate the efficacy of Early Start Denver Model (ESDM), a behavioral intervention designed to address the needs of toddlers diagnosed with autism spectrum disorder, children as young as 18 months showed significant improvements in IQ, adaptive behavior, and autism diagnosis.<sup>351</sup> It should be noted that long-term effects of Early Intervention on children with disabilities and their families is less consistent. There is no singular pattern for a child's development and deficits in some children remain even after Early Intervention services. Influences that occur after age 3 and the inherent heterogeneity of children who enroll in Early Intervention programs with a variety of impairments and varying degrees of severity influence outcomes.<sup>352, 353</sup>

<sup>346</sup> Personal communication. Scott Anderson, State of Connecticut Comptroller's Office. September 14, 2010.

<sup>347</sup> 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.

<sup>348</sup> Shonkoff JP and Meisels SJ (Eds.). 2000.

<sup>349</sup> Vanderveen JA, Bassler, D, Robertson CMT, et al. 2009.

<sup>350</sup> Yoshinaga-Itano C. 2003.

<sup>351</sup> Dawson G, Rogers S, Munson J, et al. 2010. Randomized, controlled trial of an intervention for toddlers with autism: The Early Start Denver Model. *Pediatrics* 125(1): 17-23.

<sup>352</sup> Ramey CT and Ramey SL. 1994. Which children benefit the most from early intervention? *Pediatrics* 94: 1064-6.

<sup>353</sup> Shonkoff JP and Phillips DA. 2000.

Connecticut's Early Intervention services are provided by well-trained professionals. Depending upon the specific discipline, providers are required to have a valid Connecticut certification or licensure. Each program must verify the professional credentials and maintain a copy on file. Connecticut's Birth to Three System also employs two categories of paraprofessional generalists: Early Intervention Assistants and Early Intervention Associates. The number of paraprofessionals is not to exceed 25 percent of the total direct full time equivalent (FTE) Early Intervention staff.<sup>354</sup>

## V. Financial Impact

### ***1. The extent to which the mandated health benefit may increase or decrease the cost of the Birth to Three Program over the next five years.***

The mandate is not expected to materially alter the availability or cost of birth-to-three programs over the next five years. The mandated benefit is a relatively low volume 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 Birth to Three Program over the next five years.***

For those children whose insurance plans would not otherwise cover Birth to Three programs, the mandated health benefit may increase appropriate use of Early Intervention services. For those covered by self-funded plans, who use out-of-pocket funds, or receive Early Intervention services from other sources, a mandated benefit may not increase appropriate use. Inappropriate use is not anticipated to occur. In order to be eligible for Early Intervention a child must have a confirmed medical condition that is expected to lead to a developmental delay, have an evaluation by two qualified professionals from two different professions to confirm a significant development delay, or score two standard deviations below the mean in one area or 1.5 standard deviations below the mean in two or more areas on a standardized test. Connecticut does not provide services to children deemed "at risk."

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

Children with a need for Early Intervention services benefit from Birth to Three programs. Such programs do not serve as alternatives for any other treatments, services or equipment, supplies or drugs. Lack of necessary Early Intervention services can lead to medical complications and developmental delays contributing to more extensive treatment and thus greater costs than the care forgone at the earlier treatment opportunity.

### ***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. In addition, the mandate itself limits the dollar amount which insurers and MCOs must pay to \$6400 per year per child.

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<sup>354</sup> Birth to Three Procedures. Available at: <http://www.birth23.org/providers/Procedures.html>. Accessed on May 22, 2010.

***5. The extent to which insurance coverage for the Birth to Three Program 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 medical cost of the mandate is spread to all insureds in group plans, medical costs are estimated to be \$0.22 PMPM and retention costs are estimated to be \$0.04 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$0.26 PMPM in 2010. Insurance coverage for the mandated benefit may be reasonably expected to increase group health insurance premiums accordingly, that is, \$3.12 per year per insured.

**Individual policies:** When the medical cost of the mandate is spread to all insureds in individual policies, medical costs are estimated to be \$0.25 PMPM and retention costs are estimated to be \$0.08 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$0.33 PMPM in 2010. Insurance coverage for the mandated benefit may be reasonably expected to increase individual health insurance premiums accordingly, that is, \$3.96 per year per insured.

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

***6. The extent to which the Birth to Three Program 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.***

Children with a need for Early Intervention services benefit from Birth to Three programs. Such programs do not serve as alternatives for any other treatments, services or equipment, supplies or drugs. Lack of necessary Early Intervention services can lead to medical complications and developmental delays contributing to more extensive treatment and thus greater costs than the care forgone at the earlier treatment opportunity.

***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 of insurance premiums and cost sharing. Actuarial analysis of claims data received from insurers/MCOs in Connecticut shows an expected cost in 2010 of \$3,985,825 for Birth to Three services for Connecticut residents covered by fully-insured group and individual health insurance plans.

The medical and developmental services required by the mandate may provide economic benefits to society by improving child development and functioning resulting in subsequent increased academic achievement, improved social and psychological functioning, and lifelong productivity. The economic benefits may offset the costs of Early Intervention services 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 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 Birth to Three services on the cost of health care for small employers. Although small employers may be more sensitive to premium increases than other employers, the estimated low impact of the mandate on insurance premiums in fully-insured group plans (\$0.26 PMPM) suggests little difference 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 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 is often the result of a legislative requirement.

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 July 1996, 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 incidence of Birth to Three services 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 insurance mandate is a cost shift from the public sector to the private sector. In order to participate in federal funding under Part C, the state must provide the required services whether there is private insurance or not. Therefore, the Birth to Three insurance mandate shifts a part of this liability to the private sector from 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 insurers/MCOs in Connecticut shows an expected cost in 2010 of \$4,757,056 Birth to Three services provided to 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 I

## Chapter 9

### Lyme Disease Treatments

Review and Evaluation of Connecticut Statute  
Chapter 700, § 38a-518h and § 38a-492h

Mandatory Coverage for Certain Lyme Disease Treatments

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## I. Overview

The Connecticut General Assembly (the Committee) 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 and the University of Connecticut Center for Public Health and Health Policy.

Connecticut General Statutes, Chapter 700, § 38a-518h states that each group health insurance policy...

...delivered, issued for delivery, renewed or continued in this state on or after January 1, 2000, shall provide coverage for Lyme disease treatment including not less than thirty days of intravenous antibiotic therapy, sixty days of oral antibiotic therapy, or both, and shall provide further treatment if recommended by a board certified rheumatologist, infectious disease specialist or neurologist licensed in accordance with chapter 370 or who is licensed in another state or jurisdiction whose requirements for practicing in such capacity are substantially similar to or higher than those in this state.

(P.A. 99-284, S. 48, 60; June Sp. Sess. P.A. 99-2, S. 3, 72.)

§ 38a-492d 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 January 2000 (P.A. 99-284).

### *Premium impact*

**Group plans:** On a 2010 basis, the medical cost of this mandate is estimated to be \$0.28PMPM. Estimated total cost to insurers (insurance premium, administrative fees, and profit) of the mandated services on a 2010 basis in group plans is \$0.34PMPM, which is 0.1 percent of estimated total premium costs in group plans. Estimated cost sharing on a 2010 basis in group plans is \$0.07PMPM.

**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 \$0.34 PMPM. Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services in 2010 in individual policies is \$0.44 PMPM, which is 0.2 percent of estimated total premiums in individual policies. Estimated cost sharing on a 2010 basis in individual policies is \$0.12 PMPM. Individual policies data is less credible than group plans data primarily due to small sample sizes.

### *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 90 percent of members in self-funded plans have coverage for the 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

Lyme is a complex disease involving multiple body functions. Treatment is antibiotic therapy. If Lyme is not diagnosed and treated in its early stage, it can progress to later stages which are harder to cure. Medical controversy surrounds appropriate treatment at these later stages. The Infectious Disease Society of America (IDSA) released treatment guidelines that preclude long-term antibiotic therapy (see below for a table summarizing IDSA treatment guidelines). Community-based physicians and lyme advocates contend these guidelines do not provide for adequate antibiotic therapy. Connecticut's mandate walks the fine line between these two groups. Connecticut is one of five states that mandate lyme health insurance coverage.<sup>355</sup> Other states include: Arizona, Maine, Minnesota and Rhode Island.<sup>356</sup> Connecticut's mandate allows for up to 30 days of IV antibiotics and 60 days of oral antibiotics. Any antibiotic therapy beyond this period needs to be prescribed by a board certified specialist.

Humans contract Lyme disease from a bite from an infected deer tick. Ixodes ticks are host to the source of the infection, the *Borrelia Burgdorferi* spirochete, in certain endemic areas. These areas are primarily in the northeast, coastal mid-Atlantic states, upper Midwest and northern California and Oregon. Connecticut is particularly heavily affected with an estimated 111.3 new cases per 100,000 people compared to the national average of 8.8 new cases per 100,000 people in the U.S.<sup>357</sup>

The symptoms of Lyme disease vary from stage to stage. In the early localized stage, individuals may experience flu-like symptoms. These symptoms include: fatigue, fever, headache, stiff neck and arthralgias. About 7-10 days after the bite, a bulls-eye shaped rash, known as erythema migrans (EM), may appear. The early-stage is typically lasts about a month. After this period, the infection begins to disseminate potentially causing neurological, cardiac, arthritic and lymphatic symptoms. Symptoms become chronic for some patients, resulting in chronic Lyme disease or post-Lyme disease syndrome. Neurological symptoms include facial nerve palsies and cognitive impairment.<sup>358</sup> Cardiac symptoms include irregular heart beat and ventricular blocks. Arthritic symptoms include intermittent knee or large joint swelling and pain that may destroy the joint if left untreated. People with chronic Lyme disease rate their quality of life significantly worse than people with type 2 diabetes or a recent myocardial infarction.<sup>359</sup>

Diagnosis of Lyme disease is controversial. A tick bite or EM rash are early-stage indicators of Lyme. However, many patients may miss these indicators.<sup>360, 361</sup> One study reported up to 70 percent of Lyme patients do not recall being bitten by a tick and 20-25 percent do not recall a rash.<sup>362</sup> The available blood tests, the enzyme-linked immunosorbent assay (ELISA) and Western Blot, are used in conjunction with each

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<sup>355</sup> Council for Affordable Health Insurance. 2009. Health Insurance Mandates in the States. Available at: [www.cahi.org](http://www.cahi.org) Accessed on June 16, 2010.

<sup>356</sup> *Ibid.*

<sup>357</sup> NDDS (2006-2008) 3-year average of confirmed Lyme disease cases. Available at: <http://wonder.cdc.gov/mmwr/mmwr morb.asp> Accessed on March 14, 2009.

<sup>358</sup> Neurological Lyme symptoms are most common in the European strain of the lyme spirochete. This fact is significant as most of the high quality research on Lyme treatment is from Europe. Neurological Lyme is more likely to be successfully treated by IV antibiotics and, consequently, the literature reflects this bias.

<sup>359</sup> Klempner MS, Hu LT, Evans J, et al. 2001. Two Controlled Trials of Antibiotic Treatment in Patients with Persistent Symptoms and a History of Lyme Disease. *The New England Journal of Medicine* 345(2): 85-92.

<sup>360</sup> Pavis C. 2003. Current and Novel Therapies for Lyme Disease. *Expert Opinion and Investigative Drugs* 12(6): 1003-1016.

<sup>361</sup> Savely VG. 2008. Update on Lyme Disease. *The Art and Science of Infusion Nursing* 31(4): 236-240.

<sup>362</sup> Pavis C. 2003.

other. The ELISA tests for an immune response and inflammation. This test detects lyme symptoms but does not specifically indicate lyme. If the ELISA test is positive, a Western Blot follows. The Western Blot tests for the presence of proteins known to be present in the *B. Burgdorferi* spirochete. Both tests are subject to high rates of false negatives because it takes 3-6 weeks for lyme antibodies to build up to a detectable level in the blood stream.

The academic medical establishment recommends diagnosis be made on these criteria above (i.e., tick-bite, rash, positive serology) rather than clinical review of symptoms. Lyme advocates and some studies suggest these criteria are not reliable indicators of Lyme disease and that clinical symptoms can provide a basis for diagnosis.<sup>363</sup>

Lyme is treated with antibiotics. The type of antibiotic (oral versus intravenous (IV)) and the duration of treatment vary by symptoms and stage. Table I.9.1 below provides a summary of the IDSA's guidelines for treatment.<sup>364</sup> Early stage Lyme can usually be treated with 10-21 days of oral antibiotics. Patients with more complicated or long term symptoms may need 14-21 days of IV antibiotics with or without initial oral antibiotic therapy.

Condition	IDSA Guideline
Tick Bite in Endemic Area	Single Dose of Doxycycline within 72 hours.
Early Lyme Disease with EM Rash	10-21 days oral antibiotics.
Early Neurologic Lyme	10-28 days IV antibiotics.
Cardiac Manifestations of Lyme	14-21 days of oral or IV antibiotics. Individual may require hospitalization and/or a temporary pacemaker.
Borreliol Lymphocytoma	See early lyme disease treatment.
Late Lyme Arthritis	28 days oral antibiotics.
Late Neurologic Lyme	2-4 weeks of IV antibiotics. Re-treat at discretion of physician.
Acrodermatitis Chronica Atrophicans	21 days oral antibiotics. IDSA recommends more study on IV versus oral antibiotics for this condition.
Post-Lyme Syndrome	Antibiotic treatment not recommended. Diagnosis requires positive ELISA and Western Blot blood tests.

The treatment controversy remains focused on those with chronic symptoms. As indicated above, IDSA recommends no additional treatment for those with chronic symptoms. They cite concerns about the safety of long-term antibiotics compared to potential benefits.<sup>365</sup> Lyme advocates and some physicians recommend continued treatment with IV antibiotics until patients are cured.

<sup>363</sup> Skogman BH, Ekerfelt C, Ludvigsson J, et. al. 2010. Seroprevalence of *Borrelia* IgG antibodies among young Swedish children in relation to reported tick bites, symptoms and previous treatment for Lyme borreliosis: a population-based survey. *Archives of Disease in Childhood* (Aug 10): 1-4.

<sup>364</sup> IDSA. 2010. Final Report of the Lyme Disease Review Panel of IDSA – Post-Lyme Syndromes. Available at: <http://www.idsociety.org/Content.aspx?id=16524> Accessed on July 20, 2010.

<sup>365</sup> *Ibid.*

While it is not clear what causes chronic Lyme symptoms, this review found about 23 percent of people seriously affected by Lyme continue to have symptoms after receiving the recommended treatment.<sup>366</sup> This literature review found long-term antibiotics may help alleviate some symptoms but was ineffective at ‘curing’ chronic Lyme. Lyme advocates argue that current studies do not target the right population and do not provide treatment long enough to capture the benefits of long-term antibiotic therapy.

With these deep divides in the medical community, people with Lyme have difficulty accessing antibiotic treatment beyond IDSA’s recommendations. Physicians may be unwilling to prescribe unproven treatments. Insurers may be unwilling to pay for treatment without serological diagnosis (i.e. positive blood tests). While the mandate provides for a minimum level of care, the decision to provide long-term IV antibiotics is ultimately left in the hands of the medical community.

### 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 under search terms including Lyme, chronic Lyme, post-Lyme syndrome, economic, costs, complementary treatment, alternative treatment, long-term antibiotics, safety and Connecticut.

Resources searched include:

- PubMed
- Cochrane
- Google and Google Scholar
- CDC
- Lexis-Nexis
- 2010 Connecticut insurer survey
- Council for Affordable Health Insurance
- Connecticut public health department
- Connecticut General Assembly Archives
- Personal contacts with providers, public agencies.

CPHHP staff conducted independent literature searches using the Cochrane Review, Pubmed, Google, and Google Scholar using similar search terms used by the UCHC medical librarians. From this review, 15 studies that examined the safety and efficacy of different lengths and types of antibiotic treatment were identified. Of these, 11 had a control group. Of the 15 studies, 10 were European-based. These studies were included in the review because of the relative scarcity of American trials. However, there are genetic differences between European and American Lyme disease that may make the results less applicable to the Connecticut experience. The review found 5 studies with relevant to economic costs: 2 cost-of-illness studies and 3 on the cost-effectiveness of the Lyme vaccine. Two studies were conducted prior to 2000, our cut-off date, and one yielded no relevant data. These studies were omitted.

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<sup>366</sup> Marques, A. 2008. Chronic Lyme Disease. *Infectious Disease Clinics of North America* 22: 341-360.

In other cases, articles published in peer-reviewed journals are cited to support the analysis. Other sources of information may also be cited in the absence of peer-reviewed journal articles. Content from such sources may or may not be based on scientific evidence.

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

The National Notifiable Diseases Surveillance System (NNDSS) reports an average of 23,728 people in the United States and 2883 people in Connecticut receive diagnoses of Lyme disease each year.<sup>367</sup> These figures reflect 8.8 new cases per 100,000 people in the United States and 111.3 new cases per 100,000 people in Connecticut. Between 2003 and 2008, Connecticut reported as many or more cases per 100,000 than any other New England state.<sup>368</sup> Based on total population only, an estimated average of 2883 people in Connecticut are eligible for Lyme disease treatment each year as defined in the statute.<sup>369</sup> Of these, an estimated 65 percent would be covered by group and individual insurance policies subject to the mandated benefit.<sup>370</sup>

### ***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.***

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<sup>367</sup> NDDSS (2006-2008) 3-year average of confirmed Lyme disease cases.

Available at: <http://wonder.cdc.gov/mmwr/mmwr morb.asp> Accessed on March 14, 2009.

<sup>368</sup> Only New Hampshire reported an equal number of cases per 100,000 people in 2008; tying Connecticut for the highest rate of infection.

<sup>369</sup> US Census. 2008 Population estimates for the USA and Connecticut.

Available at: <http://www.census.gov/popest/states/NST-ann-est.html> Accessed on November 21, 2009.

<sup>370</sup> Based on the estimated number of persons in Connecticut covered by group and individual insurance plans subject to state regulation.

## ***Medicare***

Our research did not find a specific policy for Medicare's Lyme disease coverage. Medicare coverage is available for individuals over 65 years of age or if they have had a qualifying disability for two years or more. Medicare covers physician and specialist services. Several Medicare part D insurers cover both oral and intravenous antibiotics.<sup>371</sup> Normal copayments and coinsurance obligations apply.

## ***Public Programs Administered by Charities***

No information was found indicating public charities make treatment for Lyme disease available.

## ***Alternative Private Programs***

Some businesses make oral antibiotics and other pain medications available at reduced prices. For example, Wal-mart offers a 30-day prescription of oral doxycycline hyclate for \$4. Doxycycline is the antibiotic of choice for Lyme disease treatment. No similar programs were found for intravenous antibiotics.

## ***Public Programs Administered by Public Schools***

No information was found that would indicate public schools would be a source of Lyme disease treatment or funding for Lyme disease treatment.

## ***The Department of Public Health (DPH)***

No information was found regarding the availability of Lyme disease treatment or funding for Lyme disease treatment through the Connecticut Department of Public Health.

## ***Municipal Health Departments***

No information was found regarding the availability of Lyme disease treatment or funding for Lyme disease treatment through local and municipal health departments in Connecticut.

## ***The Department of Social Services (DSS)***

Medicaid covers all "medically necessary and appropriate" physician visits, specialist visits and medications.<sup>372</sup> Medicaid covers services provided by internists who practice as infectious disease specialists. DSS reports that Medicaid provides coverage of oral antibiotics for 60 days or more as needed.<sup>373</sup> Currently, Connecticut's SAGA program is in the process of integrating with Medicaid based on the new Patient Protection and Affordable Care Act. This change is retrospective to April 1, 2010. Consequently, SAGA coverage can be considered identical to Medicaid coverage for the purposes of this report.

### ***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 for Lyme disease treatment in group and individual health insurance plans as of 2000.<sup>374</sup> Claims data received from six insurers domiciled in Connecticut that cover 95 percent of the insured population in Connecticut (1.25 million persons), showed evidence that claims are paid for the mandated services. Five insurers/MCOs domiciled in Connecticut provided information about their self-funded plans, representing and estimated 47 percent of the total population covered by self-funded plans in Connecticut. These five insurers/MCOs report that 90 percent of members in their self-funded plans have coverage for the benefit.

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<sup>371</sup> See for example Health Partners at <https://www.healthpartners.com/files/3330.pdf> Accessed on Sept 21, 2010.

<sup>372</sup> Personal communication with Ms. Nina Holmes, DSS Medical Policy Unit, April 7, 2010.

<sup>373</sup> Personal communication with Mr. Jason Gott, RPH, DSS Pharmacy Consultant, April 8, 2010.

<sup>374</sup> CONNECTICUT GENERAL STATUTES ANNOTATED § 38A-492H (individual insurance policies); § 38A-518H (group insurance policies) available at [www.cga.ct.gov](http://www.cga.ct.gov), Accessed on March 14, 2010.

**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.**

Connecticut's Statute Chapter 700, § 38a-518h and § 38a-492h ensures that fully insured group and individual health insurance plans cover up to 90 days of antibiotic therapy or more if recommended by a certified specialist. Anecdotal evidence from other states suggests that, without this mandate, individuals may experience barriers to receiving this level of care. These barriers result from the medical controversy and the cost of long term antibiotic therapy. An unscientific survey of 3500 'chronic Lyme patients' in California found that:

- 90 percent reported difficulty finding a physician who would treat them;
- 53 percent needed to travel out of California for a diagnosis or treatment;
- 49 percent of patients saw 7 or more doctors before being diagnosed with Lyme; and
- 41 percent reported not being able to afford needed medications.<sup>375</sup>

Data on California's insurance claims process appear to support these findings. California maintains statistics on service denials and their appeals. The claims appeal denial rate for Lyme treatment is 93 percent as compared to denial rates of 60 percent for all illnesses.<sup>376</sup>

In part, IDSA guidelines affect access to care. Based on these guidelines, insurers often deny costly extended treatment as contrary to evidence-based medical practice.<sup>377</sup> The unreliability of blood tests may also lead to under-diagnosis<sup>378</sup> and denial of treatment. Practitioners who offer extended treatment may be excluded from an insurer's network or face medical sanctions.<sup>379</sup> In 2009, Connecticut passed PA 09-128 to protect physicians from disciplinary actions for prescribing long term antibiotics for Lyme disease.

**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.**

Depending on the severity of disease and progression at time of diagnosis, a diagnosis of Lyme disease may result in significant health and economic costs for the individual and their family. On the outside, treatment of late-stage Lyme disease may require the recommended 4 weeks of intravenous ceftriaxone antibiotic therapy.

A review of the literature found medical treatment costs decreased during the 1990s.<sup>380</sup> Studies using cost inputs for their models from earlier papers tend to have higher estimated costs. Economic costs include both direct and indirect cost. Direct costs consist of the medical costs of treatment; including doctor's visits, drug administration, supplies and treatment for adverse reactions, paid for by the insurer. Indirect costs consist primarily of lost wages due to illness. In the case of Lyme disease, reported medical costs are skewed, with a

<sup>375</sup> California Lyme Disease Association. 2009. Survey of Patients with Chronic Lyme Disease. Available at: <http://www.idsociety.org/Content.aspx?id=15026> Accessed on July 10, 2010.

<sup>376</sup> Johnson, L. 2009. Prepared Statement in Support of Revision of IDSA 2006 Lyme Guidelines: Patients Need Treatment Options. Available at: <http://www.idsociety.org/Content.aspx?id=15026> Accessed on July 10, 2010.

<sup>377</sup> Connecticut Attorney General Richard Blumenthal. 2008. Connecticut Attorney General's Office Press Release and Settlement Agreement. Available at [www.ct.gov/AG/cwp/view.asp?a=2795&q=414284](http://www.ct.gov/AG/cwp/view.asp?a=2795&q=414284) Accessed on July 10, 2010.

<sup>378</sup> CDC. 2005. Notice to Readers: Caution Regarding Tests for Lyme Disease. *MMWR Weekly* 54(05): 125.

<sup>379</sup> Cameron D. 2009. Testimony Before Public Health Committee in Support of Bill 6200. Available at: [http://cga.ct.gov/2009/PHdata/Tmy/2009HB-06200-R000206-daniel%20Cameron,%20MD,MPH%20\(NON%20SPEAKING\),%20President%20International%20Lyme%20and%20Associated%20Diseases%20Society-TMY.PDF](http://cga.ct.gov/2009/PHdata/Tmy/2009HB-06200-R000206-daniel%20Cameron,%20MD,MPH%20(NON%20SPEAKING),%20President%20International%20Lyme%20and%20Associated%20Diseases%20Society-TMY.PDF) Accessed on July 10, 2010.

<sup>380</sup> Zhang X, Meltzer MI, Pena CA, et al. 2006. Economic Impact of Lyme Disease. *Emerging Infectious Diseases* 12(4): 653-660.

small number of people having very high costs. Four of five studies used modeling approaches<sup>381, 382, 383, 384</sup> to gather expenses while one study used a small survey.<sup>385</sup>

In the literature, estimated treatment costs for early stage Lyme disease ranged from \$167, with no complications, up to \$5836 with some long-term symptoms. A small survey of 60 individuals reported average costs of \$688. Late-stage Lyme treatment costs ranged from an average low of \$5200 to an average high of \$13,543. The survey reported \$2045 their average cost of medical treatment for disseminated Lyme. For early-stage Lyme, wage losses ranged from \$105<sup>386</sup> to \$603.<sup>387</sup> The survey reported \$130 of lost wages.<sup>388</sup> For Lyme with neurological or cardiac complications, estimated wage losses ranged from \$2371 to \$5339. The survey reported an average \$13,500 in wage losses from late-stage Lyme. Averaged across studies, direct and indirect costs are \$2387 and \$12,676 for early-stage Lyme and late-stage Lyme respectively.

For our cost-burden analysis, we assumed a cost of \$3,000. Our model shows that an uninsured family with \$50,000 income could spend 6 percent or more in direct medical costs associated with the Lyme disease. An insured family with the same income level and undergoing the same medical procedure could end up paying anywhere from 0.3 percent (for rich plans) to 1.8 percent of its income (for a 30 percent cost share plan). Thus the mandate reduces the family cost by a significant part. If the above family was to be insured through a high deductible plan, its cost share could be as high as 5 percent to 6 percent depending on the other services counting towards the deductible and whether the family had group or individual insurance plan (individual policies typically have higher deductibles).

INCOME ▼	BENEFIT ►					
	Rich Plan	Member Share 10%	Member Share 20%	Member Share 30%	HD Plan	Uninsured
50,000	0.30%	0.60%	1.20%	1.80%	4.95%	6.00%
80,000	0.19%	0.38%	0.75%	1.13%	3.09%	3.75%
160,000	0.09%	0.19%	0.38%	0.56%	1.55%	1.88%

Considerable variability exists in an individual household's potential burden. In severe cases, inability to work can increase the economic burden by decreasing household income.

<sup>381</sup> Maes E, Lecomte P, Ray N. 1998. A Cost-of-Illness Study of Lyme Disease in the United States. *Clinical Therapeutics* 20(5): 993-1008. Prices adjusted to \$2010 using Medical CPI.

<sup>382</sup> Hsia EC, Chung JB, Schwartz JS et al. 2002. Cost-Effectiveness Analysis of the Lyme Disease Vaccine. *Arthritis and Rheumatism* 46(6): 1651-1660. Prices adjusted to \$2010 using Medical CPI

<sup>383</sup> Shadick NA, Liang MH, Phillips CB et al. 2001. The Cost-Effectiveness of Vaccination Against Lyme Disease. *Archives of Internal Medicine* 161: 554-561.

<sup>384</sup> Meltzer MI, Dennis DT, Orloski KA. 1999. The Cost-Effectiveness of Vaccinating Against Lyme Disease. *Emerging Infectious Diseases* 5(3): 321-328.

<sup>385</sup> Zhang X, Meltzer MI, Pena CA, et al. 2006. Economic Impact of Lyme Disease. *Emerging Infectious Diseases* 12(4): 653-660.

<sup>386</sup> Meltzer MI, Dennis DT, Orloski KA. 1999. The Cost-Effectiveness of Vaccinating Against Lyme Disease. *Emerging Infectious Diseases* 5(3): 321-328.

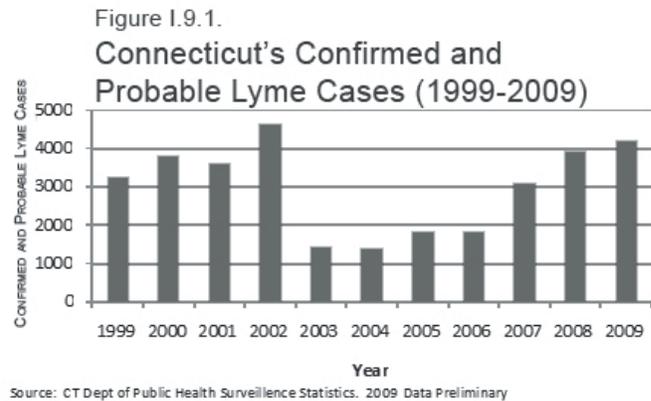
<sup>387</sup> Maes E, Lecomte P, Ray N. 1998. A Cost-of-Illness Study of Lyme Disease in the United States. *Clinical Therapeutics* 20(5): 993-1008. Prices adjusted to \$2010 using Medical CPI.

<sup>388</sup> Zhang X, Meltzer MI, Pena CA, et al. 2006. Economic Impact of Lyme Disease. *Emerging Infectious Diseases* 12(4): 653-660. Prices adjusted to \$2010 using Medical CPI.

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

Connecticut is the epicenter for *Borrelia Burgdorferi* and the *ixodes* tick (deer tick) that transmits it. In 2008, there were 2738 confirmed Lyme cases and 1158 probable cases. Preliminary numbers for 2009 show 4156 cases, probable and confirmed. Lyme disease is a category 2 reportable infectious disease. Connecticut requires doctors to report probable or confirmed cases by mail within 12 hours of diagnosis.<sup>389</sup> Connecticut labs with an electronic reporting capability to the Department of Public Health must report all positive (confirmed) cases.<sup>390</sup> In some states, there is concern of underreporting because labs are not required to report cases and there is a lack of awareness.<sup>391</sup> In Connecticut, about 85 percent of all lab results are reported. Figure I.9.1 reports the number of confirmed *and* probable cases reported to the Connecticut Department of Public Health each year since the passage of this mandate.

Because the long term consequences of not treating Lyme early can be severe, doctors likely treat all probable as well as confirmed cases. This treatment principle implies incidence rates of 114 and 122 per 100,000 people in 2008 and 2009 respectively. The incidence rate is the number of new cases each year. About 65 percent of these patients will have health insurance that falls under the mandate.



Treatment for new cases is not typically controversial. IDSA treatment guidelines recommend 10-21 days of oral antibiotics for early-stage Lyme disease without complications.<sup>392</sup> An additional 2-4 weeks of IV antibiotics may be added to this regimen for those with previously untreated late stage disease or those with neurological or cardiovascular complications.<sup>393</sup> For Lyme patients whose symptoms persist beyond 6 months, the IDSA finds that extended antibiotics are not effective and present “considerable risk of harm, including potentially life-threatening adverse events.”<sup>394</sup> The IDSA further requires objective clinical or biological evidence of *B. Burgdorferi* infection in order for individuals to receive a Lyme or post-Lyme syndrome diagnosis.

Although all Lyme patients likely demand treatment, individuals who fall outside of these current IDSA guidelines are most likely to demand and be denied treatment. These individuals may not have a clear biological diagnosis of Lyme.<sup>395, 396</sup> For others, their Lyme symptoms may persist beyond the applicable

<sup>389</sup> Connecticut Department of Public Health. Reportable Diseases.

Available at: [http://www.ct.gov/dph/lib/dph/infectious\\_diseases/pdf\\_forms\\_/reportablediseases.pdf](http://www.ct.gov/dph/lib/dph/infectious_diseases/pdf_forms_/reportablediseases.pdf) Accessed on July 20, 2010.

<sup>390</sup> Connecticut Department of Public Health. Reportable Diseases.

Available at: [http://www.ct.gov/dph/lib/dph/infectious\\_diseases/pdf\\_forms\\_/reportablediseases.pdf](http://www.ct.gov/dph/lib/dph/infectious_diseases/pdf_forms_/reportablediseases.pdf) Accessed on July 20, 2010.

<sup>391</sup> Hiu, L. Lyme and Other Tick-Borne Diseases are Under-recognized in California.

Available at: <http://www.lymedisease.org/california/pdf/HUI%20facts%20of%20LD%20in%20Calif.pdf> Accessed on July, 20, 2010.

<sup>392</sup> IDSA. 2010. Final Report of the Lyme Disease Review Panel of IDSA. Available at: <http://www.idsociety.org/Content.aspx?id=16499> Accessed on July 20, 2010.

<sup>393</sup> *Ibid.*

<sup>394</sup> IDSA. 2010. Final Report of the Lyme Disease Review Panel of IDSA – Post-Lyme Syndromes.

Available at: <http://www.idsociety.org/Content.aspx?id=16524> Accessed on July 20, 2010.

<sup>395</sup> Clarissou, J, Song A, Bernede C, et al. 2009. Efficacy of a Long-term Antibiotic Treatment in Patients with a Chronic Tick Associated Poly-Organice Syndrome. *Medecine et Maladies Infectieuses* 39: 108-115.

<sup>396</sup> Krupp, LB, Hyman LG, Grimson R et al. 2003. Study and Treatment of Post Lyme Disease (STOP-LD). *Neurology* 60: 1923-1930.

treatment window. Individuals whose symptoms do not resolve with a 14-21 day course of oral antibiotics may well demand additional courses of antibiotics until their symptoms resolve – whether this is medically warranted or not.

Within the medical profession, a schism has emerged between physicians who advocate adherence to evidence-based guidelines, and physicians who prefer to tailor treatment to the individual. The first group of physicians believes extended courses of antibiotics are not efficacious and may be dangerous. Physicians who advocate antibiotics ‘as needed’ are sometimes called ‘Lyme-literate’ physicians by patient advocacy groups. These physicians report improvements in patients receiving long-term antibiotics in a clinical setting. Frequently, Lyme patient advocacy websites make referrals to these ‘Lyme literate’ physicians available.<sup>397</sup> People with Lyme are able to self-select toward physicians who are more likely to offer long-term treatment.

The available literature with long term follow-up data shows Lyme symptoms persist after both short and long term treatment for at least some people. Studies have found that symptoms continue to resolve for 6-12 months after treatment has ended.<sup>398, 399</sup> However, a review of Lyme-treatment studies, with at least one year of follow-up, found 12-35 percent of patients still had persistent symptoms one-year after treatment.<sup>400</sup> About half of these studies focused on Lyme with neurological complications, which appear to be least likely to resolve even with long term treatment.<sup>401 402</sup> Longer term studies show that neurological and other symptoms can persist at these same rates 5-9 years after the initial illness.<sup>403, 404</sup> In addition, some researchers have documented new symptoms, including cardiac complications and EM, emerging a year or more after treatment.<sup>405, 406</sup> Interpreted appropriately, these findings suggest an upper limit of perhaps as high as 23 percent of Lyme cases may result in some form of chronic or post-Lyme syndrome.

### ***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.***

In Connecticut, the average annual incidence of Lyme disease is upwards of 100 cases per 100,000 people. Historically, as many as 23 percent of Lyme patients will have symptoms that persist at least one year. Symptoms from chronic Lyme or post-Lyme syndrome can be debilitating. Controversy exists within the medical profession with respect to the appropriate length of antibiotic treatment. Chronic Lyme patients often advocate for themselves and self-select to ‘Lyme-literate’ physicians. The cost of long-term antibiotic treatment, especially IV ceftriaxone, is substantial and perhaps even prohibitive for some. Because of this

<sup>397</sup> In Connecticut, see for instance [The Lyme Disease Foundation, Inc.](http://www.lyme.org/front.htm) available at: <http://www.lyme.org/front.htm> or the [American Lyme Disease Association, Inc.](http://www.aldf.com/programs.shtml) available at: <http://www.aldf.com/programs.shtml>.

<sup>398</sup> Dattwyler, R, Wormser FP, Rush TJ, et al. 2005. A Comparison of Two Treatment Regimens of Ceftriaxone in Late Lyme Disease. *Wein Klin Wochenschr* 117(11-12): 393-397.

<sup>399</sup> Oksi, J, Nikoskelainen J, Hiekkänen H, et al. 2007. Duration of Antibiotic Treatment in Disseminated Lyme Borreliosis. *European Journal of Clinical Microbiology and Infectious Diseases* 26: 571-581.

<sup>400</sup> The average number of patients with long term symptoms was remarkably consistent at 23% with 6 of 9 studies reported symptom rates within 2 percentage points of this average.

<sup>401</sup> Ogrinc K, Loga M, Lotric-Furlon S, et al. 2006. Doxycycline versus Ceftriaxone for the Treatment of Patients with Chronic Lyme Borreliosis. *Wien Klin wochenschr* 118(21-22): 696-701.

<sup>402</sup> Kaplan, RG, Trevino RP, Johnson GM, et al. 2003. Cognitive Function in Post-Treatment Lyme Disease: Do Additional Antibiotics Help?. *Neurology* 60: 1916-1922.

<sup>403</sup> Ljostad U, Skogvoll E, Eikeland R, et al. 2008. Oral Doxycycline versus Intravenous Ceftriaxone for European Lyme Neuroborreliosis. *The Lancet Neurology* 7: 690-95.

<sup>404</sup> Karkkonen, K, Stiernstedt S, Karlsson M. 2001. Follow-up of Patients Treated with Oral Doxycycline for Lyme Neuroborreliosis. *Scandinavian Journal of Infectious Disease* 33: 259-262.

<sup>405</sup> Barsic, B, Maretic T, Majerus L, et al. 2000. Comparison of Azithromycin and Doxycycline in the Treatment of Erythema Migrans. *Infection* 28(3): 153-156.

<sup>406</sup> Oksi, J, Nikoskelainen J, Hiekkänen H, et al. 2007. Duration of Antibiotic Treatment in Disseminated Lyme Borreliosis. *European Journal of Clinical Microbiology and Infectious Diseases* 26: 571-581.

combination of factors, the public demand for coverage of both short and long-term antibiotic regimens in Connecticut is high.

Several Lyme advocacy groups and support groups are located in Connecticut. Some of these organizations include: the Lyme Disease Foundation, Inc. (Tolland, CT), American Lyme Disease Foundation, Inc (Lyme CT), Newtown Lyme Disease Task Force (Newtown, CT) and Time for Lyme, (Stamford, CT). Regional patient groups include the International Lyme and Associated Diseases Society (ILADS) and the Lyme Disease Association, Inc. Most of these groups are active in the legislative process to secure access and coverage for Lyme treatment.

Public hearings on Public Act 99-2 drew two distinct camps to testify before Connecticut's public health committee.<sup>407</sup> At issue was whether health insurance companies should have the right to deny coverage for the more expensive, long-term IV antibiotic treatment. Connecticut's health insurance companies testified that they paid for only a maximum of 6 weeks of IV antibiotics but were willing to pay for prolonged oral antibiotics for Lyme disease. On the Lyme advocate side, patients presented their positive experience with long-term antibiotics and the frustrations with insurance company denials. Two community-based physicians presented experience to suggest that seronegative tests for Lyme disease were unreliable and should not be used by insurers as a basis to deny coverage. They recognized a place for long-term IV antibiotics in the treatment of Lyme. On the other side, two physicians presented their experience that Lyme was over-diagnosed and over-treated. They argued that 'seronegative' Lyme cases— that is, cases with Lyme-like symptoms but no biological evidence of infection – were likely not Lyme cases and would not benefit from antibiotic treatment. Further, they emphasized the serious side effects that can occur from long-term IV antibiotics.

Over the past decade, the controversy over long-term antibiotics continued. Lyme advocates, patients and doctors alike argue academic studies are insufficient and anecdotal experience supports the use of long-term antibiotics. Other physicians continue to highlight the dangers and questionable efficacy of long term antibiotic treatment. In 2009, this issue again turned political when Connecticut enacted PA 09-128. PA-09-128 protects a doctor's right to treat Lyme with long-term antibiotics without facing medical sanctions.

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

According to the Council for Affordable Health Insurance, only five states (Connecticut, Arizona, Maine, Minnesota and Rhode Island) mandate Lyme disease coverage.<sup>408</sup> Research did not locate any other state reviews of mandatory Lyme disease coverage.

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

Our review did not find any studies by any state agencies or appropriate public organizations.

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

Currently, the most effective treatment alternative is prevention and early detection of tick bites. These

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<sup>407</sup> Federer, HM. 2000. Differences are Voiced by Two Lyme Camps at a Connecticut Public Hearing on Insurance Coverage of Lyme Disease. *Pediatrics* 105: 855-57.

<sup>408</sup> Council for Affordable Health Insurance. 2009. Health Insurance Mandates in the States. Available at: [www.cahi.org](http://www.cahi.org) Accessed on June 16, 2010.

measures include public education<sup>409</sup> and personal protection measures such as daily tick checks, avoiding tick infested areas, using tick repellent and wearing protective clothing. Environmental measures include host management, spraying insecticides, and habitat modification.<sup>410</sup> Habitat modification includes cleaning up leaves and other organic detritus where tick larvae may live.<sup>411</sup>

If preventing tick bites fails, a prophylactic dose of antibiotics within 72 hours of a tick bite can effectively cure an incubating infection in an estimated 87 percent of cases.<sup>412</sup> After this window, early detection and treatment of a tick bite with a standard course of antibiotics can reduce the chances of long term complications.<sup>413</sup>

A vaccine was previously available that would decrease the number of Lyme cases. In 1998, the FDA approved LYMERix, a Lyme vaccine. A single dose of the vaccine cost \$86.80.<sup>414</sup> The vaccine was less than 100 percent effective and required multiple doses to achieve and then maintain protection.<sup>415</sup> It was withdrawn from the market in 2002 because of low public demand and concerns about patients' autoimmune responses. Work continues on developing another Lyme vaccine both for humans and Lyme hosts.

Because of limitations to conventional therapy, complementary and alternative medical approaches are sometimes sought.<sup>416</sup> These treatments range from relatively safe nutritional and herbal remedies to more controversial treatments like hyperbaric oxygen therapy.<sup>417</sup> The efficacy and safety of some of treatments has not been evaluated.

### ***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.***

Treatment for Lyme disease is a medical need. Caught early, evidence-based medical guidelines suggest Lyme disease can be successfully cured with routine regimens of antibiotics.<sup>418</sup> To do this, patients need to be aware of Lyme disease, its signs and personal preventative behaviors, such as daily tick checks. Not caught early, Lyme disease may still be cured but treatment may be more involved and have lower odds of success.

From the perspective of managed care, Lyme treatment is contentious in two areas (1) patients without a clear diagnosis, and (2) patients with persistent symptoms with and without positive biological tests. As discussed above, laboratory Lyme tests are somewhat unreliable, especially in the early stages. The tell-tale EM rash is absent or missed in as many as 20 – 75 percent of cases.<sup>419</sup> Without a clear biological basis for a

<sup>409</sup> Clark RP, Linden TH. 2008. Prevention of Lyme Disease and Other Tick-Borne Infections. *Infectious Disease Clinics of North America* 22: 381-396.

<sup>410</sup> Brei, B, Brownstein JS, George JE, et al. 2009. Evaluation of the United States Department of Agriculture Northeast Area-Wide Tick Control Project by Meta-Analysis. *Vector-Borne and Zoonotic Diseases* 9(4): 423-430.

<sup>411</sup> Connally, NP, Durante AJ, Yousey-Hindes KM et al. 2009. Peridomestic Lyme Disease Prevention. *American Journal of Preventive Medicine* 37(3): 201-206.

<sup>412</sup> Nadelman RB, Nowakowski MD, Fish D, et al. 2001. Prophylaxis with Single-Dose Doxycycline for the Prevention of Lyme Disease after an *Ixodes Scapularis* Tick Bite. *The New England Journal of Medicine* 345(2): 79-84.

<sup>413</sup> Weinstein A, Britchkov M. 2002. Lyme Arthritis and Post-Lyme Disease Syndrome. *Current Opinions in Rheumatology* 14: 383-387.

<sup>414</sup> Nadelman RB, Nowakowski MD, Fish D, et al. 2001. Prophylaxis with Single-Dose Doxycycline for the Prevention of Lyme Disease after an *Ixodes Scapularis* Tick Bite. *The New England Journal of Medicine* 345(2): 79-84. Adjusted to \$2010 using Medical Price Index.

<sup>415</sup> Nadelman RB, Nowakowski MD, Fish D, et al. 2001.

<sup>416</sup> Vojdani A, Hebroni F, Raphael Y, et al. 2009. Novel Diagnosis of Lyme Disease: Potential for CAM Intervention. *Electronic Journal for Complementary and Alternative Medicine* 6(3): 283-295.

<sup>417</sup> Pavis, C. 2003. Current and Novel Therapies for Lyme Disease. *Expert Opinion and Investigative Drugs* 12(6): 1003-1016.

<sup>418</sup> IDSA. 2010. Final Report of the Lyme Disease Review Panel of IDSA – Post-Lyme Syndromes. Available at: <http://www.idsociety.org/Content.aspx?id=16524> Accessed on July 20, 2010.

<sup>419</sup> Pavis C. 2003.

Lyme diagnosis, physicians may rely on clinical examination to begin treatment. Secondly, the appropriate length of treatment is debated by physicians. Some physicians (ILADS) suggest antibiotics should continue until a patient is cured; even if this takes a year or more.<sup>420</sup> Other physicians argue that long term antibiotics improve quality of life and should be continued whether they result in a cure or not.<sup>421</sup> Still others, including the IDSA, argue that long term antibiotics are unsafe. If a patient has not been cured by 60 days of oral antibiotics and/or 30 days of IV antibiotics, the patient does not have active Lyme disease and physicians need to consider other diagnoses.<sup>422</sup> In these two instances, managed care coverage decisions may conflict with at least some physicians' judgment.

Within limits, this mandate upholds the rights of physicians to determine the best treatment for their patients without interference from health insurers. Managed care could specify that patients have positive lab tests for Lyme disease before paying for treatment. In many instances, individuals are symptomatic but do not test positive for Lyme disease. Also, the mandate requires specialist consultation to assess long term antibiotic treatment. This provision may reduce the rate at which prolonged antibiotics are prescribed.

### ***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 Lyme disease mandate lends itself to consideration of two other types of mandates. Other tick-borne diseases are similar to Lyme; may be co-occurring with Lyme; and are sometimes mistaken for Lyme.<sup>423</sup> These diseases include Babesia, Bartonella, and Erlichia. Also, the nature of the Lyme debate brings forward the issue of patients with other long-term chronic conditions, with or without a definitive diagnosis, who may demand treatments contrary to majority medical opinion. Individuals with chronic fatigue, fibromyalgia, etc. who have had to advocate to have their conditions recognized may seek similar protections for the treatment of their chronic conditions. However, treatment options for these conditions are not as clearly defined.

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

In general, insurance companies offer richer benefits to the extent that doing so maximizes revenue. Richer benefit plans may be more attractive to portions of the market while other market sectors may opt to purchase insurance based on lower prices or premiums. In the first sector, increasing benefits will increase demand for insurance and, therefore increase revenues. In the other sector, increasing premiums decreases the demand for insurance and insurers must trade-off rising revenues from increased premiums with falling revenues from decreased demand. The rate of this trade-off is determined by how sensitive consumers (individuals or companies) are to price, known as price elasticity.

Insurers use several methods to attract consumers who are most interested in lower premiums. Individuals may pay a larger portion of the health care cost through higher deductibles or co-payments on the back-end. Insurers may use utilization review and pre-authorization protocols to decrease the use of unnecessary care. In smaller groups, individually written plans and high-deductible plans, insurers may reduce coverage for other types of care. Typically, essential or preventive services remain covered by plans that may carve out high cost services. The rising popularity of high-deductible, basic benefit plans indicates that there is a demand for less comprehensive plans.

<sup>420</sup> Savely VR. 2008. Update on Lyme Disease. *Journal of Infusion Nursing* 31(4): 236-240.

<sup>421</sup> Clarissou J, Song A, Bernede C, et al. 2009. Efficacy of a Long-term Antibiotic Treatment in Patients with a Chronic Tick Associated Poly-Organic Syndrome. *Medecine et Maladies Infectieuses* 39: 108-115.

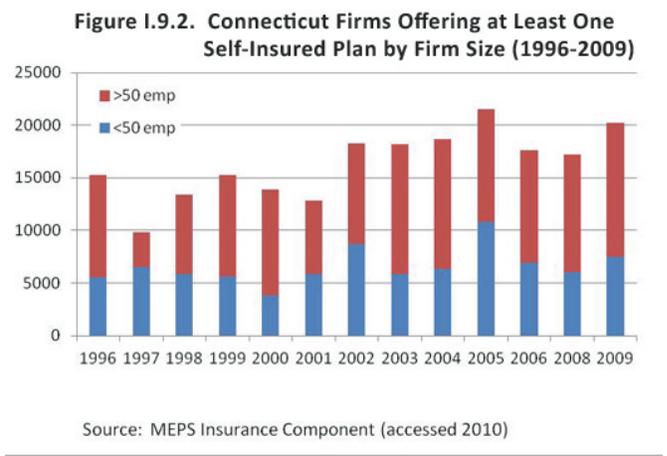
<sup>422</sup> IDSA. 2010. Final Report of the Lyme Disease Review Panel of IDSA – Post-Lyme Syndromes. Available at: <http://www.idsociety.org/Content.aspx?id=16524> Accessed on July 20, 2010.

<sup>423</sup> Savely VR. 2008. Update on Lyme Disease. *Journal of Infusion Nursing* 31(4): 236-240.

The extent to which mandating Lyme coverage engenders this behavior is unknown. Ingenix found medical and retention costs are \$0.28 for group plans and \$0.33 for individual policies, on average. Based on 2008 average enrollees with pharmacy insurance coverage, the estimated total cost of this mandate to insurers is about \$4.8 million in Connecticut. While these costs are not insignificant, these expenses alone may not be enough to change insurers' behavior but the total cost of all Connecticut's mandates may affect benefits offered.

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

Connecticut firms, particularly firms with more than 50 employees, have increasingly offered at least one self-funded plan to their employees over the past 10 years (see Figure I.9.2).<sup>424</sup> In 1999, 8.4 percent of firms with less than 50 employees and 55.2 percent of firms more than 50 employees offered at least one self-funded plan. In 2009, this percent changed to 12.6 percent and 60.4 percent respectively. For all firms, there was no significant (p=0.48) change in the percent of self-funded firms. It seems unlikely that this mandate alone has caused firms to self-fund, but the cumulative cost of multiple mandates may underlie the shift toward self-funding.



Information received from five insurers/MCOs domiciled in Connecticut representing an estimated 47 percent of the total self-funded population in Connecticut shows that 90 percent of members in self-funded plans have coverage for the 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, the claims data from the carriers and the cost projections which 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, Ingenix Consulting estimates the total annual cost to the State plans for this mandate in 2010 to be \$552,162. 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 both active employees and retirees who do not have Medicare, as reported by the State Comptroller's office.<sup>425</sup>

**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

<sup>424</sup> AHRQ. MEPS Insurance Component. Available at: [http://www.meps.ahrq.gov/mepsweb/survey\\_comp/Insurance.jsp](http://www.meps.ahrq.gov/mepsweb/survey_comp/Insurance.jsp) Accessed on August 1, 2010.

<sup>425</sup> Personal communication with Scott Anderson, State Comptroller's office, September 14, 2010

**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.***

Intravenous antibiotic use is associated with potentially life-threatening conditions both from the antibiotic treatment and the IV access devices. Major complications include infection, blood clots, embolism, drug allergies and gall bladder toxicity. This review found only one study that examined these complications.<sup>426</sup> It followed 200 patients with Lyme who had neurological complications. They received treatment for an average of 118 days (range, 7-750 days). Seven patients (3.5 percent) experienced allergic reactions to the antibiotic medication, and two patients (1.0 percent) had gallbladder toxicity. Infections related to the IV access devices occurred in 15 patients (7.5 percent) after an average 81 days of treatment. The authors concluded these complications were easily managed.<sup>427</sup> They also noted that long-term IV antibiotics are routinely used for other conditions, such as osteomyelitis and endocarditis.<sup>428</sup>

On the other side of this debate, the 2008 Infectious Disease Society of America (IDSA) reported that the risks outweigh any potential benefits of long-term IV therapy for those with post-Lyme syndrome.<sup>429</sup> The panel cited the lack of any ‘high quality’ studies that demonstrate any benefit to administering IV antibiotics beyond one month.

## **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 to provide Lyme disease treatment has been in effect since 2000. Generic versions of the antibiotics used to treat Lyme disease have become available over this time period; reducing treatment costs. However, the services and supplies covered by this mandate are not unique to Lyme disease and their price is affected by the total demand for these goods. It is unlikely that this mandate will materially alter the price of these supplies moving forward. If the rates of infection remain the same, the total cost of treatment is unlikely to increase. If the mandate is able to curtail long term antibiotic treatment, the costs of treatment may decline. For further information, please see the Ingenix Consulting Actuarial and Economic Report.

**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.***

In the case of Lyme disease, controversy exists over what constitutes appropriate use of treatment. Some physicians recommend long-term antibiotic treatment for people with continuing symptoms of Lyme disease or ‘chronic lyme’. For this contingent, Lyme disease may be diagnosed based on symptoms alone. Other physicians dispute the efficacy and safety of long-term treatment. A Lyme diagnosis is generally made with both serological and clinical evidence.

The mandate establishes a threshold level of treatment for Lyme disease. It provides for up to 30 days of

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<sup>426</sup> Stricker RB, Green CL, Savelly VR, et al. 2010. Safety of Intravenous Antibiotic Therapy in Patients Referred for Treatment of Neurologic Lyme Disease. *Minerva Med* 101(1):1-7.

<sup>427</sup> *Ibid.*

<sup>428</sup> *Ibid.*

<sup>429</sup> Lantos PM, Charini WA, Medoff G, et al. 2010. Final Report of the Lyme Disease Review Panel of the Infectious Diseases Society of America. *Clinical Infectious Diseases* 51(1). Available at: [www.aldf.com+Final\\_Report\\_by\\_IDSA\\_Guideline\\_Review\\_Panel2.pdf](http://www.aldf.com+Final_Report_by_IDSA_Guideline_Review_Panel2.pdf) Accessed on August 6, 2010.

IV antibiotics, and/or 60 days of oral antibiotics. Any treatment beyond this must be ordered by a board certified infectious disease specialist, neurologist or rheumatologist. These provisions are largely in keeping with the evidence-based approach to treating Lyme disease. Depending on the situation, IDSA guidelines provide for up to 28 days of oral antibiotics and 28 days of IV antibiotics.<sup>430</sup> A second course of antibiotics is possible at the discretion of the doctor. Antibiotic treatment is not recommended for ‘chronic Lyme’ or ‘post-Lyme syndrome’.

The mandate limits the length of treatment that can be provided by community-based or general physicians. After three months of treatment, patients must see a specialist for unresolved symptoms. The specialist may or may not continue the antibiotic treatment.

***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.***

Currently, there are no viable alternative treatments for Lyme disease other than antibiotics. While personal prophylaxis and environmental strategies can help prevent Lyme disease, they cannot cure it. To the extent the mandate reduces the unnecessary use of long-term antibiotics, it may reduce overall costs.

***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 for this condition 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. In the case of Lyme disease, insurers could require serological confirmation of the Lyme diagnosis before authorizing treatment. This provision would require a positive ELISA test followed-up by a positive Western Blot test. These tests are not entirely reliable in early stages of Lyme. Requiring them may create a barrier to needed treatment. Also, the mandate itself places some limits on treatment with the condition that long-term patients be seen by a specialist.

***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 medical cost of the mandate is spread to all insureds in group plans, medical costs are estimated to be \$0.28 PMPM and retention costs are estimated to be \$0.06 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$0.34 PMPM in 2010. Insurance coverage for the mandated benefit may be reasonably expected to increase group health insurance premiums accordingly, that is, \$4.08 per year per insured.

**Individual policies:** When the medical cost of the mandate is spread to all insureds in individual policies, medical costs are estimated to be \$0.34 PMPM and retention costs are estimated to be \$0.10 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$0.44 PMPM in 2010. Insurance

<sup>430</sup> Lantos PM, Charini WA, Medoff G, et al. 2010. Final Report of the Lyme Disease Review Panel of the Infectious Diseases Society of America. *Clinical Infectious Diseases* 51(1). Available at: [www.aldf.com+Final\\_Report\\_by\\_IDSA\\_Guideline\\_Review\\_Panel2.pdf](http://www.aldf.com+Final_Report_by_IDSA_Guideline_Review_Panel2.pdf). Accessed on August 6, 2010.

coverage for the mandated benefit may be reasonably expected to increase individual health insurance premiums accordingly, that is, \$5.28 per year per insured.

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

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

Antibiotic treatment is the standard of care for Lyme disease. There are no alternative treatments currently available. However, the length of antibiotic treatment is subject to debate. The Infectious Diseases Society of America's (IDSA) current guidelines represent the medical establishment's viewpoint (see Table I.9.1 for recommendation summary). Depending on the situation, IDSA guidelines provide for up to 28 days of oral antibiotics and 28 days of IV antibiotics.<sup>431</sup> A second course of antibiotics may be prescribed at the discretion of the doctor. This recommendation is similar to the mandate which allows for 60 days, 2 courses, of oral antibiotics and 1 course, up to 4 weeks, of IV antibiotics. Additional courses of antibiotics must be prescribed by a board certified specialist. To the extent specialists follow the IDSA guidelines, specialists will curtail the use of long-term antibiotics and reduce medical expenses. It is unclear how many courses of antibiotic treatment might be averted by this mandate. A review of the literature suggests each course of IV antibiotics averted would save between \$6500 and \$10,000.<sup>432, 433</sup>

***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 of insurance premiums and cost sharing. Actuarial analysis of claims data received from insurers/MCOs in Connecticut shows an expected cost in 2010 of \$6,062,137 for Lyme Disease Treatment for Connecticut residents covered by fully-insured group and individual health insurance plans.

To the extent this mandate increases timely access to care and raises awareness about Lyme, it can increase the number of people who receive treatment in the early stages. Late disseminated disease with neurologic or cardiac complications may require 2-4 weeks of IV antibiotics compared to early disease which is treated with 10-21 days of oral antibiotics. The total medical expenses of 3-4 weeks of IV antibiotics are between \$6,500<sup>434</sup> and \$10,000<sup>435</sup> compared to \$167<sup>436</sup> for uncomplicated, early-stage treatment. Studies report lost

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<sup>431</sup> *Ibid.*

<sup>432</sup> Maes E, Lecomte P, Ray N. 1998. A Cost-of-Illness Study of Lyme Disease in the United States. *Clinical Therapeutics* 20(5): 993-1008. Prices adjusted to \$2010 using Medical CPI.

<sup>433</sup> Hsai EC, Chung JB, Schwarz JS et al. 2002. Cost-Effectiveness Analysis of the Lyme Disease Vaccine. *Arthritis and Rheumatism* 46(6): 1651-1660.

<sup>434</sup> Maes E, Lecomte P, Ray N. 1998. A Cost-of-Illness Study of Lyme Disease in the United States. *Clinical Therapeutics* 20(5): 993-1008. Prices adjusted to \$2010 using Medical CPI.

<sup>435</sup> Hsai EC, Chung JB, Schwarz JS et al. 2002. Cost-Effectiveness Analysis of the Lyme Disease Vaccine. *Arthritis and Rheumatism* 46(6): 1651-1660.

<sup>436</sup> Meltzer MI, Dennis DT, Orloski KA. 1999. The Cost-Effectiveness of Vaccinating Against Lyme Disease. *Emerging Infectious Diseases* 5(3):321-328.

wages for late-stage disease range from an average of \$2,371<sup>437</sup> to \$5,339<sup>438</sup> compared to \$105<sup>439</sup> to \$603<sup>440</sup> for early-stage disease.

**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 Lyme disease treatment on the cost of health care for small employers. This mandate costs about \$0.28 PMPM. 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, 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 businesses tend to be more sensitive to price changes than large businesses. Also, small businesses 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. Any increase in mandates constitutes a higher percentage rise for small business compared to large businesses. While this particular benefit represents a minimal increase in premiums (0.1percent PMPM), the combined expense of all mandates may cause small businesses to discontinue providing health insurance to their employees.

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 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 became effective on 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 \$7,093,658 for Lyme disease treatment 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.

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<sup>437</sup> *Ibid.*

<sup>438</sup> Maes E, Lecomte P, Ray N. 1998.

<sup>439</sup> Meltzer MI, Dennis DT, Orloski KA. 1999.

<sup>440</sup> Maes E, Lecomte P, Ray N. 1998.

# **Volume I**

## **Chapter 10**

### **Colorectal Cancer Screening**

Review and Evaluation of Connecticut Statute  
Chapter 700, § 38a-518k and § 38a-492k  
Mandatory Coverage for Colorectal Cancer Screening

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## 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 (CID) and the University of Connecticut Center for Public Health and Health Policy (CPHHP).

Connecticut General Statutes, Chapter 700, § 38a-518k and 38a-492k mandate that group and individual health insurance policies issued, renewed or continued in this state provide coverage for colorectal cancer screening including an annual fecal occult blood test, colonoscopy, flexible sigmoidoscopy or radiologic imaging, as recommended by the American College of Gastroenterology and the American Cancer Society.

Specifically, Connecticut General Statutes, Chapter 700, § 38a-518k 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, amended, renewed or continued in this state on or after October 1, 2001, shall provide coverage for colorectal cancer screening, including, but not limited to, (1) an annual fecal occult blood test, and (2) colonoscopy, flexible sigmoidoscopy or radiologic imaging, in accordance with the recommendations established by the American College of Gastroenterology, after consultation with the American Cancer Society, based on the ages, family histories and frequencies provided in the recommendations. Benefits under this section shall be subject to the same terms and conditions applicable to all other benefits under such policies.

§ 38a-492k 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 October 1, 2001 (P.A. 01-171, S. 21.).

### *Premium impact*

**Group plans:** On a 2010 basis, medical cost is estimated to be \$3.40 per member per month (PMPM). Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services in 2010 in group plans is \$4.08 PMPM, which is approximately 1.1 percent of estimated total premium costs in group plans. Estimated cost sharing in 2010 in group plans is \$0.50 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 \$1.68 PMPM. Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services in 2010 in individual policies is \$2.19 PMPM, which is approximately 0.8 percent of estimated total PMPM medical costs in individual policies.

Estimated cost sharing in 2010 in individual policies is \$0.57 PMPM. Individual policies data is less credible than group plans data primarily due to small sample sizes.

### *Self-funded plans*

Five Connecticut carriers provided information about their self-funded plans for this mandate, which represents an estimated 47 percent of the Connecticut population in self-funded plans. For these five carriers, 98 percent of members in their self-funded plans have benefits at least equal to 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 which is included as Appendix II.

## **II. Background**

Colorectal cancer is the third most common cancer diagnosed and the second leading cause of cancer death in the United States.<sup>441</sup> It is the third leading cause of cancer-related death in Connecticut accounting for 632 deaths in 2005.<sup>442</sup> Although there is high incidence and mortality, colorectal cancer is also one of the most preventable forms of cancer. Current research has established that most colorectal cancers develop from adenomatous polyps that progress from small to large polyps and then to dysplasia and cancer.<sup>443</sup> Cancerous cells can grow through the lining and wall of the colon or rectum and penetrate blood vessels and lymph nodes spreading to vital organs throughout the body. The progression from adenoma to carcinoma is estimated to take approximately 10 years.<sup>444</sup> The slow development from polyps to colorectal cancer provides opportunities for detection and prevention of cancer related deaths by removing pre-cancerous polyps and early localized cancer cells.

The lifetime risk of colorectal cancer in the U.S. is 5.5 percent for men and 5.1 percent for women.<sup>445</sup> Risk factors include prior colorectal cancer or polyps, inflammatory bowel disease (ulcerative colitis or Crohn's disease), family history, aged 50 or older, and being of African American descent.<sup>446</sup> However, 75 percent of cases occur in people without any risk factors.<sup>447</sup> The five-year survival rate for individuals diagnosed with colorectal cancer at the localized stage is very high (90 percent) but drops considerably for more advanced stages (regional 68 percent, distant 11 percent).<sup>448</sup> In Connecticut from 1996 to 2000, 40 percent of the individuals diagnosed with colorectal cancer were detected at the localized stage and 20 percent were detected at the distant stage.<sup>449</sup>

Individuals with early stage colorectal cancer typically do not have any noticeable symptoms. Therefore,

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<sup>441</sup> Maciosek MV, Solberg LI, Coffield AB, et al. 2006. Colorectal cancer screening: health impact and cost effectiveness. *American Journal of Preventive Medicine* 31:80-90.

<sup>442</sup> Connecticut Department of Public Health. Colorectal Cancer in Connecticut: Facts and Figures. Available at: <http://www.ct.gov/dph/cwp/view.asp?a=3134&q=436344>. Accessed on April 19, 2010.

<sup>443</sup> American Cancer Society. Cancer Prevention and Early Detection Facts and Figures 2008. American Cancer Society, 2008. Available at: [http://www.cancer.org/acs/groups/content/@nho/documents/document/cped\\_2008.pdf](http://www.cancer.org/acs/groups/content/@nho/documents/document/cped_2008.pdf) Accessed on April 19, 2010.

<sup>444</sup> Fletcher, RH. 2009. Screening for colorectal cancer: strategies in patients at average risk. Available at <http://www.utdol.com/online/content/topic.do?topicKey=Screenin/4>. Accessed on March 23, 2010.

<sup>445</sup> Ries L, Melbert D, Krapcho M, et al. 2008, SEER Cancer Statistics Review 1975-2005. Available at: <http://seer.cancer.gov/csr/1975-2005/>. Accessed on March 23, 2010. Based on November 2007 SEER data submission, posted to the SEER web site. Bethesda, MD: National Cancer Institute,

<sup>446</sup> *Ibid.*

<sup>447</sup> American Cancer Society. Cancer Prevention and Early Detection Facts and Figures 2008. American Cancer Society, 2008. Available at: [http://www.cancer.org/acs/groups/content/@nho/documents/document/cped\\_2008.pdf](http://www.cancer.org/acs/groups/content/@nho/documents/document/cped_2008.pdf) Access on April 19, 2010.

<sup>448</sup> Ries L, Melbert D, Krapcho M, et al. SEER Cancer Statistics Review 1975-2005.

<sup>449</sup> Connecticut Department of Public Health. Colorectal Cancer in Connecticut: Facts and Figures. Available at: <http://www.ct.gov/dph/cwp/view.asp?a=3134&q=436344>. Access on April 19, 2010.

screening is essential to identify and remove pre-cancerous polyps and to treat early stage colorectal cancer at a more curable point. Screening has contributed in large part to the sizable decrease in incidence and mortality rates for colorectal cancer over the past two decades. Incidence rates have declined from 66.3 cases per 100,000 population in 1985 to 46.4 in 2005.<sup>450</sup> Similar results were found for mortality rates.<sup>451</sup> The U.S. Preventive Services Task Force recommends screening for individuals of average risk age 50 to 75 years.<sup>452</sup>

The American Cancer Society, the American College of Radiology, and the U.S. Multi-Society Task Force on Colorectal Cancer set forth guidelines for colorectal cancer screening emphasizing cancer prevention.<sup>453</sup> Six recommended options are available and can be categorized into two groups: 1) tests that detect cancer and precancerous polyps; and 2) tests that detect cancer. It should be noted that positive results from any of the screeners should be followed by a colonoscopy for a more detailed evaluation and subsequent treatment.<sup>454</sup> The following is a description of each of the procedures.

### ***Tests to detect both adenomatous polyps and cancer***

**Flexible Sigmoidoscopy.** A slender, flexible tube is inserted through the rectum into the colon to examine the rectum and lower two feet of the colon. A sigmoidoscopy followed with a colonoscopy when polyps or tumors are detected can identify 70-80 percent of individuals with colorectal cancer and is related to a 60 percent to 70 percent reduction of colorectal cancer mortality.<sup>455, 456</sup> This test is recommended every five years starting at age 50 for individuals in the average risk category.

**Colonoscopy.** A slender flexible tube is inserted through the rectum allowing the doctor to examine the entire colon. Strengths of this procedure include: it examines entire colon; it is the most sensitive screener for detecting colorectal cancer and adenomatous polyps; it allows for immediate removal of polyps; and it has the longest rescreening interval (10 years) for normal test results. It is estimated that colonoscopies prevent 76 to 90 percent of colon cancers.<sup>457, 458</sup> This test is recommended every 10 years starting at age 50 for average risk individuals.

**Barium enema with air contrast (DCBE)/Double contrast barium enema.** Barium sulfate is introduced through the rectum into the colon. Air is then introduced and high quality x-rays are taken of the entire colon. Detecting small polyps or cancers is difficult with this procedure. This test is recommended every five years starting at age 50 for average risk individuals.

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<sup>450</sup> American Cancer Society. Cancer Prevention and Early Detection Facts and Figures 2009. American Cancer Society, 2009. Available at: [http://www.cancer.org/acs/groups/content/@nho/documents/document/860009web\\_6-4-09.pdf](http://www.cancer.org/acs/groups/content/@nho/documents/document/860009web_6-4-09.pdf). Access on April 19, 2010.

<sup>451</sup> *Ibid.*

<sup>452</sup> U.S. Preventive Services Task Force. 2008. Screening for colorectal cancer: US preventive services task force recommendation statement. *Annals of Internal Medicine* 149(9): 627-637.

<sup>453</sup> Levin B, Lieberman DA, McFarland B, et al. 2008. Screening and surveillance for the early detection of colorectal cancer and adenomatous polyps, 2008; a joint guideline from the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. *CA: A Cancer Journal for Clinicians* 58(3): 130-60.

<sup>454</sup> American Cancer Society. 2009. Cancer Facts and Figures 2009. Atlanta, GA, Page 13, Table 6. Available at: <http://www3.cancer.org/downloads/STT/500809web.pdf>. Access on April 19, 2010.

<sup>455</sup> Imperiale TF, Wagner DR, Lin CY, et al. 2000. Risk of advanced proximal neoplasms in asymptomatic adults according to the distal colorectal findings. *The New England Journal of Medicine* 343(3): 169-74.

<sup>456</sup> Lieberman DA, Weiss DG, Bond JH, et al. 2000. Use of colonoscopy to screen asymptomatic adults for colorectal cancer. Veterans Affairs Cooperative Study Group 380. *The New England Journal of Medicine* 343(3): 162-8.

<sup>457</sup> Winawer S, Fletcher R, Rex D, et al. 2003. Colorectal cancer screening and surveillance: clinical guidelines and rationale-Update based on new evidence. *Gastroenterology* 124(2): 544-60.

<sup>458</sup> Winawer SJ, Zauber AG, Ho MN, et al. 1993. Prevention of colorectal cancer by colonoscopic polypectomy. The National Polyp Study Workgroup. *The New England Journal of Medicine* 329(27): 1977-81.

**Computed tomographic colonography (CTC)/Virtual colonoscopy.** A small, flexible tube is inserted into the rectum and air is introduced. The patient passes through a CT scanner and multiple images are taken producing a detailed, cross-sectional, 3-dimensional view of the entire colon and rectum. The CTC can detect about 96 percent of invasive colorectal cancer and has similar effectiveness as the colonoscopy at identifying large polyps.<sup>459</sup> This test is recommended every five years starting at age 50 for average risk individuals.

### *Cancer screeners*

**Fecal occult blood test (FOBT).** This screener detects small amounts of blood in the stool presumably caused by cancerous tumors and polyps that tend to bleed into the intestine. To increase accuracy, two to three samples from consecutive bowel movements must be collected. The regular use of this screener can reduce the mortality rate from colorectal cancer by 15 to 33 percent.<sup>460</sup> This procedure should occur annually starting at age 50 for average risk individuals.

**Stool DNA test (sDNA).** This test screens for altered DNA cells shed from cancerous tumors and large polyps. A one-time collection of an entire stool specimen is required. This method has been found to detect 52 percent of colorectal cancers.<sup>461</sup> The interval for this procedure is uncertain but suggested age to start is 50 years old.

Although there is extensive support for colorectal screening, less than half of the U.S. population aged 50 and older has been screened.<sup>462</sup> According to the National Health Interview Survey, 12.1 percent of adults aged 50 and older have used a FOBT in the past year and 43.1 percent have had an endoscopy (either sigmoidoscopy in the past 5 years or colonoscopy in the past 10 years).<sup>463</sup> Connecticut ranks third in the nation of adults aged 50 and older who have had a recent colorectal cancer screening test.<sup>464</sup> Currently, laws require insurance carriers to cover the full range of tests in 26 states and the District of Columbia.

Many medical procedures carry some risk to the patient. In the case of colorectal cancer screening, there is the potential of harm from the preparation, the sedation, and the procedure itself. Serious complications include death, hospitalization, perforation, major bleeding, diverticulitis, severe abdominal pain, and cardiovascular events. The U.S. Preventive Services Task Force recommends colorectal cancer screening for average risk adults ages 50 to 75. For individuals 76 to 85 years old, the benefits of screening are limited and for individuals 85 years and older the harm of the screening procedures outweighs the benefits.<sup>465</sup>

A number of studies have investigated the low rates of colorectal cancer screening. Effective communication between health care provider and patient has been found to increase colorectal cancer screening rates.<sup>466</sup> In

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<sup>459</sup> Levin B, Lieberman DA, McFarland B, et al. 2008. Screening and surveillance for the early detection of colorectal cancer and adenomatous Polyps, 2008; a joint guideline from the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. *CA: A Cancer Journal for Clinicians* 58(3): 130-60.

<sup>460</sup> *Ibid.*

<sup>461</sup> *Ibid.*

<sup>462</sup> Shaprio JA, Seeff LC, Thompson TD, et al. 2008. Colorectal cancer test use from the 2005 National Health Interview Survey. *Cancer Epidemiology, Biomarkers and Prevention* 17(7): 1623-30.

<sup>463</sup> American Cancer Society. Cancer Prevention and Early Detection Facts and Figures 2008. American Cancer Society, 2008. Available at: [http://www.cancer.org/acs/groups/content/@nho/documents/document/cped\\_2008.pdf](http://www.cancer.org/acs/groups/content/@nho/documents/document/cped_2008.pdf). Access on April 19, 2010.

<sup>464</sup> Behavioral Risk Factor Surveillance System Public Use Data Tape 2006, National Center for Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 2007.

<sup>465</sup> Screening for Colorectal Cancer: Recommendation Statement. U.S. Prevention Services Task Force. Available at: <http://www.uspreventiveservicestaskforce.org/uspstf08/colocancer/colors.htm>. Accessed on May 12, 2010.

<sup>466</sup> Brawarsky P, Brooks DR, Mucci LA, et al. 2004. Effect of physician recommendation and patient adherence on rates of colorectal cancer testing. *Cancer Detection and Prevention* 28(4): 260-8.

other words, when a clinician recommends screening, patients are more apt to follow through. In addition, African Americans are half as likely as whites to have a colonoscopy even after controlling for education, income and health insurance.<sup>467</sup> Many studies have found that medical insurance plays an important role in patient access to colorectal screening. Individuals without insurance are considerably less likely to be screened for colorectal cancer than those with coverage.<sup>468</sup>

### 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 using PubMed under search terms including: colorectal neoplasm, colorectal cancer, prevention and control, health behavior, colonoscopy, SEER Program, economics, diagnosis, cost benefits, cost savings/trends, mass screening economics, health services needs and demands, and health services accessibility.

CPHHP staff conducted independent literature searches using the Cochrane Review, Pubmed, 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. Additional sources of information (e.g. reports from CDC, NIH, ACS, etc.) were cited in addition to the peer-reviewed journal articles. CPHHP staff consulted with clinical faculty and 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.

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 Connecticut Insurance Department (CID), CPHHP and Ingenix Consulting requested and received 2007 and 2008 claims data of insurance companies and MCOs domiciled in Connecticut. Six insurers/MCOs provided colorectal cancer screening claims data for their fully-insured group and individual plan participants. Five insurers/MCOs also provided information about colorectal cancer screening coverage in the self-funded plans they administer.

### IV. Social Impact

#### ***1. The extent to which colorectal cancer screening services are utilized by a significant portion of the population.***

The Center for Disease Control and Prevention estimates that 139,127 persons in the United States were diagnosed with colorectal cancer and 53,196 people died from it in 2006 (the most recent year for which data are currently available). In 2005, 1948 new cases of colorectal cancer were diagnosed in Connecticut and 632 individuals died of the disease.<sup>469</sup> However, according to Connecticut state health officials, 30 percent of Connecticut residents over the age of 50 had never been screened by colonoscopy or

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<sup>467</sup> Murff HJ, Peterson NB, Fowke JH, et al. 2008. Colonoscopy screening in African Americans and Whites with affected first-degree relatives. *Archives of Internal Medicine* 168(6): 625-31.

<sup>468</sup> Swan J, Breen N, Coates R, et al. 2003. Progress in cancer screening practices in the United States: results from the 2000 National Health Interview Survey. *Cancer* 97(6): 1528-40.

<sup>469</sup> US Census. 2008 Population estimates for the USA and Connecticut. Available at: <http://www.census.gov/popest/states/NST-ann-est.html>. Accessed on November 21, 2009.

sigmoidoscopy in 2008.<sup>470</sup>

**2. *The extent to which colorectal cancer screening 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 has covered colorectal cancer screening since 1998.<sup>471</sup> However, Medicare claims from 1998 - 2004 indicate that slightly over half (52 percent) of the beneficiaries have had at least one claim for a colorectal cancer test during that period. Coverage for screening is based on the beneficiary's level of risk for colorectal cancer. High risk is considered to be:

- Age 50 or older
- A family history of colorectal cancer, adenomatous polyp, or hereditary nonpolyposis colorectal cancer
- A personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn's Disease and ulcerative colitis.
- Diet high in fat, especially fat from animal sources
- Other lifestyle factors such as lack of exercise, obesity, smoking or having two or more alcoholic drinks per day.

Medicare covers the following screenings at the specified frequency:

- Fecal Occult Blood Test - Once every 12 months
- Flexible Sigmoidoscopy - Once every 48 months
- Screening Colonoscopy - Once every 24 months (high risk); once every 10 years, but not within 48 months of a screening sigmoidoscopy (non-high risk)
- Barium Enema - Once every 24 months (high risk); once every 48 months (non-high risk).

Other than the fecal occult test, which the recipient pays nothing for, all of the other screening tests apply the coinsurance or copayment, though the Medicare Part B deductible is waived.<sup>472, 473</sup> However, if a screening test results in a biopsy or removal of a lesion or growth, the procedure is labeled "diagnostic" and the deductible is applied. If the flexible sigmoidoscopy or colonoscopy is done in a hospital outpatient department or ambulatory surgical center, the patient pays 25 percent of the Medicare-approved amount.<sup>474</sup>

### ***Public Programs Administered by Charities***

No information was found to indicate that charities provide funding for colorectal cancer screening. The National Colorectal Cancer Roundtable (NCCRT), co-founded by the American Cancer Society and the CDC is a national coalition of public, private, and voluntary organizations that provides leadership, strategic planning, advocacy, public awareness, and outreach efforts. It does not provide funding for colorectal cancer screening.

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<sup>470</sup> Connecticut Department of Public Health. Connecticut department of public health launches colorectal cancer screening campaign. Available at: <http://www.ct.gov/dph/cwp/view.asp?Q=456586&A=3865>. Accessed on April 20, 2010.

<sup>471</sup> Medicare Coverage Guidelines for Connecticut.

<sup>472</sup> Medicare Coverage Guidelines for Colorectal Cancer Screening- Fecal Occult Blood Test (Connecticut).

<sup>473</sup> Medicare Preventive Services Guidelines for Colorectal Cancer Screening.

<sup>474</sup> *Ibid.*

### ***Public Programs Administered by Public Schools***

No information was found that would indicate public schools would be a source of screening for colorectal cancer or funding for colorectal cancer screening.

### ***The Department of Public Health (DPH)***

Stay in the Game CT is an educational campaign funded by the State of Connecticut Department of Public Health Colorectal Cancer Control Program (CCRCP). CCRCP provides no-cost colonoscopies and referrals for diagnostic follow-up at seven selected health care facilities for Connecticut residents who meet the following initial eligibility criteria: 1) between 50 to 64 years of age; 2) income at or below 200 percent of the Federal Poverty Level ; 3) no health insurance; 4) at average risk for colorectal cancer. However, meeting the criteria does not guarantee that medical eligibility of a no-cost colonoscopy. A brief medical history and physical exam is also required to determine medical eligibility for the colonoscopy procedure.

### ***Municipal Health Departments***

No information was found regarding the availability of colorectal cancer screening or funding for colorectal cancer screening through local and municipal health departments in Connecticut.

### ***The Department of Social Services (DSS)***

Medicaid covers a number of colorectal screening tests for their clients, including fecal occult tests, colonoscopies, proctosigmoidoscopies and sigmoidoscopies.<sup>475, 476, 477, 478</sup> DSS does not specify an annual limit and enrolled providers must accept reimbursement as established on the Connecticut Medicaid fee schedules.<sup>479</sup>

The precise cost covered by Medicaid varies depending on whether the procedure is simply diagnostic, or if biopsy, removal or other medical work is needed. As long as a procedure is medically necessary, there is no copayment or coinsurance required from the patient.

### ***3. The extent to which insurance coverage is already available for the treatment, or services.***

State of Connecticut law requires coverage for colorectal cancer screening in fully-insured group and individual health insurance plans as of October 1, 2001.<sup>480</sup> 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. Five Connecticut carriers provided data on their self-funded plans for this mandate, representing an estimated 47 percent of the population covered by self-funded plans in Connecticut. For these five carriers, 98 percent of members in their self-funded plans have benefits at least equal to this mandate.

### ***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

<sup>475</sup> DSS Provider Fee Schedule: Lab Fee Schedule 2010, specifically Procedure Codes 82270-82274. Available at: <https://www.ctdssmap.com/CTPortal/Provider/Provider%20Fee%20Schedule%20Download/tabId/52/Default.aspx>. Accessed on March 23, 2010.

<sup>476</sup> DSS Provider Fee Schedule: Physician Surgical Fee Schedule 2010, specifically Procedure Codes 44388-44397 and 45355-45392. Available at: <https://www.ctdssmap.com/CTPortal/Provider/Provider%20Fee%20Schedule%20Download/tabId/52/Default.aspx>. Accessed on March 23, 2010.

<sup>477</sup> DSS Provider Fee Schedule: Physician Surgical Fee Schedule 2010, specifically Procedure Codes 45300-45327. Available at: <https://www.ctdssmap.com/CTPortal/Provider/Provider%20Fee%20Schedule%20Download/tabId/52/Default.aspx>. Accessed on March 23, 2010.

<sup>478</sup> DSS Provider Fee Schedule: Physician Surgical Fee Schedule 2010, specifically Procedure Codes 45330-45345. Available at: <https://www.ctdssmap.com/CTPortal/Provider/Provider%20Fee%20Schedule%20Download/tabId/52/Default.aspx>. Accessed on March 23, 2010.

<sup>479</sup> Personal Communication. Nina Holmes, CT DSS Medical Policy Unit. November 2, 2009.

<sup>480</sup> Connecticut General Statutes. Revised January 1, 2010. § 38a-492k (individual insurance policies); § 38a-518k (group insurance policies).

insurance plans. Available information suggests coverage is available to 98 percent of persons enrolled in self-funded plans. Persons enrolled in fully-insured and self-funded group plans represent the vast majority of covered lives. Many studies have found that medical insurance plays an important role in patient access to colorectal screening. Individuals without insurance are considerably less likely to be screened for colorectal cancer than those with coverage.<sup>481</sup>

***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 colorectal cancer screening is required to be included in fully insured 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 colorectal cancer screening depending on the type of screening completed. Because colorectal cancer screening is recommended at fairly long intervals (one to ten years depending on the type of screening and risk factors), financial hardships for those without insurance coverage are not likely to approach the financial hardships that at times result from higher frequency or higher-cost mandated benefits.

Depending on the severity of the disease and progression at time of diagnosis, a diagnosis of colorectal cancer may result in significant health and economic costs for the individual and their family, even for those with comprehensive health benefits. Delayed diagnosis of colorectal cancer is common. Only 40 percent of colorectal cancer is diagnosed at the localized stage where the five year survival rate is 90 percent. The remaining 60 percent of diagnoses are detected at the regional and distant stage where the five-year survival rate is reduced to 68 percent and 11 percent respectively.<sup>482</sup> In other words, a delay or lack of screening results in advanced disease progression that requires more intensive and costly treatment or 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.

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

Over the past decade, the number of individuals age 50 and older having some kind of colorectal cancer screening within the recommended time intervals increased from 38 percent in 2000 and 47 percent in 2005 with a subsequent increase in diagnosis and decrease in mortality.<sup>483</sup> Connecticut has a higher than average level of compliance with the recommended testing onset and frequency. According to the CDC, the percent of individuals age 50 and older who have had a sigmoidoscopy or a colonoscopy by 2008 was 69.5 percent in Connecticut as compared to the national average of 61.8 percent.<sup>484</sup> Although the number of individuals being screened is trending in a positive direction, there is still room for improvement. The rate of colorectal cancer screening among individuals with no health insurance, with no usual source of health care, and those who have not visited a doctor within the preceding year remains low.<sup>485</sup>

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<sup>481</sup> Swan J, Breen N, Coates R, et al. 2003. Progress in cancer screening practices in the United States: results from the 2000 National Health Interview Survey. *Cancer* 97(6): 1528-40.

<sup>482</sup> Ries L, Melbert D, Krapcho M, et al. SEER Cancer Statistics Review 1975-2005. Available at: <http://seer.cancer.gov/csr/1975-2005/>. Accessed on March 23, 2010. Based on November 2007 SEER data submission, posted to the SEER web site. Bethesda, MD: National Cancer Institute, 2008.

<sup>483</sup> Shaprio JA, Seeff LC, Thompson TD, et al. 2008. Colorectal cancer test use from the 2005 National Health Interview Survey. *Cancer Epidemiology, Biomarkers and Prevention* 17(7): 1623-30.

<sup>484</sup> Centers for Disease Control and Prevention. Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Available at: <http://apps.nccd.cdc.gov/brfss/list.asp?cat=CC&yr=2008&qkey=4425&state=US>. Accessed on May 12, 2010.

<sup>485</sup> Swan J, Breen N, Coates R, et al. 2003.

Several organizations and public awareness campaigns encourage individuals to seek screening. Researchers noted a significant, but temporary, surge in colonoscopies after a televised colon cancer awareness campaign.<sup>486</sup> The American Cancer Society, the American College of Radiology, and the U.S. Multisociety Task Force on Colorectal Cancer (a consortium representing the American College of Gastroenterology, the American Society of Gastrointestinal Endoscopy, and the American Gastroenterological Association) collaborated on screening guidelines published in 2008.<sup>487</sup> In addition, Stay in the Game CT is an educational campaign funded by the State of Connecticut Department of Public Health Colorectal Cancer Control Program (CCRCP) designed to increase awareness of colorectal cancer, promote the importance of colorectal cancer screening and to encourage all Connecticut residents age 50 years and older to get a colonoscopy. Despite public awareness efforts, researchers found focus group participants to be poorly informed about colorectal cancer and the possible benefits of screening, reported little or no information from physicians or mass media, and had negative attitudes about screening.<sup>488</sup>

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

Medical librarians and CPHHP staff found no published literature regarding the level of demand from the public or from providers for insurance coverage for colorectal cancer screening. However, the American Cancer Society (ACS) has advocated at the state and federal levels to encourage private health insurance plans to cover the recommended colorectal screening procedures. Currently, laws require insurance carriers to cover the full range of tests in 26 states and the District of Columbia. In addition, the ACS is working with the Centers for Medicare and Medicaid Services (CMS) to increase colorectal cancer screening among Medicare beneficiaries via public awareness campaigns and quality improvement initiatives. Expert opinion indicates that providers witness the difficulties some patients experience with accessing colorectal cancer screening, not only among the uninsured but also among the insured population and that providers support insurance coverage for colorectal cancer screening.<sup>489</sup>

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

Table I.10.1 provides details about state colorectal cancer screening laws that are similar to Connecticut's.<sup>490</sup>

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<sup>486</sup> Cram P, Fendrick AM, Inadomi J, et al. 2003. The impact of a celebrity promotional campaign on the use of colon cancer screening—The Katie Couric effect. *Archives of Internal Medicine* 163:1601–5.

<sup>487</sup> U.S. Preventive Services Task Force. 2008. Screening for colorectal cancer: U.S. Preventive Services Task Force Recommendation Statement. *Annals of Internal Medicine* 149(9): 627-637.

<sup>488</sup> Becker C, Kraft JM, Southwell BG, et al. 2000. Colorectal cancer screening in older men and women: qualitative research findings and implications for intervention. *Journal of Community Health* 25(3): 263-78.

<sup>489</sup> Personal Communication. Joel Levine, MD. Professor of Medicine, Division of Gastroenterology and Founding Clinical Director, Colon Cancer Prevention Program, University of Connecticut Health Center. May 12 and 13, 2010.

<sup>490</sup> National Conference of State Legislatures. 2010. Colorectal Cancer Screening: What are States Doing? Available at: <http://www.ncsl.org/default.aspx?tabid=14328>. Accessed on March 23, 2010.

State:	Coverage Requirements		
	Policies covered:	Consumers covered:	Benefits and Services covered:
Alaska	All individual and group plans	35-40 in high risk group, African American or anyone over 40.	Examinations and tests.
Arkansas	Individual and group HMOs, Medicaid, State Employees' and Public School Teachers' plans.	50 and older; <50 years of age and at high risk; symptomatic.	Examinations and tests in accordance with ACS guidelines. Choice of screening strategies in consultation with a health care provider.
Connecticut	All individual and group plans	Individuals defined by ACS as average and high risk.	Annual fecal occult blood test. Colonoscopy, flexible sigmoidoscopy and radiologic imaging
Delaware	All individual and group plans, HMO's, health service corporations	Average and high risk; frequency determined by physician.	Annual FOBT; colonoscopy (10 years); flexible sigmoidoscopy (5 years); or double contrast barium enema (5 to 10 years).
District of Columbia	All individual and group plans, including Medicaid	Individuals at average and high risk.	In accordance with ACS screening options.
Georgia	All health insurance plans	Individuals at average and high risk.	In accordance with ACS screening options.
Hawaii	All health insurance plans	Individuals age 50-75	In accordance with the evidence-based recommendations established by the United States Preventive Services Task Force.
Illinois	All individual and group plans	Individuals defined by ACS as average risk.	In accordance with the published ACS guidelines or other existing guidelines from government agencies professional organizations.
Indiana	Mandated offering for individual policies; mandated benefit for group plans	Individuals at average and high risk.	In accordance with ACS screening options.
Kentucky	All benefit plans	Individuals over age 50; <50 deemed high risk by the ACS.	As specified in current American Cancer Society guidelines for colorectal cancer screening.
Louisiana	All insurers or HMOs	Individuals at average risk.	Routine screening includes a fecal occult blood test, flexible sigmoidoscopy, or colonoscopy provided in accordance with ACS.

State:	Coverage Requirements		
	Policies covered:	Consumers covered:	Benefits and Services covered:
Maine	Group and individual insurers	50 years of age or older; or < 50 years of age and at high risk	As recommended in accordance with the most recently published colorectal cancer screening guidelines of a national cancer society.
Maryland	Insurers, HMOs and nonprofit plans	Individuals at average and high risk.	In accordance with ACS screening options.
Minnesota	All policies and plans	Individuals defined by standard practice.	In accordance to standard practices of medicine.
Missouri	All individual and group plans	Individuals at average risk.	In accordance with ACS screening options.
Nebraska	All individual and group plans	Individuals over 50 years old.	Annual FOBT; flexible sigmoidoscopy (5 years); colonoscopy (10 years); or a barium enema every 5 to 10 years
Nevada	All individual and group plans	Individuals at average risk.	In accordance with ACS screening options.
New Jersey	HMOs and all individual and group plans	Individuals at average and high risk.	In accordance with ACS screening options.
New Mexico	All individual and group plans	As determined by health care provider.	In accordance with USPSTF recommendations.
North Carolina	Teachers and State Employee Major Medical Plan; all health insurance plans	Individuals at average and high risk.	In accordance with ACS screening options.
Oregon	HMOs and all individual and group plans that cover medical, surgical and hospital costs.	Individuals age 50 and over and high risk as recommended by a physician.	In accordance with ACS screening options.
Pennsylvania	All health insurance policies group health, sickness or accident policy or subscriber contract or certificate offered to groups of 51 or more employees.	Nonsymptomatic covered individuals who are fifty (50) years of age or older.	A colonoscopy or any combination of colorectal cancer screening tests in accordance with the American Cancer Society guidelines on screening for colorectal cancer published as of January 1, 2008.
Rhode Island	All individual and group plans	Nonsymptomatic individuals.	In accordance with ACS screening options.
Texas	All health insurance plans	Persons 50 years or older.	Annual FOBT; flexible sigmoidoscopy (5 years); colonoscopy (10 years).

State:	Coverage Requirements		
	Policies covered:	Consumers covered:	Benefits and Services covered:
Vermont	All health insurance plans	Persons 50 years or older or high risk.	Annual FOBT; flexible sigmoidoscopy (5 years); colonoscopy (10 years).
Virginia	State employees plans; individual and group plans	Individuals at average and high risk.	In accordance with ACS screening options.
Washington	All health insurance plans	Individuals at high risk under 50 years old or anyone over 50 years old.	Examinations and laboratory tests consistent published guidelines.
West Virginia	All health insurance plans	Persons age 50 and over; Symptomatic persons less than 50 years of age.	Annual FOBT; flexible sigmoidoscopy (5 years), colonoscopy (10 years); double contrast barium enema (5 years).
Wisconsin	All health insurance plans	Under specific guidelines and risk factors.	In accordance with ACS screening options.
Wyoming	HMOs and all group plans	Nonsymptomatic individuals	Colorectal cancer examination and laboratory tests.

**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 two studies from state agencies and public organizations related to the social impact of mandated insurance coverage for colorectal cancer screening. 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.

In 2008, the Maryland Health Care Commission (MHCC) conducted a review of the impact of Maryland’s colorectal cancer screening mandate, which requires carriers to cover colorectal cancer screening in accordance with the latest screening guidelines issued by the American Cancer Society.<sup>491</sup> The Report focused on financial impact and concluded that the full cost of the mandate amounts to 0.2 percent of the premium for both groups and individuals.<sup>492</sup> Additionally, the report concluded that “almost all” insurers in the self-funded market were in compliance with the mandate.<sup>493</sup>

In 2009, Maine published a report on the “Cumulative Impact of Mandates in Maine.”<sup>494</sup> The Report contained a review of Maine’s colorectal cancer screening mandate which “requires coverage for colorectal cancer screening for persons fifty years of age or older, or less than 50 years of age and at high risk for colorectal cancer according to the most recently published colorectal cancer screening guidelines of a

<sup>491</sup> MARYLAND INSURANCE CODE § 15-837

<sup>492</sup> 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](http://mhcc.maryland.gov/health_insurance/mandated_1207.pdf). Accessed on March 23, 2010.

<sup>493</sup> *Ibid.*

<sup>494</sup> Maine Department of Professional and Financial Regulation, Bureau of Insurance. 2009. Cumulative Impact of Mandates in Maine. Available at: <http://www.maine.gov/pfr/legislative/documents/mandatecumcost2009.pdf>. Accessed on March 23, 2010.

national cancer society.”<sup>495</sup> Because no carriers in Maine stated that they denied coverage, the report did not estimate an impact on insurance premiums.<sup>496</sup>

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

According to the colorectal cancer screening guidelines set forth by the American Cancer Society, the American College of Radiology, and the U.S. Multi-Society Task Force on Colorectal Cancer, the recommended screening procedures include: flexible sigmoidoscopy, colonoscopy, double contrast barium enema, computed tomographic colonography, fecal occult blood test, and stool DNA test.<sup>497</sup> Single stool sample FOBT cards and “toilet bowl tests” are not recommended colorectal cancer screening procedures by the American Cancer Society or any other major medical organization.<sup>498</sup>

***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 colorectal cancer screening fulfills a medical need that might not otherwise be met. Early detection is critical for successful treatment, and is thus consistent with the role of health insurance. Required insurance coverage for colorectal cancer screening ensures that at least persons covered by fully insured group and individual insurance plans have access to coverage for the service.

The statutes are also consistent with the concept of managed care as they do not prohibit insurers/MCOs from using prior authorization, 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.***

It is possible that the basic structure of the mandate could be replicated for screening for other types of cancer. If denials of insurance coverage for certain screening and diagnostic tests 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.

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

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

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

Due to the relatively high utilization of colorectal cancer screening (69.5 percent of individuals age 50

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<sup>495</sup> *Ibid.*

<sup>496</sup> *Ibid.*

<sup>497</sup> Levin B, Lieberman DA, McFarland B, et al. 2008. Screening and surveillance for the early detection of colorectal cancer and adenomatous polyps, 2008; a joint guideline from the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. *CA: A Cancer Journal for Clinicians* 58(3): 130-60.

<sup>498</sup> *Ibid.*

and older have had a sigmoidoscopy or a colonoscopy) the financial impact is moderately significant.<sup>499</sup> However, it is not anticipated that employers shifted or 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 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.

Five Connecticut carriers provided information on their self-funded plans for this mandate, which represents an estimated 47 percent of Connecticut residents covered by self-funded plans. For these five carriers, 98 percent of members in their self funded plans have benefits at least equal to this mandate.

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

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 health insurance plan will total \$6,704,827 in 2010.<sup>500</sup>

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

Many medical procedures carry some risk to the patient. In the case of colorectal cancer screening, there is the potential of harm from the preparation, the sedation, and the procedure itself. The USPSTF recommends colorectal cancer screening for average risk adults ages 50 to 75. For individuals 76 to 85 years old, the benefits of screening are limited and for individuals 85 years and older the harm of the screening procedures outweigh the benefits.<sup>501</sup>

<sup>499</sup> Centers for Disease Control and Prevention. Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Available at: <http://apps.nccd.cdc.gov/brfss/list.asp?cat=CC&yr=2008&qkey=4425&state=US>. Accessed on May 12, 2010.

<sup>500</sup> 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.

<sup>501</sup> Screening for Colorectal Cancer: Recommendation Statement. U.S. Prevention Services Task Force. Available at: <http://www.uspreventiveservicestaskforce.org/uspstf08/colocancer/colors.htm>. Accessed on May 12, 2010.

## Cancer Screeners

**Fecal Tests.** According to the USPSTF, there is limited potential risk of harm to patients using fecal tests to detect colorectal cancer.

**Stool DNA test (sDNA).** Limited information is available about harm associated with this test. A common misunderstanding is that findings from this test can contribute to genetic profiling and uninsurability.<sup>502</sup>

## Adenomatous Polyps and Cancer Screeners

**Flexible Sigmoidoscopy.** Serious complications (death, hospitalization, perforation, bleeding, severe abdominal symptoms, syncope) occur in approximately 3.4 per 10,000 cases.<sup>503</sup>

**Colonoscopy.** Serious complications (e.g. deaths, adverse events requiring hospitalization, perforation, major bleeding, diverticulitis, severe abdominal pain, and cardiovascular events) occur in approximately 25 per 10,000 cases.<sup>504</sup>

**CT Colonography.** Excess burden may be placed on the patient and health care system due to necessary follow up testing and procedures required when abnormalities are detected. Risk for perforation is estimated to range from 0 to 6 per 10,000 for both symptomatic and asymptomatic patients. There are no conclusive findings addressing the level of risk associated with radiation exposure due to a CT colonography.<sup>505</sup>

## 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 mandate is not expected to materially alter the cost of colorectal cancer screening over the next five years. Colonoscopy has been a more frequently performed procedure in recent years, due in part to the aging population. Connecticut has a higher than average level of compliance with the recommended testing onset and frequency. According to the CDC, the percent of age 50 and older who have had a sigmoidoscopy or a colonoscopy by 2008 was 69.5 percent in Connecticut as compared to the national average of 61.8 percent.<sup>506</sup> Correspondingly, the rate of death due to colon cancer in women and men of Connecticut was lower in the five years post-mandate as compared to the five pre-mandated years. The cost of colorectal cancer screening 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 treatment, or service over the next five years.***

For those persons in the recommended colorectal screening population whose insurance plans would not otherwise cover colorectal cancer screening, the mandated health benefit may increase appropriate use of

<sup>502</sup> Young GP, Cole S. 2007. New stool screening tests for colorectal cancer. *Digestion* 76:26-33.

<sup>503</sup> Whitlock EP, Lin JS, Liles E, et al. 2008. Screening for colorectal cancer: a targeted, updated systematic review of the U.S. Preventive Services Task Force. *Annals of Internal Medicine* 149: 638-58.

<sup>504</sup> *Ibid.*

<sup>505</sup> *Ibid.*

<sup>506</sup> Centers for Disease Control and Prevention. Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Available at: <http://apps.nccd.cdc.gov/bfss/list.asp?cat=CC&yr=2008&qkey=4425&state=US>. Accessed on May 12, 2010.

the service. For persons covered by self-funded plans or use out-of-pocket funds or receive colorectal cancer screening financial assistance 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. The legislation requiring the coverage references professional guidelines for screening and the invasive nature of the procedures makes it unlikely that a significant amount of inappropriate use or overutilization would occur.

***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 Fecal Occult Blood Test is an affordable screening (\$5 to \$15) while a single colonoscopy can cost up to \$1,800.<sup>507</sup> Medical experts recommend colorectal cancer screening for the populations identified in the legislation. Screening can lead to early detection of colorectal cancer. Often, early detection leads to less expensive treatment. Later detection may lead to complications and more extensive treatment.

***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 the treatment, or 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). (For further discussion, please see Appendix II, Ingenix Consulting Actuarial and Economic Report, page 14-16.)

**Group plans:** When the medical cost of the mandate is spread to all insureds in group plans, medical costs are estimated to be \$3.40 PMPM and retention costs are estimated to be \$0.68 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$4.08 PMPM in 2010. Insurance coverage for the mandated benefit may be reasonably expected to increase group health insurance premiums accordingly, that is, \$48.96 per year per insured.

**Individual policies:** When the medical cost of the mandate is spread to all insureds in individual policies, medical costs are estimated to be \$1.68 PMPM and retention costs are estimated to be \$0.50 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$2.18 PMPM in 2010. Insurance coverage for the mandated benefit may be reasonably expected to increase individual health insurance premiums accordingly, that is, \$26.16 per year per insured.

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

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

As discussed in the Background section, the American Cancer Society, the American College of Radiology,

<sup>507</sup> American Cancer Society. 2009. Cancer Facts and Figures 2009. Available at: <http://ww3.cancer.org/downloads/STT/500809web.pdf>. Accessed on April 19, 2010.

and the U.S. Multi-Society Task Force on Colorectal Cancer collaborated on colorectal cancer screening guidelines.<sup>508</sup> The six recommended screening procedures are categorized into two groups: those that detect cancer, and those that detect pre-cancerous polyps and cancer. Single stool sample FOBT cards and “toilet bowl tests” are not recommended colorectal cancer screening procedures by the American Cancer Society or any other major medical organization. The benefits, limitations and estimated costs of each of the recommended screening procedures are detailed in Table I.10.2.<sup>509</sup> It should be noted that positive results based on any of the screeners should be followed by a colonoscopy for a more detailed evaluation and necessary treatment.

**Table I.10.2** Benefits, limitations and estimated costs of the recommended screening procedures

Test	Pros	Cons
Flexible sigmoidoscopy  Estimated cost: \$150-300	Fairly quick and safe Usually doesn't require full bowel preparation Sedation usually not used Does not require a specialist Done every 5 years	Views only about a third of the colon Can miss small polyps Can't remove all polyps May be some discomfort Very small risk of bleeding, infection, or bowel tear Colonoscopy will be needed if abnormal
Colonoscopy  Estimated cost: \$1,000	Can usually view entire colon Can biopsy and remove polyps Done every 10 years Can diagnose other diseases	Can miss small polyps Full bowel preparation needed More expensive on a one-time basis than other forms of testing Sedation of some kind is usually needed Will need someone to drive you home You may miss a day of work Small risk of bleeding, bowel tears, or infection
Double-contrast barium enema (DCBE)  Estimated cost: \$300-400	Can usually view entire colon Relatively safe Done every 5 years No sedation needed	Can miss small polyps Full bowel preparation needed Some false positive test results Cannot remove polyps during testing Colonoscopy will be needed if abnormal
CT colonography (virtual colonoscopy)  Estimated cost: \$1,000	Fairly quick and safe Can usually view entire colon Done every 5 years No sedation needed	Can miss small polyps Full bowel preparation needed Some false positive test results Cannot remove polyps during testing Colonoscopy will be needed if abnormal Still fairly new - may be insurance issues

<sup>508</sup> Levin B, Lieberman DA, McFarland B, et al. 2008. Screening and surveillance for the early detection of colorectal cancer and adenomatous polyps, 2008; a joint guideline from the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. *CA: A Cancer Journal for Clinicians* 58(3): 130-60.

<sup>509</sup> American Cancer Society. 2009. Cancer Facts and Figures 2009. Available at: <http://ww3.cancer.org/downloads/STT/500809web.pdf>. Accessed on April 19, 2010.

**Table I.10.2** Benefits, limitations and estimated costs of the recommended screening procedures

Test	Pros	Cons
Fecal occult blood test (FOBT)  Estimated cost: \$30	No direct risk to the colon No bowel preparation Sampling done at home Inexpensive	May miss many polyps and some cancers May produce false-positive test results May have pre-test dietary limitations Should be done annually Colonoscopy will be needed if abnormal
Fecal immunochemical test (FIT)  Estimated cost: \$30	No direct risk to the colon No bowel preparation No pre-test dietary restrictions Sampling done at home Fairly inexpensive	May miss many polyps and some cancers May produce false-positive test results Should be done annually Colonoscopy will be needed if abnormal
Stool DNA test  Estimated cost: \$350	No direct risk to the colon No bowel preparation No pre-test dietary restrictions Sampling done at home	May miss many polyps and some cancers May produce false-positive test results More expensive than other stool tests Still a fairly new test Not clear how often it should be done Colonoscopy will be needed if abnormal

**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 of insurance premiums and cost sharing. Actuarial analysis of claims data received from insurers/MCOs in Connecticut shows an expected cost in 2010 of \$61,791,095 for colorectal cancer treatments for Connecticut residents covered by fully-insured group and individual health insurance plans.

Individuals with early stage colorectal cancer typically do not have any noticeable symptoms. Therefore, screening is essential to identify and remove pre-cancerous polyps and to treat early stage colorectal cancer at a more curable point. Screening has contributed in large part to the sizable decrease in incidence and mortality rates for colorectal cancer over the past two decades. Incidence rates have declined from 66.3 cases per 100,000 population in 1985 to 46.4 in 2005.<sup>510</sup> Similar results were found for mortality rates.<sup>511</sup>

**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 colorectal cancer screening on the cost of health care for small employers. Small employers have a reduced negotiating power due to a smaller number of covered lives in their insurance plans. The relatively high estimated cost of the mandate (\$4.08 PMPM in fully insured group plans) suggests potential differences in effects among different sized

<sup>510</sup> American Cancer Society. 2009. Cancer Facts and Figures 2009. Available at: <http://ww3.cancer.org/downloads/STT/500809web.pdf>. Accessed on April 19, 2010.

<sup>511</sup> *Ibid.*

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 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 became effective in 2001, 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 \$72,793,836 for colorectal cancer screening 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 I

## Chapter 11

### **Coverage for Treatment of Tumors and Leukemia, Reconstructive Surgery, Prosthesis, Chemotherapy, Wigs, and Breast Reconstruction**

Review and Evaluation of Connecticut Statute  
Chapter 700, § 38a-542 and § 38a-504

Mandatory Coverage for Treatment of Tumors and Leukemia.

Mandatory Coverage for Reconstructive Surgery, Prosthesis, Chemotherapy,  
and Wigs.

Mandatory Coverage for Breast Reconstruction After Mastectomy.

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## 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 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-504 states that each individual health insurance policy...

...shall provide coverage under such policies for the surgical removal of tumors and treatment of leukemia, including outpatient chemotherapy, reconstructive surgery, cost of any nondental prosthesis including any maxillo-facial prosthesis used to replace anatomic structures lost during treatment for head and neck tumors or additional appliances essential for the support of such prosthesis, outpatient chemotherapy following surgical procedure in connection with the treatment of tumors, and a wig if prescribed by a licensed oncologist for a patient who suffers hair loss as a result of chemotherapy. Such benefits shall be subject to the same terms and conditions applicable to all other benefits under such policies.

(b) Except as provided in subsection (c) of this section, the coverage required by subsection (a) of this section shall provide at least a yearly benefit of five hundred dollars for the surgical removal of tumors, five hundred dollars for reconstructive surgery, five hundred dollars for outpatient chemotherapy, three hundred fifty dollars for a wig and three hundred dollars for prosthesis, except that for purposes of the surgical removal of breasts due to tumors the yearly benefit for prosthesis shall be at least three hundred dollars for each breast removed.

(c) The coverage required by subsection (a) of this section shall provide benefits for the reasonable costs of reconstructive surgery on each breast on which a mastectomy has been performed, and reconstructive surgery on a nondiseased breast to produce a symmetrical appearance. Such benefits shall be subject to the same terms and conditions applicable to all other benefits under such policies. For the purposes of this subsection, reconstructive surgery includes, but is not limited to, augmentation mammoplasty, reduction mammoplasty and mastopexy.<sup>512</sup>

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). The claims data reflect variability for this mandate due to differences in interpretation by insurers/MCOs about the procedures and services included in the mandate.

### *Current coverage*

This mandate has been in effect since 1990 or earlier. (P.A. 90-243, S. 123). The minimum benefit levels are very low compared to the actual cost of the treatments and most insurers do not limit their coverage to these minimum amounts. In assessing the cost of the mandate today, it is difficult to separate the mandate cost from what any insurer/MCO would otherwise pay on behalf of one of their members with cancer. During the past twenty years, advances in chemotherapy have led to more effective and more expensive

<sup>512</sup> Note: See Connecticut General Statutes § 381-542 for similar language related to group health insurance policies.

drugs and biologicals. The cost of chemotherapy drugs has risen substantially. Insurers and managed care organizations may pay hundreds of thousands of dollars in claims for the chemotherapeutic treatment of some patients with tumors or leukemia. The results of improved chemotherapies and the associated cost increases are higher survival and cancer-free survival rates. Similarly but to a lesser extent, advances in reconstructive surgery also contribute to the increased dollar value of claims paid by insurers and managed care organizations on behalf of their members.

### *Premium impact*

**Group plans:** On a 2010 basis, medical cost is estimated to be \$11.00 per member per month (PMPM). Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services in 2010 in group plans is \$13.20 PMPM, which is approximately 3.7 percent of estimated medical costs in group plans. Estimated cost-sharing in 2010 in group plans is \$1.17 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 \$8.60 PMPM. Estimated total cost (insurance premium, administrative fees, and profit) of the mandated services in 2010 in individual policies \$11.17 PMPM, which is approximately 4.1 percent of estimated medical costs in individual policies. Estimated cost sharing in 2010 in individual policies is \$1.52 PMPM. Individual policies data is less credible than group plans data primarily due to small sample sizes.

### *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 86.1 percent of members in their self-funded plans have coverage for the benefits.

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**

Due to the incredibly wide range of treatments, services and types of cancer included in this statute the authors attempt to condense the discussion and avoid deep analyses of any individual topic. The discussion borrows extensively from existing research summaries to detail background information.

The terms tumor, leukemia, and cancer used in this particular insurance mandate review should not be used interchangeably or considered to have the same meaning. Cancer (also known as a malignant neoplasm) is medically defined as the term for a collection of diseases characterized by rapid and abnormal cell growth.<sup>513</sup> This rapid cell growth not only can have dire effects on different systems in the body, but it can also spread to different parts of the body – a phenomenon known as metastasis.<sup>514</sup>

Often, rapid cell growth can create large masses of tissue, which can be located in or next to organs of the body. These masses are known as tumors, which can either be malignant or benign. Only malignant tumors are considered cancerous, as they can interfere with the function of certain organs they are in or next to, and have the potential to spread to different parts of the body.<sup>515</sup> Benign tumors cannot spread to other parts

<sup>513</sup> The Mayo Clinic. 2010. Definitions: Cancer. Available at: <http://www.mayoclinic.com/health/cancer/DS0107>. Accessed on November 29, 2010.

<sup>514</sup> WHO International Agency of Research on Cancer. 2009. Fact sheets on cancer. Available at: <http://www.who.int/mediacentre/factsheets/fs297/en>. Accessed on November 29, 2010.

<sup>515</sup> Cleveland Clinic. 2010. Information on cancer. Available at:

of the body, but they can be very harmful if situated next to a vital organ and obstruct the function of that organ.

Leukemia is a type of cancer that is not characterized by a tumor formation. Rather, the cancer affects the bone marrow—the body’s source for red blood cells, white blood cells, and platelets. Leukemia affects the bone marrow by producing many abnormal white blood cells that do not function properly, affecting the person’s immune system in the process.<sup>516</sup> Leukemia can affect, both children and adults. There are four types of leukemia, categorized by how quickly they affect the person (acute or chronic) and which type of white blood cell is affected (lymphoid or myeloid).<sup>517</sup>

## **Tumors and Cancer Epidemiology**

[From: CURRENT Diagnosis and Treatment: Surgery, 13e >Chapter 44. Oncology  
Michael S. Sabel, MD, FACS. Available from AccessMedicine]

### ***Tumor Nomenclature***

Neoplasms are defined as benign or malignant according to the clinical behavior of the tumor. Benign tumors have lost normal growth regulation but tend to be surrounded by a capsule and do not invade surrounding tissues or metastasize.

Benign tumors are generally designated by adding the suffix -oma to the name of the cell of origin. Examples include lipoma and adenoma. The term cancer normally refers to malignant tumors, which can invade surrounding tissues or metastasize to distant sites in the host. The nomenclature of malignant tumors is typically based on the cell’s embryonal tissue origins. Malignant tumors derived from cells of mesenchymal origin are called sarcomas. These include cancers that derive from muscle, bone, tendon, fat, cartilage, lymphoid tissues, vessels, and connective tissue. Neoplasms of epithelial origin are called carcinomas. These may be further categorized according to the histologic appearance of the cells. Tumor cells that have glandular growth patterns are called adenocarcinomas, and those that resemble squamous epithelial cells are called squamous cell carcinomas. Cancers composed of undifferentiated cells that bear no resemblance to any tissues are designated as “poorly differentiated” or “undifferentiated” carcinomas.

### ***Tumor Grade***

Beyond the type of cancer, it is important to classify tumors by their behavior and prognosis in order to determine appropriate therapy as well as evaluate different treatment modalities. Grading of a tumor is a histologic determination and refers to the degree of cellular differentiation. Separate pathologic grading systems exist for each histologic type of cancer. Depending on the type of tumor, these systems are based on nuclear pleomorphism, cellularity, necrosis, cellular invasion, and the number of mitoses. Increasing grades generally denote increasing degrees of dedifferentiation. While the grade of the tumor typically has less prognostic value than its stage, tumor grade has great clinical significance in soft tissue sarcoma, astrocytoma, transitional cell cancers of the genitourinary tract, and Hodgkin and non-Hodgkin lymphoma.

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[http://my.clevelandclinic.org/disorders/Cancer/hic\\_Cancer\\_Overview.aspx#a0](http://my.clevelandclinic.org/disorders/Cancer/hic_Cancer_Overview.aspx#a0). Accessed on November 29, 2010.

<sup>516</sup> Cleveland Clinic. 2010. Information on leukemia. Available at:

[http://my.clevelandclinic.org/disorders/Leukemia/hic\\_Leukemia.aspx](http://my.clevelandclinic.org/disorders/Leukemia/hic_Leukemia.aspx). Accessed on November 29, 2010

<sup>517</sup> Mayo Clinic. 2010. Information on causes of leukemia. Available at:

<http://www.mayoclinic.com/health/leukemia/DS00351/DSECTION=causes>. Accessed on November 29, 2010

## *Tumor Stage*

Tumor staging establishes the extent of disease and has important prognostic and therapeutic implications in most types of cancer. Clinical staging is based on the results of a noninvasive evaluation, including physical examination and various imaging studies. Pathologic staging is based on findings in surgical tumor specimens and biopsies and allows for the evaluation of microscopic disease undetectable by imaging techniques. Pathologic staging may reveal more extensive tumor spread than the clinical evaluation and is the more reliable information.

As with grading, the staging systems vary with different tumor types. Two major staging systems are currently in use, one developed by the Union Internationale Contre le Cancer (UICC) and the other by the American Joint Committee on Cancer (AJCC). The UICC system is based on the TNM classification. T refers to the primary tumor and is based on the size of the tumor and invasion of surrounding structures. Tumors are characterized as T1 to T4 cancers, with the higher T stages for larger and more invasive tumors. N refers to regional lymph nodes, and classifications of N0 to N3 denote increasing degrees of lymph node involvement. Finally, M refers to distant metastatic disease, with M0 signifying no distant metastases and M1 and M2 indicating the presence of blood-borne metastatic disease. The AJCC system divides cancers into stages 0 to IV, with higher stages representing more widespread disease and a poorer prognosis. Regardless of the staging system or the tumor type, higher stages correlate with decreased survival.

## *Cancer Epidemiology*

Cancer epidemiology is the study of the distribution of cancer and its determinants among defined populations and is used to examine cancer etiology as well as the efficacy of prevention, detection, and treatment strategies. The most basic types of epidemiologic terms describe cancer rates or cancer deaths for specific populations over a certain period of time.

While absolute numbers of cancer cases may be useful for health care planning, they do not take into account the size or nature of the underlying population at risk. For this reason, the most commonly used population-based measures of cancer are incidence and mortality. Cancer incidence rates are defined as the number of new cancer cases diagnosed during a fixed time period divided by the total population at risk. Cancer mortality rates are defined similarly, with cancer deaths replacing new cancer cases. These rates are typically expressed as the number of events per 100,000 individuals per year.

Cancer incidence examines only those diagnosed with the disease during that time period; it does not include patients diagnosed earlier who are living with cancer. Cancer prevalence describes the number of people with the disease. Prevalence is more relevant to the public health burden of cancer because all prevalent cases involve accessing health care. The relationship among incidence, prevalence, and mortality is influenced by the fatality of the disease. If the disease is highly fatal and the interval between presentation and death is short, mortality rates will be similar to incidence rates. The number of deaths from cancer divided by the total number people diagnosed with the cancer is known as the cancer fatality rate.

Examining the fatality of cancer is obviously important when comparing treatments meant to improve outcome. Overall survival (OS) is the most global endpoint and is defined as the proportion of people alive at a specified period after being diagnosed with the disease. Five years is conventionally used as the time period (i.e., 5-year survival). However, overall survival may not always reflect the success of treatment. Over that period of time, some

patients may die of disease, but others may die of other causes. In addition, some patients may have a local or regional recurrence that is successfully treated, while some may recur with distant metastases but not succumb to them. For this reason, survival rates in cancer are often qualified by the patient's disease status.

Disease-free survival refers to the proportion of patients alive and without disease over a specific period of time. A patient who developed metastases but is still alive would be included in the overall survival rate but not the disease-free survival rate. Disease-free survival and overall survival may provide different pictures of the success of treatment. A therapy that improves disease-free survival but not overall survival may still be important if quality of life is improved. In some cancers, local or regional recurrences can be readily treated with minimal impact on overall survival. In these cases, disease-free survival may present an overly pessimistic picture of outcome. Therefore, it may be more relevant to compare distant disease-free survival, which refers to the proportion of people alive and without distant metastases, regardless of local recurrence. In some cases, it is difficult to assess the efficacy of a treatment by looking at overall survival or disease-free survival if there are deaths from competing causes. It may be more helpful to compare disease-specific survival, which is the percentage of people who have survived a disease since diagnosis or treatment and does not count patients who died from other causes.

### **Basic Facts About Cancer**

[From: The American Cancer Society, Cancer Facts and Figures, 2009.]

Cancer is a group of diseases characterized by uncontrolled growth and spread of abnormal cells. If the spread is not controlled, it can result in death. Cancer is caused by both external factors (tobacco, infectious organisms, chemicals, and radiation) and internal factors (inherited mutations, hormones, immune conditions, and mutations that occur from metabolism). These causal factors may act together or in sequence to initiate or promote carcinogenesis. Ten or more years often pass between exposure to external factors and detectable cancer. Cancer is treated with surgery, radiation, chemotherapy, hormone therapy, biological therapy, and targeted therapy.

Anyone can develop cancer. Since the risk of being diagnosed with cancer increases as individuals age, most cases occur in adults who are middle-aged or older. About 77 percent of all cancers are diagnosed in persons 55 years and older. All cancers involve the malfunction of genes that control cell growth and division. About 5 percent of all cancers are strongly hereditary, in that an inherited genetic alteration confers a very high risk of developing one or more specific types of cancer. However, most cancers do not result from inherited genes but from damage to genes occurring during one's lifetime. Genetic damage may result from internal factors, such as hormones or the metabolism of nutrients within cells, or external factors, such as tobacco, chemicals, and sunlight.

Cancer is the second most common cause of death in the US, exceeded only by heart disease. In the US, cancer accounts for nearly 1 of every 4 deaths.

The 5-year relative survival rate for all cancers diagnosed between 1996-2004 is 66 percent, up from 50 percent in 1975-1977. The improvement in survival reflects progress in diagnosing certain cancers at an earlier stage and improvements in treatment. Survival statistics vary greatly by cancer type and stage at diagnosis.

The National Institutes of Health estimates overall costs of cancer in 2008 at \$228.1 billion: \$93.2 billion for direct medical costs (total of all health expenditures); \$18.8 billion for indirect morbidity costs (cost of lost productivity due to illness); and \$116.1 billion for indirect mortality costs (cost of lost productivity due to premature death).

## **Cancer Treatment and Tumor Removal Therapies**

[From: The American Cancer Society; Mayo Clinic; and Cleveland Clinic.]

### ***Chemotherapy***

Chemotherapy is the first choice for treating many cancers. It differs from surgery or radiation in that it is almost always used as a systemic treatment. This means the drugs travel throughout the body to reach cancer cells wherever they may have spread. Treatments like radiation and surgery act only in a specific area such as the breast, lung, or colon, and so are considered local treatments.

More than 100 drugs are used today for chemotherapy -- either alone or in combination with other drugs or treatments. As research continues, more drugs are expected to become available. These drugs vary widely in their chemical composition, how they are taken, their usefulness in treating specific forms of cancer, and their side effects. New drugs are first developed through research in test tubes and animals. Then the drugs are tested in clinical trials in humans to find out how safe they are and how well they work.<sup>518</sup>

The cell cycle is important to cancer doctors (oncologists) because many chemotherapy drugs work only on cells that are actively reproducing, not on cells in the resting phase. Some drugs specifically attack cells in a particular phase of the cell cycle (the M or S phases, for example). Understanding how these drugs work helps oncologists predict which drugs are likely to work well together. Doctors can also plan how often doses of each drug should be given based on the timing of the cell phases.

When chemotherapy drugs attack reproducing cells, they cannot tell the difference between reproducing cells of normal tissues (those that are replacing worn-out normal cells) and cancer cells. The damage to normal cells can cause side effects. Each time chemotherapy is given, it involves trying to find a balance between destroying the cancer cells (in order to cure or control the disease) and sparing the normal cells (to lessen unwanted side effects).<sup>519</sup>

### ***Goals of Chemotherapy***<sup>520, 521, 522</sup>

**Cure:** If possible, chemotherapy is used to cure the cancer, meaning that the tumor or cancer disappears and does not return. However, most doctors do not use the word “cure” except as a possibility or intention. When giving treatment that has a chance of curing a

<sup>518</sup> American Cancer Society. 2010. Chemotherapy principles: an in-depth discussion. What is chemo? Available at: <http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Chemotherapy/ChemotherapyPrinciplesAnIn-depthDiscussionoftheTechniquesanditsRoleinTreatment/chemotherapy-principles-what-is-chemo>. Accessed on November 29, 2010.

<sup>519</sup> American Cancer Society. 2010. Chemotherapy principles: an in-depth discussion. How chemo works? Available at: <http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Chemotherapy/ChemotherapyPrinciplesAnIn-depthDiscussionoftheTechniquesanditsRoleinTreatment/chemotherapy-principles-how-does-chemo-work>. Accessed on November 29, 2010.

<sup>520</sup> American Cancer Society. 2010. Chemotherapy principles: an in-depth discussion. Principles and Goals. Available at: <http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Chemotherapy/ChemotherapyPrinciplesAnIn-depthDiscussionoftheTechniquesanditsRoleinTreatment/chemotherapy-principles-goals-of-chemo>. Accessed on November 29, 2010.

<sup>521</sup> Mayo Clinic. 2010. Chemotherapy. Why it's done. Available at: <http://www.mayoclinic.com/health/chemotherapy/MY00536/SECTION=why%2Dits%2Ddone>. Accessed on November 29, 2010.

<sup>522</sup> Cleveland Clinic. 2010. Chemotherapy. Available at: <http://my.clevelandclinic.org/services/chemotherapy.aspx>. Accessed on November 29, 2010.

person's cancer, the doctor may describe it as treatment with curative intent. But it can take many years to know whether a person's cancer is actually cured.

**Control:** If cure is not possible, the goal may be to control the disease - to shrink any tumors and to stop the cancer from growing and spreading. This can help someone with cancer feel better and hopefully live longer. In many cases, the cancer does not completely go away but is controlled and managed as a chronic disease, much like hypertension or diabetes. In other cases, the cancer may even seem to have gone away for a while, but it is expected to come back.

**Palliation:** When the cancer is at an advanced stage, chemotherapy drugs may be used to relieve symptoms caused by the cancer. When the only goal of treatment is to improve the quality of life, it is called palliation.

For some people, chemotherapy is the only treatment used for their cancer. In other cases, chemotherapy may be given along with other treatments. It may be used as neoadjuvant therapy (before surgery or radiation), or as adjuvant therapy (after surgery or radiation).

After a cancer is removed with surgery, there may still be some cancer cells left behind that cannot be seen. When drugs are used to kill those unseen cancer cells, it is called adjuvant chemotherapy. Adjuvant treatment can also be given after using radiation to kill the cancer, for example, adjuvant hormone therapy after radiation for prostate cancer.

Neoadjuvant chemotherapy is the term used when chemotherapy is given before the main cancer treatment (such as surgery or radiation). Giving chemotherapy first can shrink a large tumor, making it easier to remove with surgery. Shrinking the tumor may also allow it to be treated more easily with radiation. Neoadjuvant chemotherapy also kills small deposits of cancer cells that cannot be seen on scans or x-rays.<sup>523, 524</sup>

Chemotherapy can be delivered in several different ways. Chemotherapy is most often given as an infusion into a vein (intravenously). Some chemotherapy drugs can be taken in pill or capsule form, while some chemotherapy drugs are injected with a needle.<sup>525</sup>

Chemotherapy creams or gels containing chemotherapy drugs can be applied to the skin to treat certain types of skin cancer. Chemotherapy drugs can be given directly to one area of the body. For example, chemotherapy drugs can be given directly in the abdomen (intraperitoneal chemotherapy), chest cavity (intrapleural chemotherapy) or central nervous system (intrathecal chemotherapy). Chemotherapy can also be given through the urethra into the bladder (intravesical chemotherapy). Chemotherapy may also be administered directly to the cancer or, after surgery, where the cancer was located prior to surgery. For example, chemotherapy drugs can be injected into a tumor or thin disk-shaped wafers containing chemotherapy drugs can be placed near a tumor during surgery. The wafers break

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<sup>523</sup> American Cancer Society. 2010. Chemotherapy principles: an in-depth discussion. Principles and Goals. Available at: <http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Chemotherapy/ChemotherapyPrinciplesAnIn-depthDiscussionoftheTechniquesanditsRoleinTreatment/chemotherapy-principles-goals-of-chemo>. Accessed on November 29, 2010.

<sup>524</sup> Mayo Clinic. 2010. Chemotherapy. Why it's done. Available at: <http://www.mayoclinic.com/health/chemotherapy/MY00536/DSECTION=why%2Dits%2Done>. Accessed on November 29, 2010.

<sup>525</sup> Mayo Clinic. 2010. Chemotherapy. What to expect. Available at: <http://www.mayoclinic.com/health/chemotherapy/MY00536/DSECTION=what%2Dyou%2Dcan%2Dexpect>. Accessed on November 29, 2010.

down over time releasing chemotherapy drugs.

Side effects of chemotherapy include anemia (low red blood cell count); fatigue (extreme tiredness); hair loss; increased chance of bruising, bleeding, and infection; fever; diarrhea; constipation; and nausea and vomiting. The patient's body may be affected in the following ways: intestinal and stomach problems; appetite and weight changes; sore mouth, gums, and throat; nerve and muscle problems; dry and/or discolored skin; kidney and bladder irritation; heart problems; risk of a second cancer; and sexual and fertility issues because of effects on reproductive organs.<sup>526, 527</sup>

### ***Radiation***

Radiation is a method of treating cancer in an acute, localized sense, unlike chemotherapy, which treats the whole body. Radiation, in essence, destroys actively and quickly dividing cells, using energy from waves or particles directed at these cells. The cells that are destroyed are not limited to cancerous cells as the body's cells constantly undergo division of cells, which leads to the side effects of radiation. Radiation therapy must be delivered over a period of time in order to destroy the desired cells because cells go through periods of active division and growth and periods of rest.<sup>528, 529</sup>

Ionizing radiation (radiation with the capacity to ionize atoms, or give them a charge) is a high energy radiation. One type of ionizing radiation used to treat cancer uses high-energy photons that come from radioactive sources such as cobalt, cesium, or a machine called a linear accelerator. This is by far the most common type of radiation treatment in use today.

The second type is particle radiation, and includes three variations:<sup>530</sup>

- Electron beams or particle beams that are produced by a linear accelerator. These are used for tumors close to a body surface since they do not go deeply into tissues.
- Proton beams are a newer form of particle beam radiation. Protons are parts of atoms that cause little damage to tissues they pass through but are very good at killing cells at the end of their path. This means that proton beams may be able to deliver more radiation to the cancer while causing fewer side effects to normal tissues nearby. Protons are used routinely for certain types of cancer, but still need more study in treating others. Some of the techniques used in proton treatment can also expose the patient to neutrons (see below). Proton beam radiation therapy requires highly specialized equipment and is currently only offered in certain medical centers.

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<sup>526</sup>American Cancer Society. 2010. Chemotherapy side-effects. Principles and goals. Available at: <http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Chemotherapy/UnderstandingChemotherapyAGuideforPatientsandFamilies/understanding-chemotherapy-chemo-side-effects>. Accessed on November 29, 2010.

<sup>527</sup> Mayo Clinic. 2010. Chemotherapy. Risks. Available at: <http://www.mayoclinic.com/health/chemotherapy/MY00536/DSECTION=risks>. Accessed on November 29, 2010.

<sup>528</sup> American Cancer Society. 2010. Radiation therapy principles. How does radiation work? Available at: <http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Radiation/RadiationTherapyPrinciples/radiation-therapy-principles-how-does-radiation-work>. Accessed on November 29, 2010.

<sup>529</sup> Mayo Clinic. 2010. Radiation therapy. Available at: <http://www.mayoclinic.com/health/radiation-therapy/MY00299>. Accessed on November 29, 2010.

<sup>530</sup> American Cancer Society. 2010. Radiation therapy principles. Types of radiation. Available at: <http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Radiation/RadiationTherapyPrinciples/radiation-therapy-principles-types-of-radiation>. Accessed on November 29, 2010.

- Neutron beams are used for some cancers of the head, neck, and prostate. They can sometimes be helpful when other forms of radiation therapy are not effective. Neutron beam use has declined over the years due to associated severe long-term side effects.

The goal of radiation therapy is to either shrink or cure early stage cancer, to stop cancer from coming back to another area, or to treat symptoms caused by advanced cancer (palliative radiation). Radiation can be used before surgery or after surgery, by itself, or sometimes in conjunction with other cancer treatment therapies.<sup>531, 532</sup>

Radiation can be delivered externally and internally. External beam radiation is the most common type of radiation delivery system used to treat cancer patients. It involves focusing a beam of radiation (usually using a linear accelerator) on the affected area.<sup>533, 534</sup> In this way, the beam can be used to treat multiple areas, and usually is done on an outpatient basis, and is conducted daily over the span of several weeks.<sup>535</sup>

Simulation generally occurs before therapy begins, in order to see what position the patient is most comfortable lying still (during actual treatment, the patient must lie completely still so that the beam is focused on the correct area of the body). Measurements are taken to ensure the patient is properly lined up with the machine that delivers the external beam radiation. Then the area of interest is marked. Simulation is about a thirty minute long procedure, and is important preparation for actual radiation therapy.<sup>536, 537</sup>

Internal radiation therapy (or brachytherapy) is slightly more invasive in that radioactive containers are placed next to the tumor (interstitial radiation), or in a body cavity that is very near to the tumor (intracavity radiation). Radioactivity stems from the container, so as soon as it is removed from the body, so is any radiation. The placement of containers can either be permanent (inducing long term radiation, until the container is no longer radioactive) or it can be temporary.<sup>538, 539, 540</sup> However, there are fewer side effects seen with brachytherapy

<sup>531</sup> American Cancer Society. 2010. Radiation therapy. Principles and goals. Available at: <http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Radiation/RadiationTherapyPrinciples/radiation-therapy-principles-goals-of-radiation-therapy>. Accessed on November 29, 2010.

<sup>532</sup> Mayo Clinic. 2010. Radiation therapy. Why it's done? Available at: <http://www.mayoclinic.com/health/radiation-therapy/MY00299/DSECTION=why%2Dits%2Ddone>. Accessed on November 29, 2010.

<sup>533</sup> Mayo Clinic. 2010. Radiation therapy. What to expect. Available at: <http://www.mayoclinic.com/health/radiation-therapy/MY00299/DSECTION=what%2Dyou%2Dcan%2Dexpect>. Accessed on November 29, 2010.

<sup>534</sup> Cleveland Clinic. 2010. Radiation therapy. What is radiation therapy? Available at: [http://my.clevelandclinic.org/services/radiation\\_oncology/therapy.aspx](http://my.clevelandclinic.org/services/radiation_oncology/therapy.aspx). Accessed on November 29, 2010.

<sup>535</sup> American Cancer Society. 2010. Radiation therapy. How is radiation given? Available at: <http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Radiation/RadiationTherapyPrinciples/radiation-therapy-principles-how-is-radiation-given-external-beam-rad>. Accessed on November 29, 2010.

<sup>536</sup> Cleveland Clinic. 2010. Radiation therapy. What is radiation therapy? Available at: [http://my.clevelandclinic.org/services/radiation\\_oncology/therapy.aspx](http://my.clevelandclinic.org/services/radiation_oncology/therapy.aspx). Accessed on November 29, 2010.

<sup>537</sup> Mayo Clinic. 2010. Radiation therapy. How to prepare? Available at: <http://www.mayoclinic.com/health/radiation-therapy/MY00299/DSECTION=how%2Dyou%2Dprepare>. Accessed on November 29, 2010.

<sup>538</sup> American Cancer Society. 2010. Radiation therapy. Internal radiation. Available at: <http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Radiation/RadiationTherapyPrinciples/radiation-therapy-principles-how-is-radiation-given-internal-radiation>. Accessed on November 29, 2010.

<sup>539</sup> Mayo Clinic. 2010. Brachytherapy? What you can expect? Available at: <http://www.mayoclinic.com/health/brachytherapy/MY00323/DSECTION=what%2Dyou%2Dcan%2Dexpect>. Accessed on November 29, 2010.

<sup>540</sup> Cleveland Clinic. 2010. Radiation therapy. What is radiation therapy? Available at: [http://my.clevelandclinic.org/services/radiation\\_oncology/therapy.aspx](http://my.clevelandclinic.org/services/radiation_oncology/therapy.aspx). Accessed on November 29, 2010.

compared to external beam radiation, as brachytherapy can more directly target the tumor, whereas external beam radiation delivers radiation to healthy tissue before it reaches the tumor.<sup>541</sup>

Additionally, patients are also able to take radiopharmaceuticals – drugs that have radioactive components in them and can deliver radiation to different parts of the body. Because this type of radiation is delivered as a drug, certain types of cancer need a specific radiopharmaceutical to treat it.<sup>542</sup>

### ***Radio-labeled antibodies***

Monoclonal antibodies are man-made versions of immune system proteins that attack only a specific molecular target on certain cancer cells. Scientists have learned how to pair these antibodies with radioactive atoms. When put into the bloodstream, the antibodies act as homing devices. They attach only to their target, bringing radiation directly to the cancer. Radio-labeled antibodies are used to treat some non-Hodgkin lymphomas, especially those nonresponsive to other treatments. They may cause allergic reactions when first infused. They may also lower blood cell counts, which can raise the risk of infections, and lower platelets causing bruising or bleeding.<sup>543</sup>

Side effects of radiation include fatigue, skin damage or skin changes, and mouth and throat problems. There is also a small risk of getting second cancers because of radiation therapy. Other side effects are specific to the part of the body which is being treated with radiation therapy.<sup>544</sup>

### ***Immunotherapies***

Immunotherapies are therapies in which the immune system of the patient is strengthened in some way. Immunotherapy works the patient's immune system to fight off remaining cancer cells. Immunotherapy treatment can either stimulate the patient's own defenses or supplement them.<sup>545</sup>

The two main types of immunotherapy are 'active' and 'passive'. Active immunotherapies stimulate the patient's own immune system to fight the disease.

Passive immunotherapies use immune system components (such as antibodies) made in a lab.<sup>546</sup> For example, in monoclonal antibody therapy, lab-created antibodies are administered that recruit other parts of the immune system to destroy the cancer cells.<sup>547</sup>

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<sup>541</sup> Mayo Clinic. 2010. Brachytherapy? Available at: <http://www.mayoclinic.com/health/brachytherapy/MY00323>. Accessed on November 29, 2010.

<sup>542</sup> American Cancer Society. 2010. Radiation therapy. Radiopharmaceuticals. Available at: <http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Radiation/RadiationTherapyPrinciples/radiation-therapy-principles-how-is-radiation-given-radiopharmaceuticals>. Accessed on November 29, 2010.

<sup>543</sup> *Ibid.*

<sup>544</sup> Mayo Clinic. 2010. Radiation therapy. Risks. Available at: <http://www.mayoclinic.com/health/radiation-therapy/MY00299/DSECTION=risks>. Accessed on November 29, 2010.

<sup>545</sup> Mayo Clinic. 2010. Adjuvant therapy. Available at: <http://www.mayoclinic.com/health/adjuvant-therapy/CA00012>. Accessed on November 29, 2010.

<sup>546</sup> American Cancer Society. 2010. Immunotherapy. Types of immunotherapy. Available at: <http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Immunotherapy/immunotherapy-types-of-immunotherapy>. Accessed on November 29, 2010.

<sup>547</sup> American Cancer Society. 2010. Immunotherapy. Monoclonal antibodies. Available at: <http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Immunotherapy/immunotherapy-monoclonal-antibodies>. Accessed on November 29, 2010.

Another type of passive immunotherapy attaches growth factors to toxins. When the growth factor-toxin combination reaches the cancer cell's growth factor receptors, it delivers its payload of toxin to kill the cell. The only growth factor/toxin currently approved by the FDA is denileukin diftitox (Ontak). It is a growth factor known as interleukin-2 (IL-2) attached to a toxin from the germ that causes diphtheria. Denileukin diftitox is used to treat a rare type of skin lymphoma known as mycosis fungoides (or cutaneous T-cell lymphoma). It is currently being studied for use against a number of other cancers.<sup>548</sup>

### ***Cancer Vaccines and Other Active Specific Immunotherapies***

A true cancer vaccine contains cancer cells, parts of cells, or pure antigens. The vaccine increases the immune response against cancer cells that are already present in the body. It may be combined with other substances or cells called adjuvants that help boost the immune response even further.

Cancer vaccines are thought of as active immunotherapies because they are meant to trigger the patient's immune system to respond. They are specific because they should only affect the cancer cells. Because the immune system has special cells for memory, it is hoped that the drugs will help keep cancer from coming back.<sup>549</sup> Some types of cancer vaccines that are undergoing clinical trials are tumor cell vaccines, antigen vaccines, dendritic cell vaccines, anti-idiotypic vaccines, DNA vaccines, and vector-based vaccines.

### ***Non-specific Immunotherapies and Adjuvants***

Biological response modifiers are substances that have no direct anti-tumor effect, but are able to trigger the immune system to indirectly affect tumors. These include cytokines such as interferons and interleukins. This strategy involves giving larger amounts of these substances by injection or infusion in the hope of stimulating the cells of the immune system to act more effectively.<sup>550</sup>

Cytokines are chemicals made by immune system cells. They have a crucial role in regulating the growth and activity of other immune system cells and blood cells.<sup>551</sup> Interleukins are a group of cytokines that act as chemical signals between white blood cells. When interleukin-2 (IL-2) was approved by the FDA in 1992 to treat advanced kidney cancer, it became the first true immunotherapy approved for use alone in treating cancer. Since that time, it has also been approved to treat people with metastatic melanoma. Because IL-2 can produce some serious side effects (such as an abnormal heartbeat), high doses of this treatment are given in an inpatient facility.<sup>552</sup>

Granulocyte-macrophage colony-stimulating factor (GM-CSF) is a cytokine/growth factor that causes the bone marrow to make more of certain types of immune system cells and

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<sup>548</sup> American Cancer Society. 2010. Immunotherapy. Therapies containing toxins. Available at: <http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Immunotherapy/immunotherapy-targeted-therapies-containing-toxins>. Accessed on November 29, 2010.

<sup>549</sup> American Cancer Society. 2010. Immunotherapy. Cancer vaccines. Available at: <http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Immunotherapy/immunotherapy-cancer-vaccines>. Accessed on November 29, 2010.

<sup>550</sup> Cleveland Clinic. 2010. Immunotherapy. What is immunotherapy? Available at: [http://my.clevelandclinic.org/services/immunotherapy/hic\\_Immunotherapy.aspx](http://my.clevelandclinic.org/services/immunotherapy/hic_Immunotherapy.aspx). Accessed on November 29, 2010.

<sup>551</sup> American Cancer Society. 2010. Immunotherapy. Non-specific immunotherapies. Available at: <http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Immunotherapy/immunotherapy-non-specific-immunotherapies>. Accessed on November 29, 2010.

<sup>552</sup> *Ibid.*

blood cells. This includes monocytes, macrophages, and dendritic cells. It also boosts the production of other blood cells. A man-made version (also known as sargramostim or Leukine®) is often used to boost white blood cell counts after chemotherapy.<sup>553</sup>

Several immunotherapies are now used to treat leukemias, lymphomas, and myelomas, and many more are being studied.<sup>554</sup>

Side effects of immunotherapy include flu-like symptoms such as fever, chills, nausea, and loss of appetite. Rashes or swelling may develop at the site where the modifiers are injected. Blood pressure also may be affected, usually with a decrease in pressure. Fatigue is another common side effect. Vaccines can cause muscle aches and low-grade fever, and serious allergic reactions may occur.<sup>555</sup>

## Leukemia

[From the Leukemia and Lymphoma Society. Leukemia facts and statistics.]

Leukemia is a malignant disease (cancer) of the bone marrow and blood. It is characterized by the uncontrolled accumulation of blood cells. There are four major types of leukemia:

- Acute Myelogenous Leukemia (AML)
- Acute Lymphocytic Leukemia (ALL)
- Chronic Myelogenous Leukemia (CML)
- Chronic Lymphocytic Leukemia (CLL)

The terms lymphocytic or lymphoblastic indicate that the cancerous change takes place in a type of marrow cell that forms lymphocytes. The terms myelogenous or myeloid indicate that the cell change takes place in a type of marrow cell that normally goes on to form red cells, some types of white cells, and platelets. Acute lymphocytic leukemia and acute myelogenous leukemia are each composed of blast cells, known as lymphoblasts or myeloblasts. Acute leukemias progress rapidly without treatment. Chronic leukemias have few or no blast cells. Chronic lymphocytic leukemia and chronic myelogenous leukemia usually progress slowly compared to acute leukemias.

The four types of leukemia each begin in a cell in the bone marrow. The cell undergoes a leukemic change and it multiplies into many cells. The leukemia cells grow and survive better than normal cells and, over time, they crowd out normal cells. Normal stem cells in the marrow form three main cell-types: Red cells, platelets and white cells. There are two major types of white cells: germ-ingesting cells (neutrophils and monocytes) and lymphocytes, which are part of the body's immune system and help fight infection. The rate at which leukemia progresses and how the cells replace the normal blood and marrow cells are different with each type of leukemia.

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<sup>553</sup> American Cancer Society. 2010. Immunotherapy. Non-specific immunotherapies. Available at: <http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Immunotherapy/immunotherapy-non-specific-immunotherapies>. Accessed on November 29, 2010.

<sup>554</sup> *Ibid.*

<sup>555</sup> Cleveland Clinic. 2010. Immunotherapy. What is immunotherapy? Available at: [http://my.clevelandclinic.org/services/immunotherapy/hic\\_Immunotherapy.aspx](http://my.clevelandclinic.org/services/immunotherapy/hic_Immunotherapy.aspx). Accessed on November 29, 2010.

### ***Acute Leukemia***

In acute myelogenous leukemia (AML) and acute lymphocytic leukemia (ALL), the original acute leukemia cell goes on to form about a trillion more leukemia cells. These cells are described as “nonfunctional” because they do not work like normal cells. They also crowd out the normal cells in the marrow; in turn, this causes a decrease in the number of new normal cells made in the marrow, resulting in low red cell counts (anemia). The lack of normal white cells impairs the body’s ability to fight infections. A shortage of platelets results in bruising and easy bleeding.

### ***Chronic Leukemia***

In chronic myelogenous leukemia (CML), the leukemia cell that starts the disease makes blood cells (red cells, white cells and platelets) that function almost like normal cells. The number of red cells is usually less than normal, resulting in anemia. But many white cells and sometimes many platelets are still made. Even though the white cells are nearly normal in how they work, their counts are high and continue to rise. If untreated, the white cell count can rise so high that blood flow slows down and anemia becomes severe.

In chronic lymphocytic leukemia (CLL), the leukemia cell that starts the disease makes too many lymphocytes that do not function. These cells replace normal cells in the marrow and lymph nodes. They interfere with the work of normal lymphocytes, which weakens the patient’s immune response. The high number of leukemia cells in the marrow may crowd out normal blood-forming cells and lead to anemia. A very high number of leukemia cells building up in the marrow also can lead to low neutrophil and platelet counts.

Unlike the other three types of leukemia, some patients with CLL may have disease that does not progress for a long time. Some people with CLL have such slight changes that they remain in good health and do not need treatment for long periods of time. Most patients require treatment at the time of diagnosis or soon after.

For most types of leukemia, the risk factors and possible causes are not known. Some risk factors for AML are:

- Certain chemotherapies used for lymphoma or other types of cancer
- Down syndrome and some other genetic diseases
- Chronic exposure to benzene (such as in the workplace) that exceeds federally approved safety limits
- Radiation therapy used to treat other types of cancer
- Tobacco smoke.

Exposure to high doses of radiation therapy is also a risk factor for ALL and CML. Other possible risk factors for the four types of leukemia are continually under study. Leukemia is not contagious.

Some signs or symptoms of leukemia are similar to other more common and less severe illnesses. Specific blood tests and bone marrow tests are needed to make a diagnosis.

A complete blood count (CBC) is used to diagnose leukemia. This blood test may show

high or low levels of white cells and show leukemic cells in the blood. Sometimes, platelet counts and red cell counts are low. Bone marrow tests (aspiration and biopsy) are often done to confirm the diagnosis and to look for chromosome abnormalities. These tests identify the leukemia cell-type. A complete blood exam and a number of other tests are used to diagnose the type of leukemia. These tests can be repeated after treatment begins to measure how well the treatment is working.

The ways in which patients are affected and how patients are treated are different for each type of leukemia. Patients with an acute leukemia need to start treatment right away. Usually, they begin induction therapy with chemotherapy in the hospital. More inpatient treatment is usually needed even after a patient is in remission. This is called consolidation therapy or post induction therapy. This part of treatment may include chemotherapy with or without allogeneic stem cell transplantation (sometimes called ‘bone marrow transplantation’).

Patients with CML need to begin treatment once they are diagnosed. They usually begin treatment with imatinib mesylate (Gleevec®). Gleevec does not cure CML, but it keeps CML under control for many patients for as long as they take it. For other patients, there are two newer drugs called dasatinib (Sprycel®) and nilotinb (Tasigna®). These drugs also block the BCR-ABL cancer gene, but each works in a different way than Gleevec. Sprycel and Tasigna are approved for certain CML patients who are resistant or intolerant to prior therapy including Gleevec. All three drugs are taken by mouth. Allogeneic stem cell transplantation is the only current treatment that can cure CML. This treatment is most successful in younger patients; however, patients up to 60 years of age who have a matched donor may be considered for this treatment. Allogeneic transplantation can be a high-risk procedure.

Some CLL patients do not need treatment for long periods of time after diagnosis. Patients who need treatment may receive chemotherapy or monoclonal antibody therapy alone or in combination. Allogeneic stem cell transplantation is a treatment option for certain patients. All leukemia patients in remission need to see their doctors regularly for exams and blood tests and bone marrow tests may be needed periodically.

[From: The American Cancer Society, Cancer Facts and Figures, 2009.]

An estimated 44,790 new cases of leukemia were expected in 2009, with slightly more cases of chronic (20,540) than acute (18,570) disease. Leukemia is diagnosed 10 times more often in adults than in children. Acute lymphocytic leukemia (ALL) accounts for approximately 70 percent of the leukemia cases among children ages 0 to 19 years. In adults, the most common types are acute myeloid leukemia (AML) and chronic lymphocytic leukemia (CLL). The incidence of AML increased by an average of 2.2 percent per year from 1988-2000, but decreased sharply by 3.2 percent per year from 2000-2005. In contrast, the incidence of CLL has remained relatively stable since 1975.

Survival in leukemia varies by type, ranging from a 5-year relative survival of 22 percent for people with AML to 76 percent for people with CLL. Advances in treatment have resulted in a dramatic improvement in survival for people with ALL, from a five-year relative survival rate of 42 percent in 1975-1977 to 66 percent in 1996-2004. Survival rates for children with ALL have increased from 58 to 88 percent over the same time period.

An estimated 21,870 deaths were expected to occur in 2009. Death rates in males and females combined have decreased by about 1.5 percent per year since 2000.

## Childhood Cancer

[From: The National Cancer Institute, Cancer Incidence and Survival Among Children and Adolescents, United States SEER Program 1975-1995; The Leukemia and Lymphoma Society; The Children's Cancer Research Fund]

Leukemia is the most common type of cancer found in children, representing 27 percent of all childhood cancers (in children younger than 20 years).<sup>556</sup> From 1999 to 2005, the five-year relative survival rates overall were:

- Acute lymphocytic leukemia (ALL): 66.3 percent overall; 90.9 percent for children under 5.
- Chronic lymphocytic leukemia (CLL): 78.8 percent
- Acute myelogenous leukemia (AML): 23.4 percent overall; 60.2 percent for children under 15
- Chronic myelogenous leukemia (CML): 53.3 percent<sup>557</sup>

Acute lymphocytic leukemia (ALL) is the most common type of leukemia to affect children.<sup>558</sup> Approximately 74 percent of all children with leukemia have ALL, which represents 20 percent of the overall childhood cancer burden in children under 20.<sup>559</sup> Survival of ALL has risen to approximately 85 percent, leaving a 15 percent mortality rate in children.<sup>560</sup>

Acute Myelogenous Leukemia (AML), also known as Acute Non-Lymphoblastic Leukemia (ANLL), represents approximately 19 percent of all childhood leukemia and approximately 5 percent of the overall childhood cancer burden in children under 20.<sup>561</sup> Survival of AML has increased to 50-60 percent in the last 25-30 years, but 10 percent of children who receive treatment for AML die from the toxicity of the treatment.<sup>562</sup>

Brain tumors (also known as Central Nervous System Malignancies) are masses of abnormally dividing and growing cells located in the brain. Most brain tumors in children are benign, but can still be harmful. They are the most common “solid tumor” found in

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<sup>556</sup> The Leukemia and Lymphoma Society. 2010. Leukemia facts and statistics. Incidence by age. Available at: [http://www.leukemia-lymphoma.org/all\\_page.adp?item\\_id=9346#\\_incidencebyage](http://www.leukemia-lymphoma.org/all_page.adp?item_id=9346#_incidencebyage). Accessed on November 29, 2010.

<sup>557</sup> *Ibid.*

<sup>558</sup> Children's Cancer Research Fund. 2010. Learning center. Understanding acute lymphoblastic leukemia. Available at: <http://childrenscancer.org/learning-center/understanding-childhood-cancer/understanding-acute-lymphoblastic-leukemia.html>. Accessed on November 29, 2010.

<sup>559</sup> National Cancer Institute. Cancer Incidence and Survival Among Children and Adolescents: United States SEER Program 1975-1995. Leukemia. Available at: <http://seer.cancer.gov/publications/childhood/leukemia.pdf>. Accessed on November 29, 2010.

<sup>560</sup> Cure Search for Children's Cancer. 2010. Acute Lymphoblastic Leukemia Committee. Acute Lymphoblastic Leukemia. Available at: [http://www.curesearch.org/our\\_research/index\\_sub.aspx?id=1760](http://www.curesearch.org/our_research/index_sub.aspx?id=1760). Accessed on November 29, 2010.

<sup>561</sup> National Cancer Institute. Cancer Incidence and Survival Among Children and Adolescents: United States SEER Program 1975-1995. Leukemia. Available at: <http://seer.cancer.gov/publications/childhood/leukemia.pdf>. Accessed on November 29, 2010.

<sup>562</sup> Cure Search for Children's Cancer. 2010. Myeloid leukemia disease committee. Myeloid leukemia. Available at: [http://www.curesearch.org/our\\_research/index\\_sub.aspx?id=1765](http://www.curesearch.org/our_research/index_sub.aspx?id=1765). Accessed on November 29, 2010.

children.<sup>563</sup> 2,200 brain tumors diagnosed every year, making up 16.6 percent of the burden of childhood cancers in children under age 20.<sup>564</sup> (Rates do not apply to other cancers that have spread into the brain). SEER program data only gives survival information until 1994, so the CNS malignancy survival rate for children under 20 from approximately 1985-1994 was about 65 percent and remained stable over this time period.<sup>565</sup>

Lymphoma is a cancer that affects the lymph system, which is responsible for part of the body's immune response. It is categorized as either Hodgkin's or non-Hodgkin's lymphoma. Lymphomas start in lymph tissues, such as the tonsils, lymph nodes, and thymus. They may spread to bone marrow and other organs, which can cause different symptoms depending on where the cancer is growing. Lymphomas can cause fever, sweats, weakness, and swollen lymph nodes in the neck, armpit, or groin.<sup>566</sup> About 15 percent of all childhood cancers are lymphomas and approximately 1,700 children under age 20 are diagnosed with lymphomas every year.<sup>567</sup>

Hodgkin's Lymphoma affects a little more than half of all children under age 20 who are diagnosed with lymphoma.<sup>568</sup> Thus, Hodgkin's disease represents about 8 percent of the burden of childhood cancers in children under age 20. The presence of Reed-Sternberg cells characterizes Hodgkin's lymphoma, yet it only makes up a small portion of the tumor.<sup>569</sup> The five year survival rate for this age group is 91 percent as of 1994.<sup>570</sup>

There are three types of non-Hodgkin's lymphoma, including: lymphoblastic lymphoma; small cell lymphoma, which includes both Burkitt's lymphoma and non-Burkitt's lymphoma; and large cell lymphoma.<sup>571</sup> Non-Hodgkin's lymphoma affects a little under half of all children diagnosed with lymphoma, and represents about 7 percent of the burden of childhood cancers in children under age 20. The five year survival rate for this age group is 72 percent as of 1994.<sup>572</sup>

Neuroblastoma is a cancer that develops from nerve cells. It is most commonly found in infants and children under five years old. It is also the most common type of cancer found in infants. Most commonly, tumors are first found on the adrenal glands above the kidneys, and can spread, although it can be found where groups of nerve cells are located, such as in the abdomen, chest, or neck. About 650 people are diagnosed with it every year.<sup>573</sup>

<sup>563</sup> Children's Cancer Research Fund. 2010. Learning center. Understanding brain tumors. Available at: <http://childrenscancer.org/learning-center/understanding-childhood-cancer/understanding-brain-tumors.html>. Accessed on November 29, 2010.

<sup>564</sup> National Cancer Institute. Cancer Incidence and Survival Among Children and Adolescents: United States SEER Program 1975-1995. CNS and miscellaneous intracranial and intraspinal neoplasms. Available at: <http://seer.cancer.gov/publications/childhood/cns.pdf>. Accessed on November 29, 2010.

<sup>565</sup> *Ibid.*

<sup>566</sup> Children's Cancer Research Fund. 2010. Cancer in children. Types of childhood cancers. Available at: <http://www.cancer.org/Cancer/CancerinChildren/DetailedGuide/cancer-in-children-types-of-childhood-cancers>. Accessed on November 29, 2010.

<sup>567</sup> National Cancer Institute. Cancer Incidence and Survival Among Children and Adolescents: United States SEER Program 1975-1995. Lymphomas. Available at: <http://seer.cancer.gov/publications/childhood/lymphomas.pdf>. Accessed on November 29, 2010.

<sup>568</sup> *Ibid.*

<sup>569</sup> *Ibid.*

<sup>570</sup> *Ibid.*

<sup>571</sup> Children's Cancer Research Fund. 2010. Learning center. Understanding non-Hodgkin's lymphoma. Available at: <http://childrenscancer.org/learning-center/understanding-childhood-cancer/understanding-non-hodgkins-lymphoma.html>. Accessed on November 29, 2010.

<sup>572</sup> National Cancer Institute. Cancer Incidence and Survival Among Children and Adolescents: United States SEER Program 1975-1995. Lymphomas. Available at: <http://seer.cancer.gov/publications/childhood/lymphomas.pdf>. Accessed on November 29, 2010.

<sup>573</sup> Mayo Clinic. 2010. Neuroblastoma. Available at: <http://www.mayoclinic.com/health/neuroblastoma/DS00780>. Accessed on November 29, 2010.

Neuroblastoma is categorized into low, medium, and high risk neuroblastoma. Both low-risk and medium-risk neuroblastomas have a cure rate of 90 percent. However, high-risk neuroblastomas do not enjoy a good prognosis and only 40 percent of patients that are high-risk live up to 3 years past completion of therapy. Half of the high-risk patients are subject to relapsed neuroblastomas – such patients do not have a good survival rate.<sup>574</sup>

Retinoblastoma is a cancer of the eyes. The tumor can either appear in the retina of the eye or in the pineal gland of one or both eyes. About 300 children under age 20 are diagnosed with retinoblastomas every year, representing about 2.5 percent of the burden of childhood cancer in children under age 20. The five year survival rate for this age group is 93 percent.<sup>575</sup>

Primary bone cancers (cancers that start in the bones) occur most often in children and adolescents. There are two main types of primary bone cancers: osteosarcoma and Ewings sarcoma. Primary bone cancer is different from metastatic bone cancer, which is cancer that has spread from another site to the bone. Metastatic bone cancer is more common than primary bone cancer because many types of cancer can spread to the bone. Primary bone cancers represent about 6 percent of the burden of childhood cancer. The five year survival rate was 63 percent as of 1994.

Rhabdomyosarcoma is a soft tissue sarcoma – a tumor that affects soft tissue that is usually near skeletal muscle. It is most commonly found on the head, neck, bladder, vagina, arms, legs, and trunk. Each year 250-350 people are diagnosed with rhabdomyosarcoma, and these patients are usually between the ages of 2 and 20.<sup>576, 577</sup> The cure rate is 70 to 80 percent.<sup>578</sup>

Wilm's Tumor is a tumor that affects one kidney or both and can metastasize. Most children are diagnosed with it before they are five. Approximately 400-500 new cases of Wilm's tumor are diagnosed each year in the U.S. About six percent of all cancers in children are Wilm's tumor. The long-term survival is approaching 90-95 percent.<sup>579</sup>

### ***Treatment Options for Children***

Generally, all cancer treatments used in adults can also be used for treating children. However, certain treatments may have negative effects on the growth and development of a child. The age and health of the child must be taken into account before considering a treatment option. As a result, the same type of cancer or leukemia may have different treatment recommendations for children and adults.

Many of the types of cancers that develop in children are very different from the types that develop in adults. There are some exceptions, but childhood cancers tend to respond better to chemotherapy. Children also tolerate the effects chemotherapy better than adults. Chemotherapy can cause long-term side effects, so

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<sup>574</sup> Cure Search for Children's Cancer. 2010. Neuroblastoma committee. Neuroblastoma. Available at: [http://www.curesearch.org/our\\_research/index\\_sub.aspx?id=1767](http://www.curesearch.org/our_research/index_sub.aspx?id=1767). Accessed on November 29, 2010.

<sup>575</sup> National Cancer Institute. Cancer Incidence and Survival Among Children and Adolescents: United States SEER Program 1975-1995. Retinoblastoma. Available at: <http://seer.cancer.gov/publications/childhood/retinoblastoma.pdf>. Accessed on November 29, 2010.

<sup>576</sup> Mayo Clinic. 2010. Rhabdomyosarcoma. Available at: <http://www.mayoclinic.org/rhabdomyosarcoma>. Accessed on November 29, 2010.

<sup>577</sup> Children's Hospital Boston. 2010. Rhabdomyosarcoma. Available at: <http://www.childrenshospital.org/az/Site1068/mainpageS1068P0.html>. Accessed on November 29, 2010.

<sup>578</sup> Mayo Clinic. 2010. Rhabdomyosarcoma. Available at: <http://www.mayoclinic.org/rhabdomyosarcoma>. Accessed on November 29, 2010.

<sup>579</sup> Children's Cancer Research Fund. 2010. Learning center. Understanding Wilms tumor. Available at: <http://childrenscancer.org/learning-center/understanding-childhood-cancer/understanding-wilms-tumor.html>. Accessed on November 29, 2010.

children who survive cancer require long-term follow-up and monitoring.<sup>580</sup>

### ***Long-Term Health***

Childhood cancer frequently has long-term impacts on physical and psychological health, as well as social and educational development. The presence of a tumor as well as treatments for specific cancers can lead to physical and developmental difficulties. For example, some of the risks of radiation include the possibility of second cancers, and neurological and developmental problems.

Researchers have found a variety of psychological difficulties in children affected by cancer and long-term survivors of childhood cancer, including anxiety and panic<sup>581</sup>; post-traumatic stress disorder (PTSD);<sup>582</sup> and depression and somatic distress.<sup>583</sup>

Physical performance limitations (as a result of therapies such as chemotherapy or radiation, or perhaps even surgery) have shown to have adverse educational and economic effects on those who survived cancer as children. The association between physical performance limitations and restricted participation in expected adult social roles has been documented in the overall Childhood Cancer Survivor Study cohort and among specific diagnosis groups. In the overall cohort, childhood cancer survivors with physical performance limitations were 43 percent less likely to graduate from high school, 60 percent less likely to be employed, 18 percent less likely to be married, and 38 percent less likely to have an annual household income of \$20,000 or more.<sup>584</sup>

### **Reconstructive Surgery and Prostheses**

Loss of tissues is an obvious result of surgical removal of tumors. Standard medical practice requires excision of the tumor as well as some level of surrounding healthy tissue. Reconstructive surgery and prostheses address the loss of bone, muscle, skin, and other tissues. The benefits of reconstructive surgery are frequently both functional and cosmetic, allowing the cancer survivor to return to similar levels of functioning and easing social interactions and psychological traumas related to loss of tissues.

Several types of cancer often require reconstructive surgery and/or prostheses, including skin cancer, breast cancer, bone cancer, and cancers of the head and neck. For skin cancer, reconstructive surgery is performed frequently in prominent and exposed areas such as lips, ears, nose, eyelids, other facial areas, and for hands and forearms. Surgical and radiologic treatment of cancers of the head and neck, including oral cancer, require reconstructive surgery and prostheses to facilitate eating, breathing, and speaking.

If a woman chooses to have a mastectomy for breast cancer treatment, she may consider having the breast reconstructed. Breast reconstruction may be done with saline-filled or silicone-filled implants or tissue from other parts of her body. Prosthetic devices may be used in lieu of breast reconstruction surgery following mastectomy.

Surgical removal of tumors in the upper or lower limbs can result in amputation of the limb, particularly

<sup>580</sup> American Cancer Society. 2010. Cancer in children. Differences between cancers in adults and children. Available at: <http://www.cancer.org/Cancer/CancerinChildren/DetailedGuide/cancer-in-children-differences-adults-children>. Accessed on November 29, 2010.

<sup>581</sup> Kazak AE, Meeske K, Penati B, et al. 1997. Posttraumatic stress, family functioning, and social support in survivors of childhood leukemia and their mothers and fathers. *Journal of Consulting and Clinical Psychology* 65(1): 120-9.

<sup>582</sup> Stuber ML, Christakis DA, Houskamp B, et al. 1996. Posttrauma symptoms in childhood leukemia survivors and their parents. *Psychosomatics* 37(3): 254-61.

<sup>583</sup> Zebrack BJ, Zeltzer LK, Whitton J, et al. 2002. Psychosocial outcomes in long-term survivors of childhood leukemia, hodgkin's disease, and non-hodgkin's lymphoma: a report from the childhood cancer survivor study. *Pediatrics* 110: 42-52.

<sup>584</sup> Gurney JG, Krull KR, Kadan-Lottick N, et al. 2009. Social outcomes in the childhood cancer survivor study cohort. *Journal of Clinical Oncology* 27(14):2390-5.

when the tumor is present in the bone. Cancer survivors can then be fitted with an arm or leg prosthesis (artificial limb) to restore some level of functioning and independence. Most amputations (82 percent) are performed due to vascular disease and cancer-related amputations have declined in recent years.<sup>585</sup> Advances in surgical techniques have made limb-salvage procedures a viable alternative treatment to amputation for many patients with bone cancer, thus it is anticipated that amputation and prostheses use may continue to decline.<sup>586</sup>

## Wigs

[FROM: UpToDate: Chemotherapy-induced Alopecia. Aimee S. Payne, MD, PhD]

Hair loss is a transient but often psychologically devastating consequence of cancer chemotherapy. For some patients, the emotional trauma may be so severe as to lead to discontinuing or refusing treatment that might otherwise be beneficial.

Chemotherapy attacks rapidly dividing cells in the body, including the dividing hair matrix cells. A wide range of chemotherapy agents can affect the growing cells of the hair follicle. The frequency and severity of alopecia varies depending upon the specific chemotherapy agent or combination regimen administered, the dosage of drugs, and the treatment schedule. It most commonly affects scalp hair; however, axillary and pubic hair and even the eyebrows and eyelashes may be lost. The majority of chemotherapy-induced alopecia is reversible once therapy is discontinued, with the possible exception of the epidermal growth factor receptor (EGFR) inhibitors.

Currently there are no available pharmacologic interventions that have been shown to decrease the risk of chemotherapy-induced alopecia. Although scalp protection through cooling or tourniquet has been reported to minimize delivery of chemotherapeutic agents to the scalp thereby potentially decreasing the risk of hair loss, case reports of cutaneous metastases or spread in these settings prevent general recommendation for their use. Use of minoxidil during the period of regrowth may help minimize hair follicle miniaturization. Head wraps, hats, and wigs are often used by persons suffering from chemotherapy-induced alopecia.

Chemotherapy-induced alopecia occurs with an estimated incidence of 65 percent.<sup>587</sup> For women undergoing treatment for breast cancer, hair loss consistently ranked amongst the most troublesome side effects.<sup>588</sup> Chemotherapy-induced alopecia made many men and women acutely aware of their visibility as a 'cancer patient'.<sup>589</sup>

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<sup>585</sup> National Limb Loss Information Center. 2008. Amputation Statistics by Cause. Limb Loss in the United States. Amputee Coalition of America: Knoxville, TN. Available at: [http://www.amputee-coalition.org/fact\\_sheets/amp\\_stats\\_cause.html](http://www.amputee-coalition.org/fact_sheets/amp_stats_cause.html). Accessed on June 16, 2010.

<sup>586</sup> Wafa H, Grimer RJ. 2006. Surgical options and outcomes in bone sarcoma. *Expert Review of Anticancer Therapy* 6(2): 239-48.

<sup>587</sup> Trüeb RM. 2009. Chemotherapy-induced alopecia. *Seminars in Cutaneous Medicine and Surgery* 28: 11-14.

<sup>588</sup> Lemieux J, Maunsell E, Provencher L. 2008. Chemotherapy-induced alopecia and effects on quality of life among women with breast cancer: a literature review. *Psycho-Oncology* 17: 317-28.

<sup>589</sup> Hilton S, Hunt K, Emslie C, et al. 2008. Have men been overlooked? A comparison of young men and women's experiences of chemotherapy-induced alopecia. *Psycho-Oncology* 17: 577-83.

### 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 under search terms including:

Tumors, leukemia, breast cancer, breast neoplasm, carcinoma of the breast, treatment, cancer screening, risk factors, economics, efficacy and safety of treatment for breast cancer, hair loss, alopecia/chemically induced, wigs, cranial prostheses, chemotherapy/side effects, mandates, state mandates, insurance coverage, cost of illness, cost savings, cost benefit analysis, health services accessibility, health status disparities, mortality, confounding factors, socio-economic factors, health care costs, health care rationing, quality-adjusted life years, health expenditures, reconstructive surgery, and prostheses.

Resources searched include:

- PubMed
- DynaMed
- Cochrane Database
- EMedicine
- Scopus
- UptoDate
- Lexis-Nexis
- PsychInfo
- Web Search-Google, Bing

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

CPHHP staff consulted with clinical faculty and staff from the University of Connecticut School of 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, 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 and individual plan participants. Five insurers/MCOs also provided information about tumors and leukemia 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 is utilized by a significant portion of the population.*

The American Cancer Society estimates that there will be 1,529,560 new cancer cases in the U.S. in 2010 and 20,750 new cancer cases in Connecticut in 2010.<sup>590</sup> Of these, 4255 are estimated to be covered by fully-insured group and individual insurance policies subject to the mandated benefit.<sup>591</sup> Please see Table 1.11.1 for American Cancer Society estimates.

**Table I.11.1: Estimated new cancer cases for selected cancer sites in Connecticut in 2010<sup>592</sup>**

All sites	20,750
Female Breast	2,960
Uterine Cervix	120
Colon and Rectum	1,770
Uterine Corpus	650
Leukemia	510
Lung and Bronchus	2,640
Melanoma of the Skin	1,090
Non-Hodgkin Lymphoma	860
Prostate	2,940
Urinary Bladder	1,110

Rounded to the nearest 10. Excludes basal and squamous cell skin cancers and *in situ* carcinomas except urinary bladder.

The types of treatment and services required by cancer patients depends on multiple variables such as tumor type, grade, and location; degree and location of any metastasis; treatment recommendations; and patient preferences. Most insured persons diagnosed with cancer or leukemia receive some type of treatment; frequently more than one treatment modality is pursued. For example, breast cancer surgery is usually followed by radiation treatment. Due to the existence of these variables and because Connecticut’s insurance mandate is broad in scope it is difficult to summarize utilization for treatment of tumors and leukemia as defined in the statute.

<sup>590</sup> American Cancer Society. Cancer Facts and Figures 2010. Atlanta: American Cancer Society; 2010.

<sup>591</sup> Based on the estimated number of persons in Connecticut covered by fully-insured group and individual insurance plans subject to state regulation and the estimated percent of cancer cases that occur in the under-65 years of age population.

<sup>592</sup> American Cancer Society. Cancer Facts and Figures 2010. Atlanta: American Cancer Society; 2010.

2. *The extent to which the treatment, service or equipment, supplies or drugs 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**

Patients aged 65 and older account for approximately 56 percent of cancer cases<sup>593</sup>; many patients aged 65 and older are covered by Medicare. Medicare covers surgical removal of tumors and treatment for leukemia under Medicare Part A (hospital benefits).

**Chemotherapy:** Medicare Part A covers chemotherapy for patients who are hospital A or B inpatients. In most cases, the patient must pay 20 percent of the Medicare-approved amount.<sup>594</sup> Medicare Part B covers chemotherapy for hospital outpatients, or patients in a doctor's office or freestanding clinic. In most cases, the patient must pay 20 percent of the Medicare-approved amount. Hospital outpatients must pay a copayment.<sup>595</sup>

**Radiation:** Medicare Part A covers radiation therapy for patients being treated in a hospital (both inpatient and outpatient). Patients must pay 20 percent of the Medicare-approved amount.<sup>596</sup> Medicare Part B covers radiation therapy for patients in freestanding facilities. The patient must pay a set copayment amount for radiation therapy in a hospital outpatient setting or in a freestanding facility.<sup>597</sup>

**Breast prostheses:** Medicare Part B covers external breast prostheses (including a surgical brassiere) after a mastectomy. Additionally, Medicare may cover new external breast prostheses if the patient has had the current prostheses for at least two years and still requires it.<sup>598</sup>

**Eye prostheses:** Medicare Part B covers eye prostheses for patients with absence or shrinkage of an eye as the result of surgical removal. The patient is responsible for paying 20 percent of the Medicare-approved amount. A single "enlargement or reduction of the prosthesis is covered without documentation, though additional enlargements or reductions are rarely medically necessary and are covered only when information in the medical record supports the medical necessity."<sup>599</sup> Replacement of the prosthesis is governed by the five-year reasonable useful lifetime rule, though exceptions may be granted in the event the prosthesis is irreparably damaged, lost or stolen. Polishing and resurfacing of the prosthesis is covered twice annually.<sup>600</sup>

**Wigs:** No information was found that indicates Medicare provides coverage for wigs.

### **Public Programs Administered by Charities**

The American Cancer Society (ACS) does not offer health care insurance, and does not have the means available to provide financial assistance to all those in need. ACS provides answers to financial and insurance questions, helps with transportation and lodging, and funds cancer research.<sup>601</sup>

<sup>593</sup> McKoy JM, Fitzner KA, Edwards BJ, et al. 2007. Cost considerations in the management of cancer in the older patient. *Oncology* 21(7): 851-7.

<sup>594</sup> Medicare Coverage Guidelines for Inpatient Chemotherapy (Connecticut)

<sup>595</sup> Medicare Coverage Guidelines for Outpatient Chemotherapy (Connecticut)

<sup>596</sup> Medicare Coverage Guidelines for Inpatient Radiation (Connecticut)

<sup>597</sup> Medicare Coverage Guidelines for Outpatient Radiation (Connecticut)

<sup>598</sup> Medicare Coverage Guidelines for External Breast Prostheses (Connecticut)

<sup>599</sup> Medicare Coverage Guidelines for Eye Prostheses (Connecticut)

<sup>600</sup> *Ibid.*

<sup>601</sup> American Cancer Society. 2007. "Access to Health Care." Available at: [http://www.cancer.org/docroot/subsite/accesstocare/content/Frequently\\_Asked\\_Questions.asp](http://www.cancer.org/docroot/subsite/accesstocare/content/Frequently_Asked_Questions.asp). Accessed on June 1, 2010.

There is a wide array of cancer- and leukemia-related charities and foundations throughout the country that offer financial assistance for treatment of cancer and leukemia, including chemotherapy, radiation, surgery; required and recommended cancer-associated devices and supplies such as prosthetics and wigs; and financial assistance for travel and related expenses for patients and their families. The charities' resources are limited due to their own financial constraints and eligibility is generally based on income and assets.

### ***Public Programs Administered by Public Schools***

No information was found that would indicate public schools would be a source of treatment for tumors and leukemia or provide funding for treatment for tumors and leukemia.

### ***The Department of Public Health***

The Connecticut Department of Public Health (DPH) website includes information and resources related to cancer, including in-depth information about breast cancer, cervical cancer, colorectal cancer, and ovarian cancer. DPH sponsors the Connecticut Breast and Cervical Cancer Early Detection Program (CBCCEDP), a comprehensive screening program available throughout Connecticut for medically underserved women. The primary objective of the program is to significantly increase the number of women who receive breast and cervical cancer screening, diagnostic and treatment referral services. All services are offered free of charge through DPH contracted health care providers located statewide.<sup>602</sup> DPH-sponsored services for tumors/cancer are generally for screening and surveillance rather than treatment. No information was found regarding any DPH-sponsored funding or programs for leukemia treatment; however, leukemia is included in reports and tables related to cancer incidence and prevalence in Connecticut that are maintained and published by DPH.

### ***Municipal Health Departments***

No information was found that would indicate municipal health departments would be a source of treatment for tumors/leukemia or provide funding for treatment of tumors and leukemia. Municipal health departments routinely provide cancer/cancer prevention information and resources, early detection and screening services or referrals, and treatment referral services for residents.

### ***The Department of Social Services (DSS)***

**Tumors:** DSS covers the cost associated with tumor removal. Costs allowed per specific procedure can be found on the DSS surgical fee schedule.<sup>603</sup>

**Reconstructive Surgery:** DSS covers dozens of reconstructive surgical procedures.<sup>604</sup> As it pertains to subsection c of this statute (reconstructive breast surgery), procedure codes 19000-19499 of the DSS surgical fee schedule detail coverage of specific breast reconstruction procedures. Three procedures included in subsection c of the statute are listed in the DSS fee schedule: augmentation mammoplasty,<sup>605</sup> reduction mammoplasty<sup>606</sup> and mastopexy.<sup>607</sup>

**Prostheses:** Medicaid covers a variety of prosthetic and orthotic devices. Specific coverage amounts and codes can be found on the DSS Prosthetic/Orthotic Fee Schedule.<sup>608</sup> Prosthetic eyes are covered by DSS,

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<sup>602</sup> Connecticut Department of Public Health. 2007. "Breast Cancer." Available at: <http://www.ct.gov/dph/cwp/view.asp?a=3134&q=397344&dphPNavCtr=|47735|#47736>. Accessed on June 1, 2010.

<sup>603</sup> DSS Provider Fee Schedule: Surgical, 2010.

<sup>604</sup> *Ibid.*

<sup>605</sup> *Ibid.*, procedure codes 19324 and 19325

<sup>606</sup> *Ibid.*, procedure codes 19318

<sup>607</sup> *Ibid.*, procedure code 19316

<sup>608</sup> DSS Provider Fee Schedule: MEDS- Prosthetic/Orthotic 2010.

but are listed on a separate fee schedule from other prostheses.<sup>609</sup>

**Wigs:** Connecticut Medicaid criteria require that a wig be medically necessary and be prescribed by a physician. The Medicaid client must be eligible and provide the prescription for the item to an enrolled Medicaid supplier. The Medicaid fee schedule lists wigs (procedure code A9282) at \$250.00.<sup>610</sup>

**Chemotherapy, radiation and leukemia:** Medicaid covers medically necessary and appropriate services, which include chemotherapy, radiation and leukemia treatments.<sup>611</sup> The physician administered drugs section of the DSS Physician Office and Outpatient Fee Schedule includes chemotherapy drugs.<sup>612</sup>

***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 for surgical removal of tumors and treatment of leukemia, and several related treatments/services related to tumors and leukemia in fully-insured group and individual health insurance plans.<sup>613</sup> 2007 and 2008 claims data from six insurers/MCOs domiciled in Connecticut 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 which represents an estimated 47 percent of the total population in self-funded plans in Connecticut shows that 86.1 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.***

Coverage is required and generally available for persons enrolled in fully-insured group and individual health insurance plans. Coverage is typically included in self-funded plans; persons enrolled in fully-insured and self-funded group plans represent the majority of the insured population under age 65 in Connecticut. Medicare and Medicaid also cover treatment of tumors and leukemia and the related treatments/services included in the mandated benefit.

Most of the persons unable to obtain necessary health care treatment are uninsured or underinsured.

***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 treatment of tumors and leukemia is required to be included in fully-insured group and individual insurance plans 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 treatment of tumors and leukemia depending on the type of cancer, treatments, disease progression at time of diagnosis, etc. which may result in significant health and economic costs for the individual and their family, even for those with comprehensive health benefits. Delayed diagnosis of some cancers results in advanced disease progression that requires more intensive treatment. Some cancer types are more aggressive than others. In cases such as these, lost work time and income are common, as well

<sup>609</sup> DSS Provider Fee Schedule: MEDS- Hearing Aid/Prosthetic Eye, Specifically Procedure Codes V2623-V2628.

<sup>610</sup> Personal communication. G. Mahoney. State of Connecticut Department of Social Services. November 12, 2009.

<sup>611</sup> Personal communication. Nina Holmes. State of Connecticut Department of Social Services, Medical Policy Unit. April 8, 2010.

<sup>612</sup> DSS Provider Fee Schedule: Physician Office and Outpatient Fee Schedule, Specifically J, Q and S Codes

<sup>613</sup> CONNECTICUT GENERAL STATUTES ANNOTATED § 38A-504 (individual insurance policies); § 38A-542 (group insurance policies).

as other costs associated with treatment (e.g., travel) that are not covered by health insurance.

Further discussion of financial and socioeconomic effects of the mandated benefit may be found in Appendix II: Ingenix Consulting Actuarial and Economic Report, page 55-56.

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

Incidence of cancer is slightly higher in the state of Connecticut than it is in the United States. In Connecticut, the incidence of cancer in 2006 was 552.8 per population of 100,000, compared to 492.4 per population of 100,000 in the United States.<sup>614</sup> Connecticut's cancer rates have steadily been increasing, totaling a 25 percent increase in breast cancer incidence from 1980 to 1998, and ranking third in the country for the highest incidence of non-Hodgkin's lymphoma.<sup>615</sup> Recognition of the higher incidence rate of cancer indicates high levels of public and provider demand for potential life-saving treatment and reconstructive surgery.

In the case of reconstructive surgeries, prostheses, and wigs, there is clearly a psychosocial benefit to cancer patient if they receive these treatments. Studies have shown that chemotherapy-induced alopecia results in "anxiety, depression, a negative body image, lowered self-esteem, and a reduced sense of well-being."<sup>616</sup> Patients may refuse life-saving treatment if they fear the development of chemotherapy-induced alopecia, indicating a demand for treatment that can cosmetically mitigate the effects of cancer treatment on body image.

Likewise, women who have undergone breast reconstruction after mastectomies or partial mastectomies were happier with their body image, and suffered less depression and anxiety than their counterparts who only underwent a mastectomy with no reconstructive surgery.<sup>617</sup>

**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.***

Several members of the public and providers testified in favor of insurance coverage for the wig portion of the mandate during the time legislation for the mandate was under consideration by the Connecticut General Assembly.<sup>618</sup>

Some studies have shown that insurance coverage greatly affects the availability of certain life-saving treatments in cancer patients. Specifically, one study showed that uninsured cancer patients, although they still had access to chemotherapy, had significantly less access to surgical treatments and were more likely to present with late-stage cancer. The uninsured patients had twice the risk of death as insured patients.<sup>619</sup>

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<sup>614</sup> Centers for Disease Control and Prevention and National Cancer Institute. 2010. U.S. Cancer Statistics Working Group. United States Cancer Statistics: 1999–2006 Incidence and Mortality Web-based Report. Available at: [www.cdc.gov/uscs](http://www.cdc.gov/uscs). CT information available at: <http://apps.nccd.cdc.gov/uscs/statevsnational.aspx>. Accessed on July 28, 2010.

<sup>615</sup> American Cancer Society. 2003. Press release. Connecticut is among states with highest cancer rates in nation. Available at: [http://www.ehhi.org/cancer/pr\\_cancerrates.shtml](http://www.ehhi.org/cancer/pr_cancerrates.shtml). Accessed on July 28, 2010.

<sup>616</sup> Hesketh PJ, Batchelor D, Golant M, et al. 2004. Chemotherapy-induced alopecia: psychosocial impact and therapeutic approaches. *Support Care Cancer* 12(8):543-9.

<sup>617</sup> Markopoulos C, Tsaroucha AK, Kouskos E, et al. 2009. Impact of breast cancer surgery on the self-esteem and sexual life of female patients. *Journal of International Medical Research* 37(1):182-8.

<sup>618</sup> Connecticut General Assembly. Report on Bills Favorably Reported By Committee. Insurance and Real Estate Committee. HB-5464. March 4, 2004.

<sup>619</sup> Zaydfudim V, Whiteside MA, Griffin MR, et al. 2010. Health insurance status affects staging and influences treatment strategies in patients with hepatocellular carcinoma. *Annals of Surgical Oncology* 17:3104–11

Another study focused on the treatment of breast cancer patients, including reconstructive surgery, and found that more uninsured patients have more severe stages of breast cancer as well as fewer reconstructive surgeries, even though reconstructive surgery has been found to have a positive psychosocial impact on breast cancer patients.<sup>620</sup>

Additionally, Ingenix Consulting reported that the average cost of a patient undergoing chemotherapy using newer and more expensive oral agents was between \$65,000 and \$75,000 in 2009. Patients who were commercially insured could afford an average out-of-pocket payment of \$1,500 (please see Appendix II, Ingenix Consulting Actuarial and Economic Report, page 55).

Thus, the high cost of potentially life-saving treatments combined with the lack of patient ability to pay indicates a strong public and provider demand for insurance coverage of cancer treatments and reconstructive surgeries.

**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 (NAIC), as of August 2008, Connecticut is the only state that requires coverage for “treatment of tumors and leukemia.” Twenty-five states require insurance coverage of chemotherapy; five states require insurance coverage for prostheses; and four states require insurance coverage for wigs for alopecia associated with cancer treatment.<sup>621</sup> Please see Tables 1.11.2-4 for additional details regarding state health insurance mandates for tumors, leukemia, and related services documented by the NAIC.

State	Coverage
Alaska	Coverage for outpatient chemotherapy required in state health insurance plans.
Arizona	Coverage required for chemotherapy if prior authorized and coordinated with a member’s contractor.
Arkansas	Group contracts must cover inpatient and outpatient chemotherapy.
California	Coverage required for chemotherapy on an inpatient and outpatient basis.
Delaware	Coverage required for chemotherapy under a policy for cancer-only coverage or on an expense incurred basis.
Idaho	A policy that provides cancer-only coverage must provide chemotherapy.
Illinois	A policy that provides cancer-only coverage must provide chemotherapy.
Indiana	Self insurance policy must provide covered individuals with outpatient chemotherapy for breast cancer.
Florida	If chemotherapy is part of bone marrow transplant, treatment must provide chemotherapy.

<sup>620</sup>Coburn N, Fulton J, Pearlman DN, et al. 2008. Treatment variation by insurance status for breast cancer patients. *Breast Journal* 14(2): 128-34.

<sup>621</sup> National Association of Insurance Commissioners. 2008. NAIC Compendium of State Laws on Insurance Topics.

<b>Table 1.11.2: States with Mandated Coverage for Chemotherapy</b>	
State	Coverage
Kentucky	All insurers that provide coverage for treatment of breast cancer by chemotherapy on an expense-incurred basis shall also provide coverage for treatment of breast cancer by high-dose chemotherapy with autologous bone marrow transplantation or stem cell transplantation.
Maine	Coverage required for radiation and chemotherapy if medically necessary.
Missouri	Individual and group health insurance policies shall offer coverage for the treatment of breast cancer by dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants.
Montana	Required coverage includes outpatient chemotherapy. A plan of health coverage must offer high dose chemotherapy bone marrow transplantation.
New Jersey	Group and individual contracts must offer coverage for outpatient chemotherapy for breast cancer. All group and individual policies must provide benefits for the treatment of cancer by dose-intensive chemotherapy/autologous bone marrow transplants and peripheral blood stem cell transplants
New York	Ambulatory care in outpatient facilities includes services and medications used for nonexperimental cancer chemotherapy.
Pennsylvania	Any individual or group policy that provides for cancer benefits must include benefits for cancer chemotherapy and cancer hormone treatments in any medically appropriate treatment setting.
Rhode Island	The standard health benefit plan shall include outpatient hospital care for chemotherapy.
South Dakota	The standard health care plan shall include benefits for chemotherapy services for treatment of a malignancy.
Tennessee	Chemotherapy coverage may be offered at an additional cost but shall not be subject to any greater deductible than any other health care service
Utah	Covered benefits under accident and health insurance policies shall include chemotherapy.
Vermont	Medically necessary growth cell stimulating factor injections taken as part of a prescribed chemotherapy regimen.
Virginia	Individual or group accident and sickness insurance policies must include coverage for the treatment of breast cancer by dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants. Outpatient diagnostic and therapeutic services including testing and treatment upon referral by the primary care provider including outpatient radiation or chemotherapy treatment when medically necessary and upon referral by the primary care provider
Washington	A health insurance policy must provide benefits for chemotherapy.
West Virginia	A cancer-only policy must provide benefits for chemotherapy.
Wyoming	No expense reimbursement cancer policy shall provide benefits for any type of radiation therapy without also providing the same benefits for chemotherapy or any other therapy prescribed by a doctor of medicine and designed to destroy or to arrest the uncontrolled spread of cancer cells.

State	Coverage
Alaska	State insurance plans must provide nondental prosthesis and maxillo-facial prosthesis used to replace any anatomic structure lost during treatment for head and neck tumors or additional appliances essential for the support of the prosthesis.
Maryland	Nonprofit health service plans that provide hospital benefits shall provide hospital benefits for prosthetic devices and orthopedic braces.
Michigan	Health care corporations shall offer or include coverage for prosthetic devices to maintain or replace the body part of an individual whose covered illness or injury has required the removal of that body part.
New Hampshire	Plans with hospital expenses must provide coverage for prosthesis to replace arm or leg. May not impose separate lifetime maximum on coverage for prosthetic devices.
Oregon	Maxillofacial prosthetic devices included for group policies.

State	Coverage
Maryland	Requires coverage, not to exceed \$350, for hair prosthesis to replace hair lost due to chemotherapy or radiation treatment for cancer. Must be prescribed by oncologist.
Massachusetts	Scalp hair prosthesis for hair loss suffered as a result of cancer treatment if doctor certifies is medically necessary. Limit of \$350 a year.
New Hampshire	For groups, scalp hair prosthesis for hair loss suffered because of alopecia areata, alopecia totalis, alopecia medicomentosa from cancer treatment, or permanent loss due to injury. Coverage for alopecia medicomentosa may not exceed \$350 per year. Need statement from doctor that medical necessity.
New Jersey	Requires coverage for scalp hair prostheses and for hair headpieces for patients receiving chemotherapy for cancer.

The Council for Affordable Health Insurance (CAHI) also tracks state health insurance mandates. According to CAHI, all 50 states and the District of Columbia have a mandate for breast reconstruction; 7 states have a mandate for chemotherapy (CAHI does not include Connecticut in their count); 3 states mandate ambulatory cancer treatment; 11 states mandate hair prostheses; 23 states mandate mastectomy surgery; 25 states mandate a minimum stay following mastectomy; 16 states mandate orthotic and/or prosthetic devices; 2 states mandate reconstructive surgery (Connecticut is not listed); and 3 states mandate treatment for testicular cancer (Connecticut is not listed).<sup>622</sup> CAHI does not list states with benefit mandates for “treatment of tumors” or “leukemia.”

<sup>622</sup> Craig Bunce V, 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](http://www.cahi.org/cahi_contents/resources/pdf/HealthInsuranceMandates2009.pdf). Accessed on June 7, 2010.

**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.<sup>623</sup> Internet searches and telephone inquiries found no studies from state agencies and public organizations related to the social impact of mandated insurance coverage for an omnibus tumors and leukemia treatment mandate such as the existing Connecticut mandate under review. Searches and inquiries found a Maine study that reviews the financial impact of breast cancer and breast reconstruction but no discussion of social impact; a Massachusetts study related to scalp hair prostheses (wigs); and reviews of proposed or enacted mandates for coverage of prosthetic devices for Maryland, Maine, Massachusetts, New Jersey, Pennsylvania, Virginia, and Washington.

Massachusetts reported on the social impact of scalp hair prostheses for cancer patients in 2008.<sup>624</sup> The Massachusetts mandate requires fully-insured plans to cover up to \$350 per year for scalp hair prosthesis (wig) for a member experiencing hair loss secondary to cancer or leukemia treatment. Discussion of the social impact of insurance coverage for wigs include the difficulty in estimating the clinical efficacy of a scalp hair prosthesis and that it would seem reasonable to assume that a wig may help a patient cope with the effects of chemotherapy by fostering a better self-image, allowing the patient to focus on treatment and recovery.

No state prostheses study focused exclusively on prostheses required following treatment of tumors or leukemia and described prostheses for limb loss rather than maxillofacial prostheses commonly associated with head and neck cancers and breast cancer prostheses. The National Limb Loss Information Center reports that the majority of new amputations occur due to complications of the vascular system; rates of cancer and trauma-related amputations are decreasing.<sup>625</sup> In general, state reports discussing the social impact of insurance coverage for prostheses found such coverage to provide a positive impact on cancer survivors due to increased functional capabilities facilitated by prosthetic devices.

States searched included Arkansas, California, Colorado, Louisiana, Maine, Maryland, Massachusetts, Minnesota, New Jersey, New York, Ohio, Oregon, Pennsylvania, Rhode Island, Texas, Virginia, Washington, and Wisconsin.

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

Cancer is a highly researched disease. A multitude of clinical trials are conducted in the United States in efforts to discover more effective treatments for cancers and leukemia. Clinical trials may include chemotherapies, chemotherapies in conjunction with radiation or other treatments, and other designs including immunotherapies. Often, clinical trials will add an investigational drug to delivery of standard of care treatment.<sup>626</sup> In some cases, a clinical trial may meet the need as an alternative treatment, method, or procedure; however, the availability of a clinical trial that meets the needs of any single cancer or leukemia patient is limited. Thus, clinical trials should not be viewed as a reliable alternative to standard treatment.

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<sup>623</sup> 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 on May 7, 2010.

<sup>624</sup> Bachman SS, Highland J, Nordahl K, et al. 2008. Comprehensive review of mandated benefits in Massachusetts. Commonwealth of Massachusetts. Division of Health Care Finance and Policy. Available at: [http://www.mass.gov/Eeohhs2/docs/dhcfp/r/pubs/mandates/comp\\_rev\\_mand\\_benefits.pdf](http://www.mass.gov/Eeohhs2/docs/dhcfp/r/pubs/mandates/comp_rev_mand_benefits.pdf). Accessed on September 17, 2010.

<sup>625</sup> National Limb Loss Information Center. 2008. Amputation Statistics by Cause: Limb Loss in the United States. Available at: [http://www.amputee-coalition.org/fact\\_sheets/amp\\_stats\\_cause.html](http://www.amputee-coalition.org/fact_sheets/amp_stats_cause.html). Accessed on June 7, 2010.

<sup>626</sup> Personal communication. Biree Andemariam, MD. July 14, 2010.

Additionally, covered costs of care in a clinical trial are generally restricted to the agent or therapy under investigation. All other costs of treatment, including standard of care treatment and routine medical costs are generally covered by the patient's health insurance or, if the patient is uninsured, through sources other than the clinical trial.

***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.***

Treatment of tumors and leukemia, chemotherapy, reconstructive surgery, prostheses, and provision of wigs for hair loss associated with chemotherapy fulfill medical needs and are medically necessary. Lack of treatment for tumors and leukemia generally results in pain, suffering, and death. Early detection is critical for successful treatment and timely recovery, and reduces chances of relapse. Required insurance coverage for treatment of tumors and leukemia ensures that at least persons covered by fully-insured and individual insurance plans have access to coverage.

Cancer and leukemia treatments are generally high-cost medical expenses that few individuals could afford on an out-of-pocket basis, thus the benefit is consistent with the role of health insurance and the concept of managed care.

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

It is possible that the basic structure of the mandate could be replicated for treatment of other diseases. If denials of insurance coverage for certain treatments 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.

Any new mandated benefit for high-cost, complex services (such as treatment for tumors and leukemia) with mandated benefit levels (dollar limits) at a fraction of the actual costs of the service may not serve to increase coverage as intended. For example, should mandated coverage for heart disease be enacted with low mandated dollar limits for individual treatment options with the intention of improving heart disease treatment and outcomes for the fully insured population, insurers and MCOs would have the option of reducing benefits to mandated levels for services covered comprehensively at present (in the absence of a mandate). If insurers and MCOs decided to limit coverage to the mandated benefit dollar limits, the social implications would be negative in terms of population health and economic security of heart disease patients and their families.

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

The actuarial analysis conducted by IC showed benefit levels unconstrained by the dollar limits of the mandated benefit (other than for coverage of wigs), which indicates the various aspects of treatment for tumors and leukemia included in the mandate would be provided even in the absence of a mandate. While treatment of tumors and leukemia is a high-cost benefit, purchasers of health insurance (employers and individuals) expect coverage for these diseases and there is little in the mandate that most insurers/MCOs would argue against covering. Thus it is expected that the benefit 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-insured plans and the extent to which the benefit is currently being offered by employers with self-insured plans.***

Because this benefit has been in effect since at least 1990, it is not possible to determine the extent to which

required coverage for treatment of tumors and leukemia contributed to employer decisions to shift to self-funded plans. It is not anticipated that any more employers will shift to self-funded plans as a result of this mandate. It is also not anticipated that repeal of this mandate would lead to a shift from self-funded plans to 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 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.

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 86.1 percent of enrollees in their self-funded plans have coverage for the mandated services. Most residents of Connecticut in self-funded plans have coverage for treatment of tumors and leukemia at higher dollar amounts than the current benefit requires. Because treatment for tumors and leukemia is typically included in health insurance plans not subject to state regulation at higher dollar amounts than mandated coverage, it is unlikely that the mandate has any 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 tumors and leukemia mandate is a current benefit that has been included in the state employee health insurance and health benefits plans at least in part for over 20 years. 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<sup>627</sup> 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; however, coverage for tumors and leukemia is a benefit typically included in self-funded plans in Connecticut.

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 \$21,692,088 in 2010.<sup>628</sup>

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<sup>627</sup> Personal communication. Scott Anderson, State of Connecticut Comptroller’s Office. September 14, 2010.

<sup>628</sup> 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.

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

The safety and effectiveness of treatment for tumors and leukemia and the associated services covered in the required benefit is well-represented in the medical literature. Cancer is a widely-researched disease; safety and effectiveness of treatment and disease management are frequently improved through the emergence of new or improved surgical techniques, chemotherapies or drug combinations, immunotherapies, and radiotherapies. Due to the expansive nature of the required benefit, a detailed review of the safety and effectiveness of all of the mandated services is not attempted.

## **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 cost of treatment for tumors and leukemia and the associated benefits listed in the statute over the next five years. Treatment for tumors and leukemia is generally included in self-funded plans and would be expected to be covered in most fully-insured group and individual policies in the absence of the mandate due to policyholder demand. The cost of most of the mandated treatments and services is likely to increase (or decrease) at the same rate as other medical services.

Drug costs associated with outpatient chemotherapy may be increasing at a higher rate than other medical services but the presence of the health insurance mandate is not expected to contribute to the increase. Rather, the prescription drug market environment and the manner in which prescription drugs are developed (large upfront research costs recouped through costs charged following FDA approval) are the main contributors to chemotherapy drug costs.

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

For those persons diagnosed with cancer or leukemia whose insurance plans would not otherwise cover treatment for tumors and leukemia, the mandated health benefit may increase appropriate use of the mandated treatments and services. For the uninsured, those covered by self-funded plans, persons enrolled in Medicaid or Medicare, or who use out-of-pocket funds for mandated treatments and services, the mandated benefit may not increase appropriate use. It is expected that little inappropriate use occurs because false-positive diagnoses of tumors and leukemia followed by treatment is generally rare.

Should insurers and MCOs limit payments to the mandated dollar limits associated with several covered benefits listed in the mandate, the mandate may not increase their appropriate use. The mandated dollar limits for surgery, prostheses, wigs, and breast reconstruction are far lower than the costs of the treatment, service, or equipment. Other than for wigs, there is no indication that insurers and MCOs are currently limiting payments for claims for the treatment or services to mandated amounts listed in the statute.

**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.***

Due to the expansive nature of and wide range of services included in the mandate for tumors and leukemia treatment, the alternatives would seem to be limited. Depending on the stage when cancer is detected and the type of tumor present, surgical, chemotherapeutic, radiation and other widely utilized treatments for

tumors and leukemia generally save lives and extend lifespan. Prostheses allow patients to return to normal levels of functioning and independence. Wigs for persons with chemotherapy-induced alopecia and breast reconstruction relieve some of the psychological impact of cancer treatment. Less expensive but equally effective treatments would have to be determined through comparative effectiveness research methods which have yet to be fully developed and implemented. Additionally, for mandated services with dollar limits, alternatives are not likely to be less expensive because the mandated dollar limits are far lower than actual costs of treatment and current claims paid by insurers/MCOs.

***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 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. Based on claims data, insurers and MCOs are paying claims at higher amounts than the statute requires for those services with dollar limits attached, thus management of the costs of the benefits at mandated dollar amounts is of no practical importance.

***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 medical cost of the mandate is spread to all insureds in group plans, medical costs are estimated to be \$11.00 PMPM and retention costs are estimated to be \$2.20 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$13.20 PMPM in 2010. Insurance coverage for the mandated benefit may be reasonably expected to increase group health insurance premiums accordingly, that is, \$158.40 per year per insured.

**Individual policies:** When the medical cost of the mandate is spread to all insureds in individual policies, medical costs are estimated to be \$8.60 PMPM and retention costs are estimated to be \$2.57 PMPM in 2010. Thus the total effect on insurance premiums is estimated at \$11.17 PMPM in 2010. Insurance coverage for the mandated benefit may be reasonably expected to increase individual health insurance premiums accordingly, that is, \$134.04 per year per insured.

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

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

Not applicable. The analysis herein reviews existing treatments for and services related to tumors and leukemia.

***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 of insurance premiums and cost sharing. Actuarial analysis of claims data received from insurers/MCOs in Connecticut shows an expected cost 2010 of \$199,237,485 for treatment for tumors and leukemia and other services included in the mandate for Connecticut residents covered by fully-insured group and individual health insurance plans.

In terms of potential benefits or savings to insurers and employers resulting from prevention or early detection of disease or illness, economic benefits of the mandate may accrue to employers in terms of worker productivity. The economic benefits to business of employees with cancer or leukemia returning to work or on-the-job productivity may offset a portion of the treatment costs covered by the mandate. The mandate under review is related to treatment of established disease (rather than disease prevention or early detection) thus no benefits or savings to insurers or employers are likely to result prevention or early detection of disease related to such coverage.

***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 treatment of tumors and leukemia on the cost of health care for small employers. Small employers may be more sensitive to premium increases than other employers and the estimated cost of the mandate (\$10.10 PMPM in 2008) suggests potential differences in 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 30.)

***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 to 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 services 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, at least in part in 1979, 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.

Treatment of tumors and leukemia is a high-cost medical service; however, the coverage provided by insurers/MCOs is not likely to be substantially influenced by the existence of the mandate. Purchasers of health plans expect coverage for tumors and leukemia to be included and insurers/MCOs cover the costs of the mandated benefits at higher dollar amounts than are mandated in most cases.

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 2010 of \$236,790,751 for treatment for tumors and leukemia and other services included in the mandate 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 I**  
**Appendix I**

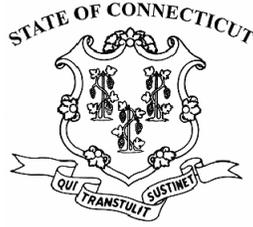
**House Bill No. 5018**

**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

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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

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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

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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

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(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;

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(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 I**

**Appendix II**

***Ingenix Consulting***

**Actuarial Report**

**On set one, the first 11 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 One, The First 11 Of The 45 HEALTH INSURANCE  
MANDATES Covered By PUBLIC ACT NUMBER 09-179

December 10, 2010

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## I. INTRODUCTION:

This report serves to record the findings of Ingenix Consulting (IC) pursuant to our engagement to provide actuarial services to the State of CT in conjunction with Substitute House Bill No. 5021, Public Acts 09-179. This report is intended to communicate the results of our work.

Ingenix Consulting is pleased to have been chosen to serve the state of CT in this valuable project. A team approach was used with the workgroup that included the CT Department of Insurance, the Center for Public Health and Health Policy, and IC. 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. Earl Hoffman, FSA, MAAA and his staff carried out the actuarial work on hearing aids. 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 our extensive commercial health claims databases.

The financial economic work was lead by Tanvir Khan who worked with a team of associates located throughout the nation, including Lincy Lal, PhD, and Ming Bai, MPH and MBA. The financial / economic report is embedded in section III of this Set One 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, our findings and conclusions are presented. These findings relate to the actuarial evaluation of each mandate in the first set of 11—Set One. 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 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, cost results are presented in summary form, and subsequently, additional data and calculations that support the findings will be layered into the document.

### I.1 IC reviewed the following eleven mandates (Section numbers, individual then group, and date of passage are shown in parentheses):

1. **Diabetic Self Management Training:** Anyone diagnosed with diabetes is eligible for three types of training of up to 10, 4, and 4 hours respectively for initial training, change in condition, and change in technology. This training is intended to help diabetic people to help themselves better self-manage their diabetes. Includes education in proper use of equipment and supplies and nutrition therapy. (38a-492e and 38a-518e; Jan. 2000).

2. **Prostate Screening—PSA Test:** Requires insurers to pay for PSA tests in accordance with standards established by the mandate. The frequency of testing in unspecified. (38a-492g and 38a-518g; Jan. 2000).
3. **Ostomy Supplies:** Requires insurers to cover up to \$1,000 per year of medically necessary ostomy supplies for people with a colostomy, urostomy and ileostomy. Cannot be considered DME (Durable Medical Equipment) or be included with a DME annual maximum. (38a-492j and 38a-518j; Oct. 2000).
4. **Hearing Aids:** Through age 12. Limit of \$1,000 every two years will continue to be permitted—this is \$1,000 in total, not per ear. Hearing aids shall be considered durable medical equipment (DME). (38a-490b and 38a-516b; Oct. 2001).
5. **Orthodontic Treatment for Cleft Palate:** Requires medical insurers to pay for orthodontic treatment for those with cleft palate. (38a-490c and 38a-516c; Oct. 2003).
6. **Hospital Dental:** Inpatient, outpatient, or one-day dental services for special populations requiring general anesthesia for dental work under certain conditions. (38a-491a and 38a-517a; Jan. 2000).
7. **Diabetes Equipment & Supplies:** Insurers must cover diagnosis and treatment of diabetes, including equipment, drugs, and supplies for people with diabetes. (38a-492d and 38a-518d; Oct. 1997).
8. **Birth to Three Program:** Requires medically necessary early intervention habilitation services to \$3,200 per year for three years. (38a-490a and 38a-516a; July 1996).
9. **Lyme Disease:** Requires coverage of not less than 30 days IV antibiotic treatment and or 60 days oral antibiotics. Further treatment is permitted based on recommendation of board-certified specialist. (38a-492h and 38a-518h; Jan 2000).
10. **Colorectal Cancer Screening:** Requires annual fecal blood test or sigmoidoscopy, colonoscopy, radiologic imaging at frequency per age/family history standards established by American College of Gastroenterologists after consultation with the American Cancer Society. (38a-492k and 38a-518k; Oct 2001).
11. **Cancer, Tumors, Leukemia, etc.:** Requires coverage of the same plus reconstructive surgery, prosthesis, chemotherapy, wigs, and breast reconstruction after mastectomy. Certain limits apply. (38a-504 and 38a-542; July 1994).

Note: All eleven mandates apply the same to group and individual coverage. All eleven mandates apply to comprehensive health insurance plans such as Health Maintenance Organizations (HMOs) and Preferred Provider Organizations (PPOs). The mandates do not apply to disability plans, workers compensation, or medical indemnity plans that pay a set amount for each day that the person insured is a hospital inpatient. Only the eleventh mandate applies to limited medical benefit plans; it applies for individual limited benefit plans but not limited 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 expense. The latter consists of administrative cost and profit. Much greater emphasis has been placed on medical cost since it represents the far larger portion of

overall cost. The annual medical cost in 2007 and 2008 dollars, as reported by the carriers, was reviewed. Elsewhere in the report, non-medical expense is also referred to as retention. It represents roughly 17% of premium for group plans. Some mandates may involve more administrative expense than others, especially at the time they are 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 by the medical insurers and HMOs. The focus in this report 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. The cost that 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. It is Paid cost that drives the cost of insurance. When the member's financial burden is discussed later in this report, however, member cost-share will be the topic of focus. Member cost share is the difference between the Allowed and Paid Cost.

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. There were far more members in the group data than in individual plans; thus the group data was substantially more credible than the individual data. (Credible is used here in the actuarial and statistical sense, which relates to the law of large numbers.) The numbers referred to below in the cost summary of section I.3 are for group plans. Later in the report, individual plans and the individual data are discussed at greater length. As a reference, for some mandates, IC's internal commercial health claims data for 2007 and 2008 was also extracted and reviewed, both CT-specific as well as national data in some instances. Outside data sources were also reviewed for incidence and prevalence rates.

First, a summary is presented of the expected 2010 medical cost without detail or long-range projections. Later in this report, there will be further elaboration on the medical cost of each mandate, and we will also include socio-economic consequences and ramifications on the finance and delivery system, including the effect on health insurance cost and availability. This will be followed by commentary 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 our 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 the mandate or in the absence of the mandate.

Where available, for some of the mandates, 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, such as cancer, were more difficult and may have involved additional analytic complexity.

In the estimates below, a point estimate of cost is presented. 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 in selecting the claims. 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. Some mandates protected small vulnerable populations. The hearing aids for children, ostomy supplies, hospital dental, and orthodontia for cleft palate mandates are examples of this. Some effectively established a new minimum standard of care and treatment, such as the diabetes supplies mandate or the Lyme disease treatment. The diabetes self management training ushered in a new mode of disease management that helps produce better health outcomes for diabetics.

The cancer screening mandates were part of a movement premised on the belief that early detection results in better outcomes with respect to mortality and morbidity. At the time they were introduced, they were thought to produce better medical outcomes. While this is generally true, recent findings with mammography and especially prostate screening have caused public health experts to raise questions about the efficiency of screening and the appropriate frequency and initial age. For colorectal cancer screenings (CRC), it is clear that it is effective at saving lives, but the cost of mass-screening is high and raises the question of whether there might be a more cost-effective approach. One gastroenterologist, with whom our work-team met, explained that the screening criteria applies a general rule to all, which may be inadequate for those with higher risk factors and more than adequate for those at lower risk. He envisioned that the future would bring a more personalized approach to preventive care, and individual risk factors would be considered in establishing the initial age and subsequent frequency of colonoscopies. Some of these findings will be discussed further later in the report.

The following eleven mandates are the first 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.**

Note: The numbering of the following mandates does not reflect their relative importance.

1. Mandate one covers the cost of professional self-management training for diabetics (DSMT). This type of training is designed so that diabetics can learn to use their equipment and supplies and better self-manage their condition with training in self-care and nutrition. Diabetes can be a costly medical condition, especially when the disease progresses. DSMT

is inexpensive but cost-effective and highly desirable with respect to public health. Medicare has a similar DSMT benefit. Experts assert that savings result from diabetic disease management programs in general. These savings have not been estimated in our calculation, but based on the literature that was reviewed, it is expected that DSMT savings exceed the cost by preventing costly premature complications of diabetes. The observed weighted average of the carrier data is \$0.06 PMPM for 2008, and is projected to be the same in 2010. The 2010 medical cost for fully insured plans based on Ingenix data is \$0.04 PMPM. This is the gross cost of the benefit in the sense that it does not factor in any savings that result from it. DSMT is not covered in all states.

2. Mandate two requires coverage of Prostate Specific Antigen Testing (PSA) to screen for prostate cancer. The frequency is not specified in the mandate. In the 50 – 64 age range, about 42% of the men in the IC data for CT were PSA tested annually. According to the same data, the medical cost of the testing is about \$0.31 PMPM. The expected range of the gross medical cost based on IC data is \$0.20 to \$0.30 PMPM. The overall benefit of early prostate screening is unproven in the medical literature. PSA testing detects both the non-life threatening cancers as well as those likely to cause significant mortality and morbidity. Most prostate cancer is a slow-growing and “indolent” type. Early detection of indolent prostate cancer has psychological implications and leads to radical prostatectomies that come with the risk of incontinence and sexual dysfunction for individuals that might have otherwise led lives unaffected by prostate cancer. Early detection does not necessarily mean that savings result after the PSA testing. For example, an English study estimated that of 1,410 men screened, 48 men diagnosed with prostate cancer would need to undergo risky medical treatment in order to save one life. A US study concluded that PSA testing does not save lives. Given the cost and benefit, the value of PSA testing for all men over 50 has come into question.

Based on the insurers’ data, a weighted average 2008 paid cost of \$0.17 PMPM was observed. The Ingenix data was \$0.25 on a 2008 basis. On a 2010 basis, the paid cost is \$0.19 based on the carrier data. It is \$0.27 PMPM based on IC data.

It would seem self-evident that early detection resulting from cancer screening would result in a decrease in mortality and morbidity. However, in the case of prostate screening, with the presently available PSA test, there is evidence there is no impact on mortality and an increase in morbidity due to complications resulting from overtreatment of what would have otherwise been indolent cancers.

Fortunately, the PSA test itself is low-cost—approximately \$20 - \$30 when done by an outside lab for a physician; the data shows that it costs more if done by a hospital.

The US Preventive Services Task Force concludes that the current evidence is insufficient to assess the balance of benefits and harms of prostate cancer screening in men younger than age 75 years; it recommends against screening for men 75 years or older.

3. Mandate three involves the coverage of ostomy supplies for three types of ostomates. There are very few ostomates in the fully insured or self funded populations in CT. In the IC data for CT, it was discovered that about 0.004% to 0.005% of those in the self funded population had annual spending over \$100. We found only two fully insured members in the IC data for CT with annual spending greater than \$100 in 2007; there were

three in 2008. Using the self-funded members in the IC data, we found that the medical cost of the ostomy supplies mandate is about \$0.04 PMPM. Based on the insurers' data, the weighted average for 2008 paid cost is \$0.06. We expect these to be about the same in 2010.

During phase one of this project, it was found that removing the \$1,000 maximum was worth about \$0.01 PMPM in annual medical spending when the annual cost of supplies greater than \$1,000 was spread to all members. When this mandate was passed in October 2000, \$1,000 then was equivalent to about \$1,250 today, adjusting for general inflation only. Medicare covers ostomy supplies without limit, but unlike the commercial sector, it is able to establish the cost it will pay for the ostomy supplies. For this reason, those who procure ostomy supplies through commercial insurance plans are likely paying a higher price for these supplies than Medicare members.

4. Mandate four involves the provision of hearing aids to children 12 and under. The cost of doing so ranges from about \$0.01 to \$0.05 PMPM based on the carrier data. Based on a limited amount of IC data, the cost is about \$0.05 PMPM. Since a single hearing aid often costs significantly more than \$1,000, the \$1,000 limit every two years imposes a substantial cost-burden on the family of the insured. This is especially true for children that need two hearing aids. When this mandate was passed in 2001, digital hearing aid technology was not as widespread, and the technology in general was not as advanced or expensive as it is today. The cost of living in the meanwhile has also risen. If the \$1,000 limit were raised, it is likely that utilization would increase because some children are using fewer and less expensive types of aids than they would if more cost were covered. This is a relatively low-cost benefit with obvious public health advantages. The \$1,000 maximum is low in relation to the cost of hearing aids.

The carrier data showed a 2008 weighted average paid cost of \$0.01 PMPM. This was lower than expected and could indicate that the use of hearing aids in children is lower than the prevalence of hearing loss and need would indicate. It is possible that the \$1,000 limit plays a role in discouraging parents from obtaining them since it is low in relation to the cost of one or two hearing aids. It is also possible that families may not realize that their health insurance covers this expense. This is a relatively low cost mandate on a PMPM basis, but its impact has been lessened by significant advances in technology resulting in better and more expensive devices whose cost exceeds the \$1,000 cap. By including hearing aids in the category of durable medical equipment (DME), the \$1,000 annual hearing benefit could be further reduced for people who also need other DME such as wheelchairs or home oxygen.

5. Mandate five requires insurers to pay for the cost of orthodontic treatment for those with cleft palate. The cost of orthodontic treatment may range from \$1,000 to \$10,000 depending on the amount of work required, and it may take place in phases over a time frame of several years. There are so few individuals with cleft palate in the carrier data whose orthodontic treatment was paid under medical insurance that the cost has been *de minimis*. The same is true for the IC data. In discussing the frequency of this service with one of the few orthodontists in CT who handles these cases, he pointed out that it is often difficult for him to get paid for his services, despite the mandate. This may be an example of a mandate that is not well known and perhaps under-utilized for that reason. Those families

that have dental plans that cover orthodontia may already have these costs covered by their dental plan for children with cleft palate.

6. Mandate six involves hospital dental. It requires health insurers to cover the facility, nursing, and anesthesia costs for those who need to have dental procedures performed in a hospital inpatient or outpatient setting under general anesthesia. All the dental costs are paid for under a separate dental policy or rider. Only the facility costs apply to the medical insurance. The medical cost of an individual hospital dental encounter may range from \$4,000 to \$10,000. According to a dentist who performs these services, the average cost is about \$8,000 for a 2 ½ hour operation under general anesthesia. Such treatment is reserved for those who cannot have dental treatment without general anesthesia. One example provided was a patient who is profoundly developmentally disabled and has cerebral palsy. Because there are so few individuals undergoing this treatment, the cost is de minimis.

7. The seventh mandate requires insurers to cover diabetes equipment and supplies. Implicit in the mandate is the requirement that the diabetes benefit be as rich as other medical benefits; insurers cannot apply separate limits to diabetes care or otherwise limit diabetes care relative to other benefits. Insurers may not apply higher cost-sharing to diabetes than other diseases or medical conditions. When the bill was passed in 1997, less was known about diabetes and the importance of proper management of diabetes so as to prevent the premature cascade of worsening health that can result from inadequate care. More is known today about the importance of proper medical care for this chronic disease. It is difficult to separate out the 2010 cost of this mandate from what would have been paid in the absence of such a mandate. This mandate applies to the diagnosis as well as the treatment of diabetes.

There was some variation in the carrier data for diabetes, which showed a total average paid cost of about \$4.17 PMPM in 2008. It is likely that all or the vast majority of this amount would be paid, mandate or not. One of the consequences of this mandate may be that insurers, in their desire to comply with the mandate, may err on the safe side when it comes to establishing cost-sharing for diabetic equipment, supplies, and especially drugs. The IC data shows a 2008 paid cost of \$4.47 PMPM for diabetes-related care for diabetics, which would be about \$5.00 for 2010. The weighted average of the carriers for 2008 was \$4.17, which is about \$4.60 PMPM on a 2010 basis; this is about 1.5% of a \$300 monthly paid medical cost.

8. The eighth mandate, birth to three, is for habilitative services up to \$3,200 per year for three years for detection, diagnosis, and treatment of autism and developmental disability. Whether these habilitative services should be paid by medical insurance has been debated, since they were not historically a traditional medical benefit in the same way that rehabilitative services are for those who have strokes, for example. The majority of the cost of these services is absorbed by the state, with a sliding scale contribution from the families of those children covered. Only a portion of these habilitative services is paid by health insurance. The rest is paid by the state and the families of children with special needs. The carriers' 2008 paid cost was \$0.15 PMPM. This will likely be greater in 2010 because the limit has been increased to \$6,400, but probably not 2 times as much because not all families will use twice as many services. This is estimated to cost \$0.22 PMPM in 2010. Proponents of birth to three programs cite that these programs save states money by

detecting and supporting young children with autism and developmental disabilities early in a child's life.

9. Lyme Disease testing and treatment costs \$0.20 to \$0.50 PMPM. When this mandate was passed in 2000, there were some doctors who believed that chronic Lyme disease should be treated with long-term antibiotics. Other doctors believed such a long term course of antibiotics would be injurious to the patient; and they argued that if the patient did not respond in some finite period of time, good medical practice dictated a search for a different diagnosis. Long term antibiotic therapy can carry significant risks and is recommended against by the Infectious Diseases Society of America. The mandate granted coverage of up to 30 days of intravenous and 60 days oral antibiotics administered by a doctor. A longer course of antibiotics, however, requires the recommendation of a board-certified specialist. Based on the IC data, the cost is somewhat higher than the carrier data--about \$0.45 PMPM. The carrier data shows an average of \$0.25 PMPM for 2008. The IC data would be about \$0.50 on a 2010 basis. The carrier data is \$0.28 PMPM on a 2010 basis. What this cost does not capture is the savings, if any, that result from the requirement that a board-certified specialist recommend treatment beyond the initial 30/60 day period.

10. Screening for colorectal cancer: The primary expense under this mandate is colonoscopies. According to the IC data, carriers spent about \$2.50 PMPM on screenings alone in 2008. This would be about \$2.75 on a 2010 basis. Although the colonoscopy has emerged as the most thorough approach for colon cancer screening, it is an expensive procedure and many are performed for the few cancers detected. Colonoscopy, using the same initial age and frequency criteria for all, appears to be somewhat inefficient as a way to detect colon cancer for the general population. It has been thought of as a preventive to colon cancer for those individuals with pre-cancerous intestinal polyps that are removed during the procedure thereby preventing the polyp from growing into a cancerous tumor. However, gastroenterologists place less confidence in the effectiveness of this approach than they did ten or twenty years ago. IC separated the cost of screening from that of treatment and intervention. Post-screening treatments increase the 2008 cost by another dollar to about \$3.50 PMPM for this mandate. The insurers' data show a 2008 paid cost of \$3.10 for screening, which would be about \$3.40 PMPM on a 2010 basis—about 1.1% of a \$300 total monthly paid medical cost.

11. The eleventh and final mandate is broader than the others. It covers several aspects of cancer aggregated into one mandate. The treatment of tumors and leukemia, radiation therapy and chemotherapy for cancer treatment, reconstructive surgery, implantable prostheses, wigs for those who lose their hair during chemotherapy, and removal of breast implants obtained prior to 1994 are all covered under this mandate.

This was a more difficult mandate to assess the cost of than the others, and different carriers approached it differently. The carrier data reflected more variability for this mandate. At this point in time, there is little in the mandate about which most carriers would argue against covering. Twenty years ago, some carriers might have taken the position that their contracts excluded payment for wigs or reconstructive prostheses because that was considered to be cosmetic surgery. In assessing the cost of the mandate today, it is difficult to separate the mandate cost from what any carrier would otherwise pay on behalf of one of their members with cancer. In that sense, the mandate has done what it was intended to do.

The weighted average cost of the carrier data in 2008 is \$10.10 PMPM for the cancer mandate. On a 2010 basis, this would be about \$11 PMPM, which is about 3.3% of a \$300 total paid medical cost.

### I.3A SUMMARY OF EXPECTED MEDICAL COSTS OF MANDATES IN 2010, Carriers' Cost (PAID Basis)

1.	Diabetes SMT	\$0.06 PMPM		0.02%
2.	PSA	\$0.19	"	0.06%
3.	Ostomy Supplies	\$0.06	"	0.02%
4.	Hearing Aids	\$0.01	"	less than 0.01%
5.	Ortho, Cleft Plate	\$0.02	"	0.01%
6.	Hosp Dental w/ GA	\$0.05	"	0.02%
7.	Diabetes Test & Trtmnt	\$4.60	"	1.5%
8.	Birth to 3	\$0.22	"	0.07%
9.	Lyme Disease	\$0.28	"	0.09%
10.	CRC Screening	\$3.40	"	1.1%
11.	Tumors. Leuk, etc	\$11.00	"	3.7%

**Total** (for Group plans): **\$19.79 PMPM**, which is **6.6%** of paid medical cost using a \$300 base.

A range of medical cost for the eleven would be \$15 to \$25 PMPM. In terms of three scenarios, low, medium, and high, \$15 PMPM is our low estimate and \$25 PMPM is the high estimate. The cost estimate for the medium scenario is **\$20 PMPM**.

In calculating the percentage of overall medical cost, a denominator of **\$300 PMPM** was used for all calculations. This is medical cost only and does not include administrative cost or profit.

Looking at the cost of the mandates as a percent of the overall health insurance premium, and using an assumed premium cost of \$360 PMPM based on a medical cost ratio of about 83%, then the \$19.79 represents about 5.5% of the total health insurance premium. It should be noted that the top half of the fraction does not include administrative cost and profit, but the bottom half does. For this reason it is not an appropriate measure to use. 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. Outliers were investigated and questioned. Carriers were allowed to ask questions and resubmit scrubbed data. 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 in the table in 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 and 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 was developed using paid medical cost 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

Similar information 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 thousand individual members in the 2007 medical. Of these members, only 829,000 and 79,000 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.

<b>AVERAGE MEMBERS</b>	<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

Because of 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 ELEVEN 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. Non-medical expense means the same thing as retention.

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 payment 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 self-funded plans and Medicaid or Medicare.

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 different mandates. One component of administrative cost is state premium tax, which is 1.75% of premium in CT for fully insured plans. This premium tax expense is avoided by those employers that self-fund their employee health benefits.

Since all the mandates are ongoing, we estimated the administrative costs 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 ( $25\% = 20\% / 80\%$ ).

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 = Claims / Premium). Since retention is  $1 - \text{MCR}$ , we can use the target MCR 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. The term "retention" is used to describe administrative cost plus profit, which is all non-medical expense.

The vast majority of the incremental expense for the eleven mandates is medical cost.

For all eleven mandates combined, the cost of administration plus profit is about \$4. This is approximately 17% of overall premium and about 20% of the total medical cost of these mandates. [ $\$4 \sim = 0.167 \times (\$19.79 / 0.833)$ ]. As a range, this total retention is about \$3.50 to \$4.50 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. We have not included any such reductions to administrative cost in the range above because we believe it would 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, admin 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 \$15 to \$25 PMPM was used, and a point estimate of \$20 PMPM for a medium-cost scenario. For retention, administrative cost plus profit, a range of \$3.50 to \$4.50 PMPM was assumed, with a point estimate of \$4. The expected total cost, including all retention, for these 11 mandates in 2010 on a paid basis is \$24 PMPM. ( $\$24 = \$20 + \$4$ ). For future calculations later in this report, 6.7% of premium is used as the incremental cost of insurance due to the eleven mandates ( $6.7\% = \$24 / \$360$ ).

It is likely that most of this cost would be part of insurance plans, 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 insureds. This \$24 represents the full cost of the mandates as written, using the

medical cost data provided by the carriers. This is not the net new cost only, however. Much of the cost of cancer care, for example, was already covered by the CT carriers. Embedded in the \$24 PMPM total amount is a large portion of the cost of cancer treatment, which in total is typically about 5% of the overall cost of medical care on a nationwide basis—somewhat higher for Medicare, and somewhat lower for commercial plans, which cover a smaller portion of elderly people. \$24 PMPM includes the medical cost to the insurers as well as the cost of administration and profit. It does not include any of the cost-sharing paid by the member for these services. Included in the administrative cost is a state premium tax of 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 effect of some mandates on medical practice and patient health. In some cases, the mandate effectively pushes the health care system to a new level. Some mandates, such as PSA testing, may force the adaptation of new technology that becomes the de facto “best practice,” or standard of practice. Over time, however, it may be revealed that the mandated benefit leads to some unintended adverse or otherwise suboptimal consequences. In the following section we focus on a basic explanation.

1. **DIABETES SELF MANAGEMENT TRAINING:** This mandate gives people with diabetes certain instructional training that will help them keep their blood sugar within an acceptable range and control their diabetes. It is highly useful because untreated diabetes leads to expensive complications. Those who can manage their condition to achieve better health have lower overall healthcare costs and can live a more active lifestyle, remain in the workforce, and enjoy higher quality of life. Initial individual and group training of up to ten hours is intended to help the patient learn how to use diabetic equipment and supplies including self-injection of insulin for those with Type 1. Subsequent training of up to four hours is available if the patient has a change in condition or if the technology changes and thereby requires patient re-training. This is similar to a benefit offered under traditional Medicare Part B.
2. **PSA TEST:** This mandate requires insurers to pay for prostate cancer screening including PSA tests for males of 50 or older and men who are symptomatic or have a family history of prostate cancer. The frequency is unspecified. Recent reports question the value of PSA testing and a major US study concluded that screening over a 7 to 10 year period did not reduce the rate of death in men 55 and older. A European study was slightly more positive, but it stated that 48 men would need to undergo medical treatment to save one life. Positive PSA tests sometimes lead to radical prostatectomy which comes with high risk of adverse side-effects such as sexual dysfunction and incontinence. Some early proponents of PSA testing, including the inventor of the test, have recently come out against routine testing. Prostate cancer screening is also covered by Medicare.

3. **OSTOMY SUPPLIES:** This mandate requires insurers to pay for up to \$1,000 annually for ostomy supplies and appliances for ostomates with an ileostomy, colostomy, or urostomy. These three ostomies are used by patients in conjunction with the elimination of bodily waste. For these three different types of ostomates, their need for supplies and their consumption rates differ. Ostomy supplies and appliances consist primarily of either a one-piece pouch with attached wafer or two-piece pouch and separate wafer. Technically, the wafer itself is an “appliance.” For simplicity, we will use only the term supplies here. There are also numerous ancillary supplies used in conjunction with these three ostomies, such as belts to hold the device in place. There are about four dozen different HCPCS codes that apply to ostomy supplies. Ileostomates and urostomates consume supplies at a faster rate than colostomates. There may be individuals with both a urostomy and either a colostomy or ileostomy. Urostomies are not temporary. Ileostomies are rarely temporary. As many as 40% of colostomies, however, are temporary for about two to five months, often following a colon resection. There are various reasons why some ostomates may consume supplies at a faster rate than others. The presence of a fistula at the stoma may exacerbate need. In our research, we spoke with an ostomy nurse who cited the alkalinity and hardness of effluent or stool as factors that affect individual consumption rates. Hygiene dictates changing ostomy supplies at an appropriate frequency. Those who cannot afford an adequate number of supplies tend to withdraw from social contact, live a less active lifestyle, leave the workforce, or never re-enter it. Under this mandate, ostomy supplies cannot be considered durable medical equipment. When this mandate was passed in October 2000, the \$1,000 limit was not indexed or otherwise adjusted to the rising future cost of living. Consequently, in 2010, the \$1,000 buys fewer supplies than it did when the mandate was initiated.
4. **HEARING AIDS TO CHILDREN TWELVE AND UNDER:** This mandate requires insurers to pay for hearing aids for children up to \$1,000 every two years. Hearing devices usually cost more than \$1,000 each; in fact, they often cost more than \$1,500 per ear. At the low end, an analog hearing aid may cost \$500. At the high end, a digital may cost as much as \$5,000. Children may outgrow them as their craniums grow. Thus they need to be replaced periodically. Most of this cranial growth occurs prior to the onset of puberty. Hearing loss in children is generally detected prior to the age of 13. There will be fewer new cases of hearing loss reported between 13 through 18 compared with 0 through 12. A much higher rate of hearing loss is reported in the elderly population. However, for a child, the reduction or loss of hearing can interfere with learning and social development. Under this mandate hearing aids may be considered durable medical equipment (DME). Thus, if there is a \$1,000 annual limit on DME, the \$1,000 maximum cost of the hearing aids may be included in it. This is distinctly different than the manner in which ostomy supplies are handled, since they cannot be considered durable medical equipment. When this mandate was passed in October 2001, hearing aids cost less and the cost of living was lower. The more expensive digital hearing aids were not yet as widely available as they are today. Many insured policies cover more than \$1,000 every two years. Hearing aids are not covered by Medicare—they are considered a supplemental benefit and not part of the “basic” Medicare benefit.

5. **ORTHODONTIC TREATMENT FOR CLEFT PALATE:** This mandate requires healthy insurers to pay for the cost of orthodontic treatment for those with cleft palate. For the general population, the cost of orthodontic treatment is not covered by a medical plan. It is covered by a dental plan with a supplemental rider that specifically covers orthodontics; often, there is a great deal of member cost-sharing associated with orthodontic services under a dental plan, as well as a per person spending maximum. The cost of orthodontic treatment for those with cleft palate may range from roughly \$1,500 to \$8,000 depending on the amount of work required, and it may take place over a time frame of roughly one to three or four years. Some families have dental plans that cover orthodontia; it is possible that their plans already pay for children with cleft palate.
6. **HOSPITAL DENTAL:** Some people must have dental work performed in a hospital facility environment under general anesthesia. This may include those who are developmentally disabled. Hospital inpatient and outpatient facilities are much better equipped, in terms of resuscitation equipment, to handle the administration of general anesthesia. This mandate covers the facility cost and costs of general anesthesia and nursing. Medicare and Medicaid also cover this benefit for special populations.
7. **DIABETES EQUIPMENT AND SUPPLIES:** This mandate requires that diabetes be covered like any other medical benefit. It was originally passed in October 1997. It covers prescribed equipment, drugs, and supplies for diabetes, and it does not specify minimums or maximums. This is a good example of a mandate that, in 2010, covers what health insurers would likely cover without the mandate. It is difficult to assign a net new cost to his mandate. Particularly because effective management of diabetes is one of the most effective forms of chronic disease management in 2010. For the sake of comparison, Medicare covers this benefit with the usual cost-sharing of a \$155 deductible in 2010 and 20% coinsurance without an out of pocket maximum.
8. **BIRTH TO THREE PROGRAM:** This mandated benefit was passed in July 1996. It provides diagnosis and up to \$3,200 of annual treatment under a family service plan for children that show signs of developmental deficiency prior to age three. It can be thought of as an educational benefit as well as a medical one. Most of the cost of this program for autistic and developmentally disabled youth is borne by the state. In addition to their insurance coverage, the families of children in this program also pay fees on a sliding scale. The annual maximum has increased to \$6,400 in 2010.
9. **LYME DISEASE:** Lyme disease originated in CT, where it has a higher incidence rate than any other state. It is caused by the bite of a deer tick, which transmits spirochetal bacteria of the genus *Borrelia*. It is characterized by three stages, and the disease becomes more difficult to cure as time since transmission increases. The remedy is antibiotics administered either intravenously or orally or both. The mandate covers 30 days of IV and 60 of oral antibiotics. More antibiotic treatment requires the prescription of certain board-certified specialists. Some practitioners believe that antibiotic use is required until no further symptoms remain. The CDC recommends that patients receive no more than 2 four-week courses of antibiotics.

Most practitioners believe that antibiotic use should be limited. In examining claims, we noticed that many patients are tested for other things at the same time they have a blood test for Lyme disease. That is, at the time the Lyme disease diagnosis is recorded on the claim, it might not be definitive.

10. **COLORECTAL CANCER SCREENING:** This mandate requires insurers to cover fecal occult blood testing annually, and sigmoidoscopy, colonoscopy, and radiographic imaging periodically per standards established by the American College of Gastroenterology in consultation with the American Cancer Society. The primary cost is associated with the colonoscopy procedure, which is generally performed in an outpatient facility rather than in a physician's office. Medicare also covers this benefit, and it does not cover virtual colonoscopy.
11. **CANCER, TUMORS, LEUKEMIA, ETC:** This mandate covers cancer and reconstructive surgery. It combines what could be several separate mandates into one. It covers surgical removal of tumors and treatment for leukemia, including outpatient chemotherapy, reconstructive surgery, and non-dental prostheses to replace surgically removed anatomic structures. It also covers \$350 for a wig for hair loss following chemotherapy. The yearly benefit for tumor removal is \$500; it is \$500 for reconstructive surgery, and \$500 for outpatient chemotherapy. The mandate also provides \$300 for prostheses and at least \$300 for each breast removed. These dollar limits are low, and there was no evidence in the data to conclude or suggest that insurers limit their coverage to these minimum amounts.

Over the past twenty years, the advances in chemotherapy have led to more effective and more expensive drugs and biologicals. The cost of chemotherapy drugs has risen substantially. Insurers may cover hundreds of thousands of dollars in claims for the chemotherapeutic treatment of some cancer patients. This higher cost has led to a higher survival rate. Similarly, but to a lesser extent, advances in reconstructive surgery also contribute to the increased claims that insurers and HMOs pay on behalf of their members.

### **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 metric to represent mandate cost. In this report, the intent is to measure the effect the mandate on health insurance premiums. 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 PMPM cost represents the average cost of one insured person for one month based on the demographic mix in the covered population.

The primary data used for this project was supplied by the 6 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 asked 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.

The carriers were asked to provide the allowed and paid PMPMs for each mandate by year by group vs. individual. This allowed IC 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, we were sometimes able to make use of IC data and outside literature. This provided a better understanding of the financial burden of cost-sharing for some of the mandates, in addition to knowing the average PMPM cost-sharing. 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. A doctor may test for Lyme disease but not be 100% certain that her patient has that condition. Lyme may be one of several possible diagnoses that show up on the claim form as the doctor tests for it and other things.

Other ambiguities made it difficult to determine the cost of some mandates, such as hospital dental in which general anesthesia is administered in an inpatient or outpatient hospital setting in order for dental work to be performed on people from special populations under certain conditions. This is a very low frequency service, and it is not easy to distinguish these claims from other inpatient or outpatient claims.

In evaluating these 11 mandates, it was sometimes possible to see evidence of the evolution of medicine over the past 15 years. For example, the view of cancer fifteen years ago was to diagnose all types of cancer as early as possible and treat it as soon as possible. This was thought to produce optimal patient outcomes at the lowest cost for all types of cancer. Some would argue with that logic as it applies to prostate cancer screening today. Other types of cancer screening may be moving to a more personalized approach in determining initial age and frequency of screening and surveillance whereby personal risk factors such as race, gender, smoker status, and family history may be taken into account in addition to age.

In this report, the terms "gross cost" and "net new cost" are 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 often a difficult task because it is unclear what insurers would cover in the absence of the mandate. In the case of hearing aids, for example, some fully insured and self-funded plans may actually cover more than the minimum \$1,000 required by the mandate. If we look at the cost of this mandate, we include all hearing aid costs for children through 12 years of age. For diabetes supplies and equipment, there is a gross cost for all the diabetes equipment and supplies, but the vast majority of this would still be covered in the absence of a mandate. At this point in time, insurers and doctors alike understand the importance of effective diabetes care. At the time the mandate came into effect in 1997, it is possible that some insurers subjected

diabetes costs to the maximum amount for durable medical equipment or perhaps other limits on annual cost. Immediately after the mandate was passed, you could think of the net new cost as the cost of treatment that exceeded the prior level of coverage. Now that the diabetes equipment mandate has been in existence for 13 years, it is difficult to assign any net new cost for it. It is possible to quantify what carriers spend on diabetes equipment and supplies, but it is unknown if insurance carriers would spend less in the absence of that particular mandate.

Some of the mandates that were examined are extremely low cost. These tend to be benefit mandates that protect small vulnerable subgroups. The cost per treatment is not necessarily low, but these claims may occur so infrequently that, when the cost is spread to all members, it has virtually no effect on overall premium rate levels for the insured pool. An example of this is coverage for ostomy supplies since so few people in the population actually have an ostomy. Other mandates may affect a much larger percentage of individuals in the pool. Prostate and colon cancer screening are good examples. Prostate cancer screening primarily affects men over 50; colon cancer screening mostly affects men and women over forty. Although the colonoscopy may be performed only once every five years, it is a much more costly procedure than a PSA lab test. Since it is performed on an outpatient basis in a hospital or ambulatory surgical center, it comes with the cost of facility usage as well as the gastroenterologist's bill for services.

In the section that follows, each mandate is again considered and the comments made in the executive summary are expanded upon.

**1. Diabetes Self- Management Training:** About 3.9% of the members in the CT IC data were listed with an ICD-9 diagnosis code for diabetes. This is consistent with an insured population, which is predominantly less than 65 years of age. It was found that 1.34% of the people with diabetes availed themselves of training in each of 2007 and 2008. The cost of training proved to be about 5 or 6 times greater in the fully insured than in the self-funded population, perhaps on account of the presence of the mandate itself in the fully insured population and the absence of it in the self-funded arena. The training can consist of instruction in the specific use of equipment and supplies, or it may involve more general self-help such as nutritional instruction. When diabetes is well-managed, the patient avoids the premature cascade of ill health that can result from the progressive worsening of the condition and its deleterious effect on various body parts and systems. Self management training is a form of preventive health. It does not lead to unnecessary diabetes care, but rather, it does postpone and eliminate some. Assuming that the patient complies, the savings that result from diabetes self-management exceeds the cost. This mandate can be thought of as a form of disease management for the most costly but treatable chronic medical condition. The prevalence rate of diabetes in fully insured populations and the value of self-management are sufficient to outweigh the cost of the benefit.

**2. Prostate Cancer Screening, PSA Test:** Recent evidence has emerged that diminishes the public health value of PSA testing. The test identifies many cancers that result in interventions without which a person would otherwise live a normal life without consequences. Surgery comes with high risk of incontinence and sexual dysfunction. In the IC data for CT, it was found that about 12% of males of all ages were PSA tested in 2007 and 13% in 2008. In examining the data by age group, it was found that men 50 and older had a test rate of 42% per year. Although the self funded and fully insured populations had

the same average age, the test rate was roughly two percent higher in the self-funded population than the fully insured.

When one tests positive for PSA level, it is followed by a biopsy of the prostate gland and analysis of pathology to determine whether and what type of cancer is present. This can be thought of as adding to the cost of the mandate, but it is not a screening cost. Some men, when learning that they have prostate cancer, will choose the more radical surgical approach, prostatectomy, rather than watchful waiting or active surveillance. This too adds to the cost of the mandate. It may be a matter of life or death for some. For others, it is not.

A US study indicated that PSA tests do not save lives. A European study shows that 1,410 men would need to be screened and 48 additional cases of prostate cancer would need to be treated to prevent one death. They concluded that PSA screening reduces the death rate from prostate cancer by 20%, but it is associated with a high risk of overdiagnosis. Of all the types of cancer, prostate is the only one that comes with some potential disadvantage to early detection using available screening tests. This occurs because most prostate cancer is indolent and slow growing. A smaller number of men with prostate cancer have an aggressive form of the disease that could prove life-threatening, but men who learn that they have prostate cancer generally fear that they may have the rarer but more serious form.

The cost per PSA test is about \$20 to \$30 when performed in an outside lab for a doctor. It is generally just one of many annual lab tests done as part of an annual patient physical exam.

**3. Ostomy Supplies:** The prevalence and incidence rates of ostomy in the fully insured population are very low—ostomy occurs very infrequently, and only a miniscule fraction of the insured population has an ostomy. Our data indicate that about 0.08% of the fully insured population has one of these three ostomies; this is eight in every ten thousand people. Our data show that about 0.03% undergo an initial ostomy surgery annually. Additionally, one of three of them, about 0.01%, underwent an ostomy reversal and will no longer need ostomy supplies.

The overall spending on ostomy supplies under the current mandate is about \$0.04 PMPM.

If we limit the distribution to those who have \$100 or more of spending per year on ostomy supplies, we find that many of them will spend more than \$1,000 per year. In the self-funded population, some members have annual spending of about \$3,000 per year. For this reason, we believe that the \$1,000 limit on annual spending creates a financial hardship for the small number of individuals with high utilization of ostomy supplies.

In the phase one study, it was concluded that increasing the annual spending limit on ostomy supplies for ostomates would have a *de minimis* effect on overall medical cost. This is because this mandate affects such a small portion of the population and because the incremental cost of the additional supplies is relatively small. Most ostomates currently spend less than \$1,000 annually on supplies and appliances. There is a minority that spends more than \$1,000, some spend much more. For them, the limit of \$1,000 causes substantial economic burden.

To the medical layperson, the cost of the pouches and wafers seems high relative to the cost of band-aids and similar mass-produced medical goods. Since the sales volume is much lower for ostomy supplies than band-aids, the unit cost of ostomy supplies remains high. Medicare has been able to keep the reimbursement for these supplies low, but it is unknown how much more commercial insurers pay for the same supplies. If the cost is substantially greater than what Medicare pays, then this is evidence of cost-shifting from the public to the private sector. Cost-shifting occurs when providers and medical equipment or drug suppliers charge more to private payers than public ones.

Although the one thousand dollar limit may have been more appropriate when the mandate was first passed in October, 2000, the effect of inflation during the intervening years has eroded the spending power of \$1,000. In order to preserve the original benefit level with a cost of living adjustment, the limit today would need to be about \$1,250. This would still be a burden to some individuals who use more supplies than the annual limit affords them.

One of the requirements of the ostomy mandate is that ostomy supplies cannot be considered part of DME. This means that an ostomy patient who needs both ostomy supplies and other types of durable medical equipment, such as oxygen or a wheelchair, will not have to include the cost of ostomy supplies and DME in one limited benefit. By separating DME and ostomy supplies, the member has a richer (better) benefit. This benefit-specific cost cap may have also created some additional set-up costs for insurers at the time the mandate was implemented.

**4. Hearing Aids to Children 12 and Under:** In addition to observing carrier data and the IC data, another cost estimate was developed for hearing aids based on the prevalence rate of childhood hearing loss in the CT population. Assuming an average \$2,250 cost per hearing aid, we project that the maximum biennial \$1,000 benefit will be paid by all but the highest deductible plans we tested. Assuming that 15% of employees leave their jobs and terminate coverage each year, the average annual benefit would be \$575 (equals  $\$1,000 * 15\%$  plus  $\$500$  times 85%). Note that a significant percentage of children who need aids required them in both ears (binaural). Because the mandated benefit does not cover the entire cost of the aids, we assumed that 30% of children who need aids would not utilize the benefit.

To project the prevalence of hearing loss that may require aids, data was reviewed from both the Ingenix Consulting (IC) database of claims from a commercially insured population and information from public sources. 2008 IC database claims were examined from fully insured groups in seven states (including Connecticut) that have mandated these benefits for children since at least 2007. The utilization rates and PMPMs are low, indicating perhaps low awareness of the benefit or the fact that the benefit covers only part of the overall hearing aid cost. Note that only Connecticut data is shown for ages 0-12.

The public source data show a relatively wide variance of child hearing loss prevalence, in general ranging from 0.7% to 3.5%. Eliminating the high and low values and adjusting for the differences between children of employees likely to be covered by group plans versus all children, we estimate the overall prevalence to be approximately 1.75%.

Thus the PMPM cost is estimated to be \$.05 ( = \$575 \* 70% \* 1.75% \* 8.8% of all commercially-insured members are children 0 -12 divided by 12 months). This is considerably more than the \$0.01 PMPM actual that was indicated by the carrier data.

Because this mandate has a benefit of only \$1,000 every two years, the cost burden to the member may be high. If a child needs two aids every two years at a cost of \$2,000 per aid, 75% of the cost is thus borne by the member's family and 25% (\$1,000) is borne by insurance.

One of the requirements of the hearing aid mandate is that hearing aids must be considered durable medical equipment (DME). This means that if the DME benefit is limited to \$1,500 per year, the purchase of the hearing aid during the year reduces the amount left to pay for other DME. By including hearing aids in DME, the benefit is made less rich than if hearing aids were considered a separate benefit from DME.

**5. Orthodontic Treatment for Cleft Palate:** Very few children are born with cleft palate—about 6 per 10,000 in the US annually, 0.06%, according to the CDC. A lower prevalence rate was found in the IC data for people in CT with that diagnosis—about .010% in 2007 and .016% in 2008. No orthodontic treatment cases were found for those members in the IC data for CT, however, in the national IC data, 5 members were found with orthodontic treatment at an average cost of \$1,664 per year. Spreading the cost to all members, the cost of the mandate is de minimis—less than \$0.01 PMPM. Even if the number of children born with a cleft palate each year underwent orthodontic treatment for a cost of \$1,664, the incremental cost would be about \$0.02 PMPM based on the IC rate of 0.016%. This mandate adds very little to the cost of medical care, but it is unusual in that it requires medical insurers to pay a dental cost.

Orthodontic services, when paid by private commercial insurance, are generally paid under a dental plan that is separate from medical coverage. Orthodontic services are generally not part of a base dental plan but are an optional extra added for additional premium cost. Not every group or individual with medical coverage has dental coverage, and not every group or individual with dental has orthodontic coverage. Dental benefits are often thought of as supplemental to the more basic health care needs provided by medical coverage. For the individual with cleft palate, orthodontia may be a more essential service and have a more significant effect on ability to chew food and quality of life—a medical need rather than a want. This mandate effectively makes orthodontic treatment a basic benefit for children with cleft palate rather than a supplementary one.

**6. Hospital Dental:** This is an infrequently performed service. It is not a treatment mode for the general population, but is reserved for people with special needs such as those with profound developmental disability or behavioral problems that prevent them from having dentistry conducted in any setting other than in the hospital under general anesthesia. It is not an alternative form of dental treatment for all. Doctors and dentists would disapprove this service for the vast majority of people. This mandate does not cover the cost of the dental treatment, but it covers the cost of the use of the inpatient or outpatient hospital facility, nursing costs, and the costs of anesthesia. Although general anesthesia comes with risks of its own, it is safer when performed in a hospital than an office setting because of the presence of resuscitation equipment. Medicare also pays for this service for special populations.

**7. Diabetes Equipment and Supplies:** About 3.9% of the members in the IC data for CT were listed with an ICD-9 diagnosis code for diabetes, either Type 1 or Type 2. The actual percentage is probably greater because some diabetics are not coded as diabetic on every one of their medical claims. The 3.9% figure is reasonably consistent with an insured population, which is predominantly less than 65 years of age. (The prevalence of diabetes is higher in an over-65 population.) Diabetic supplies consist of insulin and syringes for those who are insulin dependent, and glucose monitoring supplies, equipment, and devices. A small percentage of insulin-dependent Type I diabetics wear a glucose pump that functions somewhat like an artificial external pancreas. It periodically checks glucose levels and administers insulin to maintain it within a specific range. These cost around \$4,000 - \$5,000, and there is an ongoing monthly cost of several hundred dollars. This mandate encompasses a large number of different medical codes. On an all else equal basis, we can demonstrate that the average diabetic member costs more than the average non-diabetic member. It is not only the testing, diabetic equipment & supplies that explain the cost difference, but also the higher general medical cost for the comorbidities of diabetes.

As this mandate is written, it is broad in scope and requires insurers to cover essentially all diabetes costs for all patients with all types of diabetes. The mandate does not allow insurers to cover diabetes less adequately than other diseases. It is likely that cost savings result from this mandate, since effective diabetes care slows the progression of the disease, but no attempt was made to estimate them in this report.

**8. Birth to Three Program:** This is as much an early intervention educational program as a medical one. It is intended to detect, diagnose, and treat children with developmental disabilities up to age three, at a cost of up to \$3,200 per child per year. It provides developmental evaluations and early intervention services for infants and toddlers (from 0-36 months of age) who have significant developmental disabilities or a diagnosed medical condition such as Down syndrome, spina bifida, autism, blindness, deafness, or others that have a high probability of resulting in a developmental delay.

Specific areas of development that are evaluated include:

- cognitive development
- physical development, including vision, hearing, motor and health
- communication development
- social or emotional development
- adaptive skills development (known as self-help or daily living skills)

Early intervention services may include:

1. Assistive technology devices and services
2. Audiological services
3. Speech and language services
4. Family training, counseling, and home visits
5. Health services necessary to benefit from other early intervention services
6. Medical services for Birth to Three diagnostic or evaluation purposes only
7. Nutrition services

8. Occupational therapy
9. Physical therapy
10. Psychological services
11. Service coordination
12. Special instruction
13. Social work services
14. Transportation or mileage reimbursement when necessary to receive other early intervention services
15. Vision and mobility services

Services are usually delivered in settings that are natural for the child, including the family home, child care settings, and other places where children usually spend time. These services are described as habilitative (rather than rehabilitative) because normal function and skills have not yet been acquired.

During 2007 and 2008, up to \$3,200 annually could be paid by the insurer. The state pays much of the cost associated with services under the birth-to-three program, which may vary with the developmental needs of the child. Participating families pay into the program monthly according to a sliding scale that is based on income.

**9. Lyme Disease:** There is not unanimous agreement on the best practices for treatment of Lyme disease. Ideally, anyone bitten by the deer tick which transmits the disease will be immediately treated with a short course of doxycyclin. Some people might not immediately realize they have been bitten, and their treatment may begin later and take longer. The symptoms of Lyme disease can resemble rheumatoid arthritis. When doctors initially test for Lyme disease, they are uncertain of the diagnosis.

There are two camps of thought when it comes to treatment and some disagreement between them. One group believes that a regimen of antibiotic treatment should occur until the symptoms disappear and this may take as long as 18 months. Another group believes that if it has not resolved within six months, further antibiotic treatment is of no use and may be injurious to the patient's health—at this point an alternate explanation should be sought for the patient's symptoms. The mandate provides that everyone must be covered for Lyme disease and that after 30 days of IV and or 60 days oral antibiotics, the patient needs a referral from a board-certified specialist to undergo further antibiotic treatment. Thus, it accommodates both camps while providing an oversight mechanism for those patients who will be treated for an extended period of time. At this point in time, no one has died of Lyme disease; however, death is a rare but potential danger from overuse of antibiotic treatment.

**10. Colorectal Cancer Screening:** The American Cancer Society recommends colon cancer screening begin at age 50 for people without a family history of colorectal cancer or a history of intestinal polyps and consist of one of the following modalities:

- Flexible sigmoidoscopy every 5 years
- Colonoscopy every 10 years
- Double contrast barium enema every 5 years
- CT colonography every 5 years
- Fecal occult blood testing annually.

The colonoscopy has become a more frequently performed procedure over the past several years. By mandating coverage for it in 2001, the state effectively established a level of care that assured fully insured residents that the best modalities of screening would be available. This is not an inexpensive procedure, however, and it has added to the overall cost of care.

An annual fecal blood test costs only about \$5 to \$15, and not all patients chose to follow through with the test. The advantage of the colonoscopy over the sigmoidoscopy is that it can view the entire colon. A new mode of colon cancer detection came about after the mandate was introduced. It is virtual colonoscopy and involves evacuatory intestinal preparation, but the scoping is done from outside the body by CT scan. If a polyp or cancer is detected, however, a colonoscopy must be performed nonetheless. For this reason, Medicare does not cover the virtual colonoscopy.

This mandate also covers radiologic imaging, which consists of barium enemas. For an insured individual, the cost of a colonoscopy in an outpatient facility ranges from about \$1,000 to \$1,800. This includes the cost of the facility in which it is performed.

The colonoscopy is perceived as the gold standard for CRC screening. It has been popularized by television and the media over the past several years and thus the utilization rate has increased.

**11. Cancers, Tumor, Leukemia, etc.:** Unlike the other ten mandates, this mandate includes multiple aspects. It is a combination of cancer-related mandates. In addition to covering the removal of tumors and reconstructive surgery, it requires insurers to pay up to \$350 for a wig for those who lose their hair in chemotherapy. It also requires insurers to pay for an implantable prosthesis as part of reconstructive surgery after an individual has a portion of their body removed. It covers reconstructive surgery and prostheses following mastectomies. This mandate also covered the removal of silicon and saline breast implants obtained prior to 1994. No additional implant reversals are expected to be performed at this time.

Variability was observed in the carrier data with respect to the codes gathered and the cost of this mandate. If one interprets the mandate as pertaining to all cancer-related claims, the cost could be greater than those represented in the carrier data. IC data was extracted for all claims for members with cancer. This was done by extracting all claims with a primary cancer diagnosis in the ICD range of 140 to 239. For medical claims only (excluding RX) the total paid amount was about \$29.89 PMPM. This is about 10% of all medical claims and twice as high as the national statistic of 5%. (Cancer claims constitute about 5% of annual medical claims.) In examining these claims, we observed many claims that were not cancer-related. We think \$29.89 is an overstated amount that includes some claims of cancer patients that are not cancer-related, including routine care for patients in treatment and those in remission. None of the carriers however initially interpreted the data to include such a broad set of all neoplasm-related claims. Each carrier presented some subset of the superset of all cancer-related claims.

By applying a similar logic to the IC superset of all cancer-related claims, the IC cost was reduced by 76% from \$29.89 PMPM to \$7.13 PMPM.

IC also conducted a study whereby the superset of all claims for all cancer patients was matched against the codes submitted by carrier B for the cancer mandate. In this case, the \$29.89 PMPM superset was reduced by 36% to \$19.24 PMPM for the 2008 data.

Although the various carriers interpreted the results somewhat differently, the resulting weighted average of about \$10 PMPM represents about 3.3% of overall medical claims, which is less than the full 5% national average for all claims.

This is the only one of the eleven mandates that applies to individual limited benefit plans. These limited benefit plans may have an annual limit to how much they will pay in member claims or other plan features that render them less rich than other HMO and health insurance plans.

## PERCENTAGE CALCULATIONS

### Denominator Used in Medical Cost Percentage Calculations:

From the CT DOI, we were able to obtain these arithmetic (not weighted) averages for filed 2010 insured HMO premiums (includes administrative cost and profit) for medical and RX combined:

Individual	\$245.22
SG	\$316.06
LG	\$349.92

Note: This does not include any PPO or other non-HMO health insurance policies. To compute the premium, these assumed average retention factors (administrative cost plus profit) were used:

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, we decided 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**. 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. Individual insurance is not inexpensive, however, and the policy-holder must bear the entire 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.

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. 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, we used \$300 PMPM as the assumed average medical cost for the CT insured population in 2010, since we do not have the exact number. We were provided with medical costs for 2007 and 2008 by each carrier. We developed a weighted average paid medical cost 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

We were also provided with the same 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.

Bearing in mind the relativities of the filed insurance premiums, we assume this medical cost breaks down roughly as follows:

	PREMIUM	MEDICAL COST
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.

In comparing the mandate cost between group and individual plans, we noticed that there is lower cost for diabetes and CRC screening in the individual data than the group. The cost of cancer, as a PMPM, is not much different for individual than group. This may indicate a less healthy population in the individual plans than in group policies.

As a percent of total, the 2008 paid cost for all 11 mandates is \$14.73 for individual plans. Most of this amount is for the cancer mandate. The data was skewed by one carrier who was unable to obtain cancer data initially and was subsequently able to gather it using a diagnosis based approach only. Adjusted for this skewing reduced the average cost of cancer in individual plans by about \$4.00 PMPM and gave us a total weighted average of \$11.75 on a 2010 basis.

\$210 PMPM was used as the average medical cost of individual plans in CT. For individual plans, these 11 mandates cost 5.6% of the total medical cost. (  $5.6\% = \$11.75 / \$210$  ). This is lower than the 6.6% for group plans, and the difference may reflect the role that initial individual underwriting and pre-existing exclusions play in individual insurance. Group insurance cannot apply individual underwriting or pre-existing exclusions.

One last point to note regarding individual coverage is that conversion policies fall into this category. These policies can experience significant adverse selection as the small pool acquires an increasing percentage of higher risk individuals with known health conditions. It was observed that for some individual carriers, for some years, their cost of cancer or diabetes was considerably greater than average.

## **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. A small group employer is defined as having 50 or less employees. Ultimately, the person insured through a small employer group will likely pay more for their care. Small groups tend to purchase lower cost, leaner plans than large groups. A “leaner” plan has more member cost sharing than a “rich” plan, for example, higher copays, coinsurance, or deductibles. Employees of small business also tend to pay a larger share of the health insurance premium. In this respect, the cost burden of the mandates will be somewhat greater for small group than large.

Like individual coverage, there is typically more adverse selection of benefits among small groups than large groups. 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.

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 explained further in the next section.

## **II.6 EFFECT OF MANDATES ON THE AVAILABILITY AND COST OF HEALTH INSURANCE:**

In this section of our report, the increase in total insurance premium cost caused by the eleven mandates will be considered. This affects the insurance consumer's decision whether or not to purchase or renew health insurance coverage, especially those in individual plans since they pay 100% of the premium cost themselves. In the case of group coverage, most of the premium cost is borne by the employer, so it is the employer that decides whether or not to purchase or renew. 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, we mentioned the difference in lapse rate between small and large groups that results from the same-sized annual premium increase. 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. 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 it is introduced because that is the time the price increase would be noticed.

This is a consideration that should be noted. As employer groups reduce the level of coverage by shifting more cost to the insureds year after year, two things happen. One is that members pay a larger portion of the total plan cost, and the other is that members may forego some medically important services to avoid the 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 for free. This report does not cover the effect of the PPACA on the CT health insurance system.

On an ongoing basis, the group or individual insurance consumer tends not to notice the cost of mandates buried in the plan. Although actuaries have estimated lapse rates as a function of premium increases, there is not a great deal of hard data to work with. As a result, many of the expected lapse rate estimates tend to be “soft.” In this study, for the eleven 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 the administrative fee that the insurer charges them to administer their self-funded business. Self funded groups also do not pay state premium tax. It is likely that the administrative economies of scale play a much more important role in the size of the self-funded sector than the existence of mandates.

These 11 mandates add approximately 6.7% to the cost of group health insurance plans on a gross basis. Some groups (or individuals who are offered group coverage by their employer) 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 the cancer or diabetes 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.

## **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. This is true for ostomates, for example, who will be able to

afford to maintain their personal hygiene, thereby reducing their level of social and workforce withdrawal.

It is similarly true for children through 12 year olds who have hearing loss and cannot afford assisted hearing that will enable them to obtain a better education, social development, and quality of life.

Some mandates, such as ostomy and hearing aids, serve a very small and vulnerable minority; others, such as the cancer screening mandates, affect a larger portion of the population in an effort to promote early detection for the few who will develop cancer.

Some mandates are introduced to push the practice of medicine to a new level of effectiveness. This is the case with mandates for cancer screening—PSA testing, colonoscopy, and the like. Some states have introduced mandates with this effect in mind only to discover that the treatment mandate is not a best practice. Bone marrow transplants for breast cancer, which were previously mandated by some states, are an example of such a well-intended but medically outmoded treatment. The history of medicine is a path with abandoned medical practices lining both sides. Currently in the US, medical experts are re-evaluating the recommended circumstances under which screening for various types of cancer is performed. Mammography, PSA testing, and even colonoscopies have come under increased scrutiny as public health experts consider the proper manner and recommended schedule by which these screenings are administered. Most medical tests have a risk of a false positive, which may cause psychological harm, but is not as potentially harmful as a false negative.

Some mandates have a medical management component. The Lyme disease mandate requires detection and treatment, but it also manages the treatment by requiring the recommendation of a board-certified specialist who serves as gatekeeper for antibiotic administration that goes past thirty days of intravenous and 60 days of oral antibiotics. Long-term antibiotic use can have adverse side effects, and implicit in the design of this mandate is a control on those physicians who might indiscriminately prescribe extended use of antibiotics. In this respect, this mandate uses insurance law to institute a standard of care for a recently emerged medical condition native to the state.

Diabetes self-management training is another example of a mandate, which, at the time of introduction, helped push the practice of medicine to a new level by implementing what is effectively a disease management approach. One could think of this mandate as one of the early disease management tools used to control diabetes. Of the five major chronic diseases, management of diabetes has proven to be most cost-effective. Medicare pays for such training. The fact that there is a lower rate of diabetic self-management training occurring in the self-funded population supports the conclusion that the mandate serves to improve the way care is delivered in the fully insured sector.

The application of many of the mandates to CT insurance law served to protect the public health of CT by assuring that certain services be covered. Twenty years ago, most health insurance excluded cosmetic surgery. Under that logic, reconstructive surgery following the removal of tumors was deemed an excluded service. The advances in reconstructive surgery in the past twenty years have been significant and the cancer mandate has helped to enable that process. The cancer mandate in CT did not only broaden the list of covered

services, but it also helped finance the advance in medical technology. Health insurance used to cover sickness and accidents. The concept of keeping people healthy is a relatively new development.

One of the reasons why insurers might not embrace a new and better way of providing care or an advance in medical technology is that there is little scientific evidence supporting best practices. A good example of this was the use of bone-marrow transplants for breast cancer. Patient advocacy groups lobbied for the coverage. Some states went so far as to mandate that insurers cover this expensive mode of treatment only to find out that it not an effective form of treatment as hoped and in fact shortened the survival time of some breast cancer patients..

The federal level effort to promote evidence based medicine will help states and their residents by eliminating some unnecessary care and directing practice to higher value services. This federal effort, however, will not change the current system overnight.

## **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 one observes the evolution of Medicare over the past forty plus years, we can see similar actions and reactions 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.

These eleven mandates are all “service” mandates, which by definition require the provision of a specified medical service in health insurance plans. Another type of mandate requires that the services of certain providers be covered. Yet a third category of mandates defines the individuals who are eligible for group or individual coverage.

Some mandates, such as prostate cancer screening, can lead to subsequent medical cost such as prostate biopsies and prostatectomies, which are tests or treatments following the screening. That is, the mandate may set a sequence of medical treatment into motion after the PSA test, some of which may prove unnecessary.

Studies of medical technology have shown that there is not as brisk a post-invention secondary market for medical technology and equipment as there is for manufactured technological goods, such as computers and televisions. Medical technology does not generally enjoy the same simultaneous benefit of tumbling prices and the advances of Moore’s law. While mandates may encourage the development of new medical equipment,

the market for the same medical equipment produced less expensively is reported to be less efficient than the secondary electronics market. As such, new mandates that involve medical equipment, such as insulin pumps and ostomy supplies can contribute to the increase in the overall cost of health insurance.

**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 their 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.

As a result of the mandates, it is believed that the following has occurred on the part of providers and suppliers—those who provide treatment, drugs, supplies, and equipment, and the like:

1. The number of trained medical providers associated with diabetic self-management training has been increasing according to one doctor with whom we spoke. The training covers not only the use of equipment and supplies, but also self-care such as good nutrition and exercise.
2. The prostate cancer screening mandate has increased the rate at which PSA testing is performed. More men die with prostate cancer than from it, that is, often it is not the cause of death for a man with prostate cancer. An increased rate of PSA testing has likely increased the rate at which prostate biopsies occur.
3. Ostomy supplies are utilized by an extremely small percentage of the insured population. Their demand is so low that they are relatively expensive. If the demand for them were as high as it is for band-aids, their price would decrease.
4. The provision of hearing aids to children through 12 has not altered the market or otherwise increased the demand and price for assisted hearing devices. Most childhood hearing loss is diagnosed before age 12. Plans with low cost-sharing may see a more frequent rate of replacement. Recent advances that affect hearing aid quality and cost involve the transition from analog to digital technology. The mandate may encourage more upgrades from analog to digital aids. These factors alone will not cause a significant increase in utilization since parents already desire to equip their children with the best hearing aid technology available. Since hearing aids cost from \$1,000 to \$4,000 dollars per ear, the mandate and its limit (of \$1,000 once every two years for both ears) will act as a subsidy rather than a comprehensive benefit. There is actually a much higher prevalence rate for hearing aid need in the elderly population, and this tends to drive the supply and demand curve for hearing aids more than this mandate for children has. Another effect on the demand for hearing

aids in children has to do with the increased use of the cochlear implant as a cure for deafness or hard-of-hearing as opposed to the hearing aid, which only treats the symptom.

5. The mandate to cover orthodontic work for those with cleft palate affects very few individuals. Because the incidence rate for cleft palate is so low, the mandate has had very little effect on the system for the finance and delivery of health care except to pay the cost of coverage for the affected minority.
6. The mandate for inpatient dental affects very few individuals, in part because physicians are reluctant to use general anesthesia if conscious sedation will work instead. In a study conducted in another state, it was determined that the introduction of such a mandate would increase the number of individuals that present for dental work under general anesthesia. So few seem to use this benefit currently, however, that even if the utilization increases, it will remain *de minimis*.
7. Diabetes equipment and supplies has gained increased attention as advances in public health underscore the importance of effective maintenance treatment for diabetes. Today, primary care physicians are better equipped to handle diabetic patients than previously, and much of what diabetics know about managing their condition comes from their PCP and those that provide DSMT. Many health insurers and HMOs also have come to realize the importance of diabetic care apart from the presence of the mandate. Some plans have emerged that recognize the higher value of certain services, such as diabetes treatment, and those plans reduce cost-sharing accordingly on those services. From the perspective of insurers and HMOs, one of the problems with providing chronic disease management programs like those for diabetes is that the insurer does not generally retain the member long enough to witness the lower medical cost on that member. The average member may stay in the plan two or three years. The mandate for diabetic care and DSMT levels the playing field by requiring all carriers to cover these services, which then improves the state's public health. Diabetes management programs are generally considered the most cost-effective disease management programs of all chronic diseases.
8. The Birth to Three mandate serves to help children acquire basic life skills that pertain to the activities of daily living and speech. Whether this program actually relieves the public education system of some burden is difficult to determine, but the intent is that early intervention for the developmentally disabled ultimately leads to fewer problems later on. Much of the care for this program is delivered by organizations such as Easter Seals that have the trained staff who can work with children who qualify.
9. One obvious outcome of the Lyme disease mandate is that long-term antibiotic use is not permitted without the approval of a board-certified specialist. The mandate was able to bridge the different approaches to treatment while protecting those who need treatment longer than the 30/60 day IV/oral program. The mandate has also caused the state to look more closely at how Lyme disease is diagnosed and treated. Lyme disease originated in CT, and we have the highest incidence rate of any state. The cooperation of the insurance industry in meeting this mandate helps CT achieve a

higher level of public health in combating a disease that is more prevalent here than elsewhere.

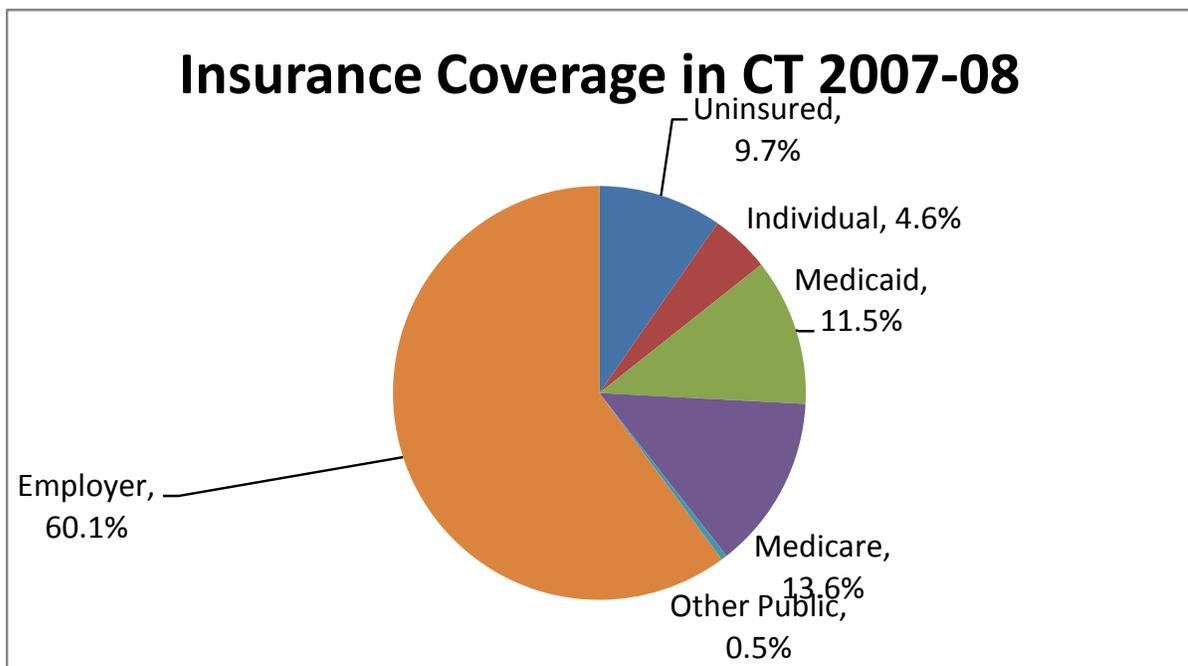
10. The Colorectal Cancer Screening mandate has helped the state achieve a higher level of compliance with recommended testing onset and frequency. It is difficult to separate out how much of this can be attributed to the mandate vs. the general increase in public awareness about the importance of this screening. While this has added a few dollars to the cost of insurance over the past fifteen years, which is significant, it has also had an offsetting positive benefit to public health. The next question is whether the realized public health benefit could be obtained more cost-effectively in the future. Going forward, the frequency and initial age for testing will be considered on a more individualized basis than the one size fits all approach we have today. By taking into account individual risk factors, CT may reduce the number of citizens who die from colon cancer each year and avoid more frequent colonoscopies than necessary for those at low risk.
  
11. Cancer: This mandate has several aspects that help assure that insured cancer patients are protected. The mandate requires coverage of reconstructive surgery which was previously deemed an excluded service. This obviously helps women who have undergone mastectomies. It also similarly helps those who have undergone tumor removal that leaves the patient with an altered appearance. The coverage of wigs for those who lose their hair in chemotherapy is another component of the bill that was an excluded benefit prior to the mandate. This benefit is more a psychological one than physical, but does affect patient well-being like the reconstructive surgery and prosthesis aspect of the bill. One note we would make is that the dollar limits in the bill pertaining to surgery are outdated at this time. Mandates that have internal limits and specified dollar amounts should be reviewed periodically to see if they continue to make sense after the passage of time. Inflation and advancements in medical technology affect these dollar limits.

### III. FINANCIAL AND ECONOMIC ASPECTS OF THE MANDATES

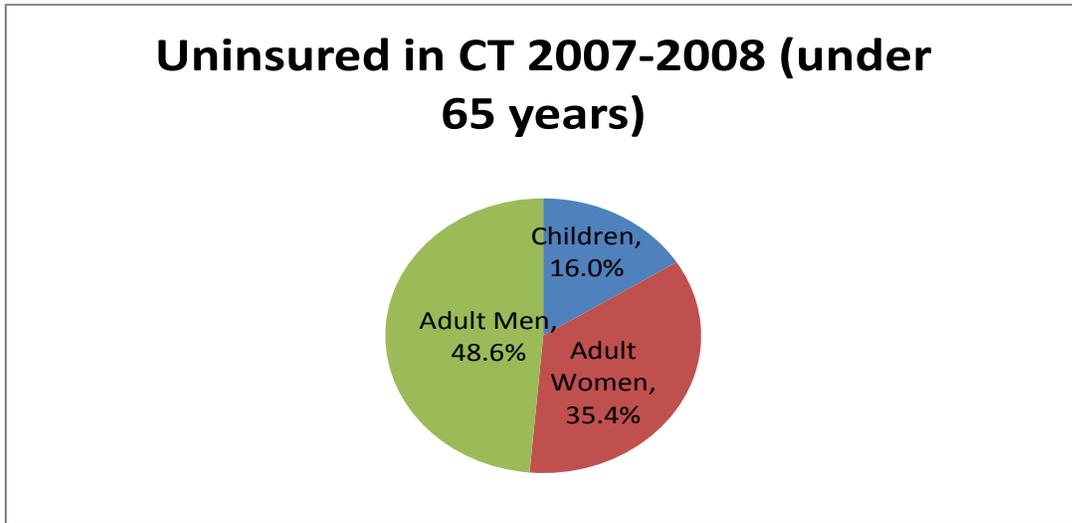
In this section of the Set One report, the financial burden of the services covered by the mandate will be considered. This will be done both in the presence and absence of the eleven mandates. This financial burden analysis takes a broader interpretation that includes socioeconomic factors in addition to the cost burden considerations. The medical aspects of the mandates as well as elaboration of the mandates were covered in the earlier sections of this report and therefore not reported here.

In 2008, about two-thirds of Connecticut residents were covered<sup>1</sup> by private insurance (60.1% had employer based policies and 4.6% had individual policies); about a quarter were covered under public programs (Medicare 13.6% and Medicaid 11.5%); and 9.7% did not have any insurance. Among the privately insured, a third<sup>2</sup> were enrolled in HMO plans and the rest had PPO or other non-HMO coverage. Of those with HMO coverage, about 66% are fully insured. Of those with non-HMO coverage, about 45.6% are fully insured. Unless stated otherwise, the mandates discussed here, in general, apply to these fully insured group and individual policy holders only, that is, about 32% to 35% of the CT population. Although 60.1% of CT residents have private, employer-based group coverage, about half of that is self-funded (not fully insured) and is not subject to the state health insurance mandates. The charts below provide the overall coverage information as well as the demographics of the uninsured. Even though the state mandates are not applicable to this population, it provides us a baseline against which we can measure the impact of the mandates on the cost and financial burden.

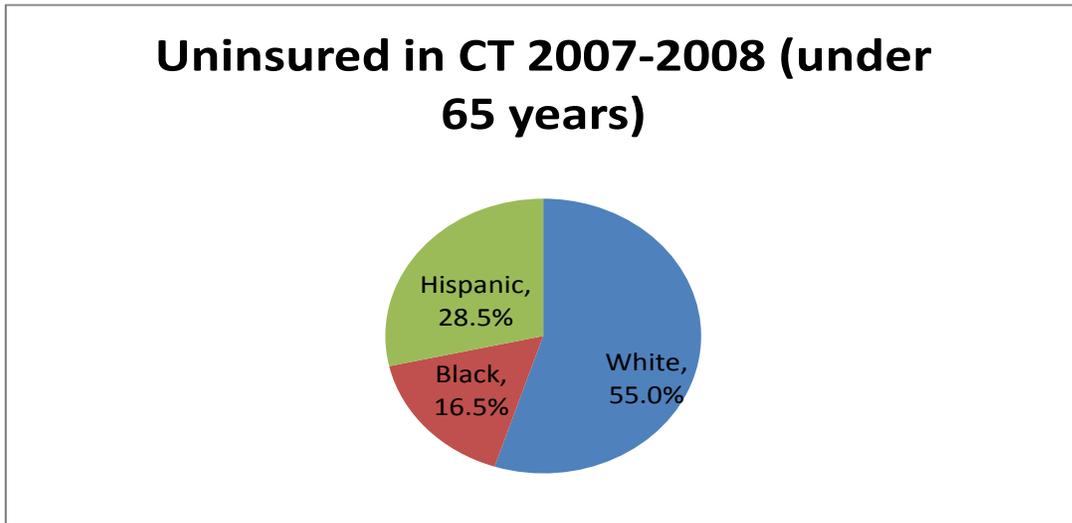
FIGURE 1(a)



**FIGURE 1(b)**



**FIGURE 1(c)**



Source: Urban Institute and Kaiser Commission on Medicaid and the Uninsured estimates based on the Census Bureau's March 2008 and 2009 Current Population Survey (CPS: Annual Social and Economic Supplements). Accessed August 20<sup>th</sup>, 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).<sup>3</sup> In Connecticut, 7.1% of the lives covered by commercial health insurance have a 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 the mandates which work mainly through the pharmacy benefits of an insurance policy or have a significant pharmacy services component has been somewhat reduced by the penetration of fourth or even fifth copayment tiers. These higher tiers may require members to pay \$100 or more for a prescription. Mandates regarding treatments for diabetes, Lyme disease, and chemotherapies fall under this category.

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, such as cancer screening in general and mammograms in particular, 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 or coinsurance, 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. This would apply to PSA tests, and colon cancer screening. Some carriers' plans might also cover diabetic self management training and some diabetic medications and supplies with no cost sharing and not subject to the deductible. The other mandates would be subject to the deductible.

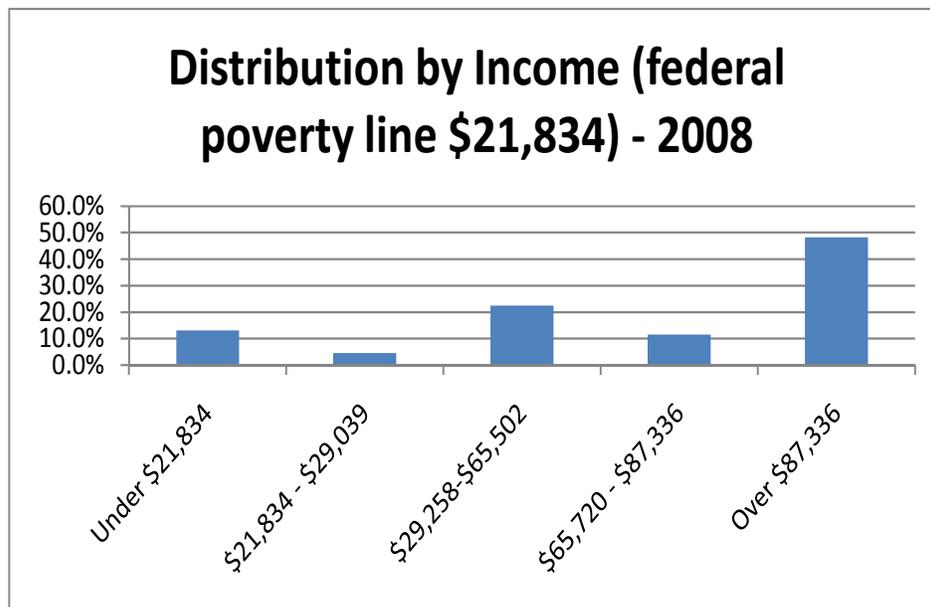
Many self-funded plans provide diabetic members with their equipment, drugs, and supplies for reduced cost-sharing in order to encourage better self-management of their chronic condition. These are called value-based benefits because they have a greater effect on health outcomes than other benefits.

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, such as hearing aids for children, the cost-sharing can be significant to the family. For the most expensive mandates, cancer in particular, the cost burden to the patient and their family is substantial. New chemotherapy drugs can be very expensive, and to compound the problem, some of these new drugs may be assigned to a new specialty drug tier that requires a higher level of cost-sharing to the member. In looking at the financial/economic aspect of the mandates, Ingenix Consulting used the model involving family income and level of cost-sharing in the member's plan, and we also took into consideration other factors unique to the mandate.

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. For example, with respect to benefit plan only, if a person needs \$1,850 annually in ostomy supplies and must first satisfy a \$1,000 deductible, this person has higher personal cost burden than someone who has no deductible. 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 families with income of \$50,000, \$80,000, and \$160,000, and calculated how much they 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 cost sharing associated with the incremental medical cost of each mandate only. Our analysis using this model did not consider the member contribution to the premium, which is money paid for insurance by the insured prior to actual treatment and regardless of whether any medical care occurs. Families benefiting from the mandates would have paid a premium contribution 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 share which would represent the State averages. Therefore we used our knowledge of health insurance plans to define a “rich” plan with member share 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. We used three levels of annual family income to compute the cost burden. For the most part, we have discussed the cost burden to families using the lowest income (annual family income of \$50,000). Detailed results of our calculations are presented in the Appendix Three.

**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>

Some of the mandates have either achieved their objectives or have been rendered less relevant either due to changes in the medical technology or delivery, higher cost of care or due to the evolution in thinking of insurance companies, payers or the society in general. For instance, ten to twelve years ago the cost effectiveness of preventive services was being discussed in academic and professional circles. However, most insurers realize the value of these services now, and it can be argued that the mandates have contributed to this belief. The mandates covering PSA testing, colorectal cancer screening, and diabetes self management training fall under this category. To the extent that uncontrolled diabetes can cause significant cost burden due to complications and co-morbidities, we place the mandate regarding diabetes treatment in the above class too.

In the case of the two mandates covering cancer and tumor removal and treatment, etc., and the hearing aids, the cost of treatment has gone significantly over the mandated coverage levels. Most of the insurance policies cover cancer related expenses up to tens or even hundreds of thousands, and the mandated levels of \$300 - \$500 do not make any difference in the coverage. The birth to three mandate covers services which are considered part of the larger societal responsibility. A federal mandate and funding covers these services. Since these services would have been covered by public resources even if the mandate did not exist, it can be argued that the main consequence of this mandate today is a shift of cost from the public to the private sector rather than expanded coverage of the services per se.

For three mandates – ostomy supplies, hearing aids, and birth to three – the mandates' limits cover a significant portion of but not all the prevailing cost of the service. For these mandates, we also looked at the marginal cost burden. This analysis provides insights into the cost burden for the coverage gap (difference between the cost of service and the dollar limit set by the mandate).

Table 1 summarizes our findings and is followed by the analysis for each of the mandates.

**Table 1**

	<b>Impact on Premium (Paid PMPM in 2008)*</b>	<b>Financial Burden due to Non-Coverage</b>	<b>Medical or Social Need</b>	<b>Preventive Service/Any Savings to Health Care Cost</b>	<b>Limits Set by Mandated Coverage/Mandated Limit enough to Cover Cost</b>	<b>Richness of Insurance Type Matters</b>
<b>Diabetes Self Testing Education</b>	\$0.06	Lack of insurance coverage does not add financial burden since the education is widely	Medical	Preventive with potential savings for total health care cost	Number of hours limit. Hours limit is sufficient to provide needed service	No

		available for free				
<b>PSA Testing</b>	\$0.17	Lack of coverage does not add financial burden	Medical	Preventive		No
<b>Ostomy Supplies</b>	\$0.06	There is a financial burden due to non-coverage	Medical. Some services may be considered social		\$1,000 per year limit which is insufficient to cover all costs for all ostomates covered under the mandate	Yes
<b>Hearing Aids</b>	\$0.01	There is a financial burden due to non-coverage	Medical		\$1,000 for two years limit which is insufficient to cover all costs covered under the mandate	Yes
<b>Cleft Palate</b>	\$0.02	Some free service may be available for cleft repair	Medical			Yes
<b>Hospital Dental</b>	\$0.06	There is a financial burden due to non-coverage	Medical			Yes
<b>Diabetes Treatment</b>	\$4.17	There is a financial burden due to non-coverage. Most plans would cover this even without the mandate	Medical	Preventive with potential savings for total health care cost		Yes
<b>Birth to Three</b>	\$0.15	Most plans would not cover this without the mandate	Social. Some aspects may be considered medical		\$3,200 annual limit which increases to \$6,400 in 2010. Probably enough to cover most of the services. There is a family out-of-pocket	Yes
<b>Lyme Disease</b>	\$0.25	Most plans would not cover indefinite or long-term use of antibiotics	Medical		Therapy duration limit which is clinically effective for most cases	Yes

		without the mandate				
<b>Colorectal Screening</b>	\$3.10	There is a financial burden due to non-coverage. Most plans would cover this even without the mandate	Medical	Preventive with potential savings for total health care cost		Yes
<b>Cancer, Tumor</b>	\$10.10	There is a financial burden due to non-coverage. Most plans would now cover most of these services even without the mandate	Medical			No

\* Weighted average cost (group insured) across all carriers.

## DIABETIC SELF MANAGEMENT TRAINING

As pointed out in the actuarial analysis, the overall financial burden of this mandate is small (\$0.06 PMPM), especially when compared to the potential savings resulting from better management of diabetes. The cost to patients covered by this mandate is small, too. Our estimate, based on the carriers' data, is that the average out of pocket per patients associated with this mandate in 2008 was less than \$27.

A number of studies have shown favorable cost effectiveness of programs to improve diabetes self management, especially as it relates to self-monitoring.<sup>2</sup> Self-monitoring of blood glucose alone has shown large savings due to cost avoided through delaying and/or avoiding cardiovascular complications, blindness, end-stage renal disease, and amputations. Similarly, significant improvements in cost per quality adjusted life-year and incremental cost per effectiveness ratio have been reported due to self monitoring of blood glucose. A distinction needs to be made between diabetes self management and a diabetes self management training program. While DSM generally saves money and improves patient outcomes, the success of a DSMT program will depend on its quality.

Despite the low cost for the patient and the obvious benefit, there are socioeconomic barriers to the full utilization of this mandate. For instance, the self management training is done in a series of visits to the training center (usually located in the large hospitals and clinics in the area). These visits involve time, transportation and lost income due to absence from work costs. Usually the participants in the programs covered under this mandate are required to

fax/mail their blood tests and food logs to the case managers. In order to reduce some of these burdens, an increasing number of large employers, especially self-funded ones have initiated on-site blood sugar testing, education and wellness programs. This means the people with small group insurance and individual insurance – who on average tend to have lower income – have to face the above mentioned barriers to a larger extent. These barriers to participation in self-management programs put an additional burden on women with gestational diabetes as the program intensity for them is usually greater than that for Type II diabetics. For gestational diabetes, DSM is of a limited duration.

In terms of the type of diabetes, the above mentioned barriers probably have a lesser impact on the participation rates for the Type I diabetics as self monitoring and management of sugar levels is a life or death issue for them. These barriers influence the behavior of Type II and gestational diabetics because, in these cases, diabetes is not a symptomatic disease while the impact of time and financial cost associated with participation is immediate. The same is even more applicable for the uninsured population. To the extent that these barriers reduce the participation and retention rates for self management training programs, they add to the social and economic cost of care.

## **PROSTATE SCREENING – PSA TEST**

According to the data collected from the CT payers, the average paid cost per patient was \$31.40 for group insurance plans. The cost per patient was \$21 for the individually insured population. Neither the cost per patient nor paid PMPM (\$0.19) for prostate screening makes this mandate onerous for the insurer or the member. Our Income-Benefit model shows that even if the mandate did not exist (and assuming the member pays full cost of the testing) the financial burden for a family would range from less than 0.01% to 0.06% of the income based on the family income. Regardless of one's plan of benefits or family income level, the cost burden is relatively low for this mandate.

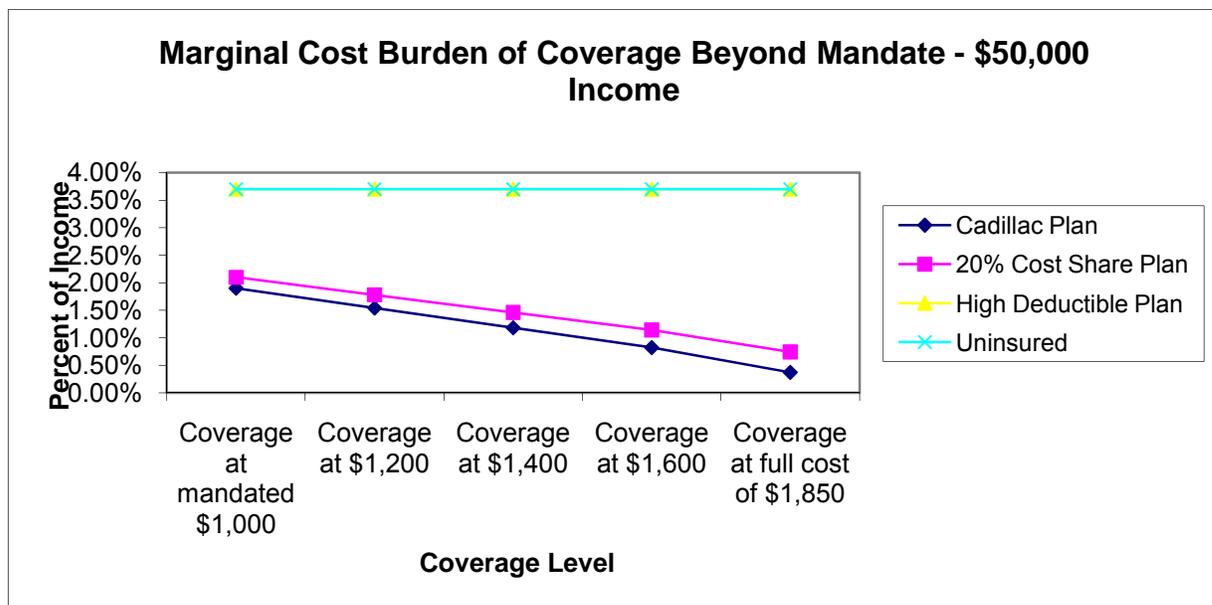
There is a chance that like most of the broad coverage mandates, this one may be simultaneously over- and underutilized for different segments of the population. With respect to under-testing, lack of detailed data makes it hard to analyze if African American males in CT are getting adequate testing. Since African American males are at highest risk for prostate cancer, and African Americans seek preventive care less frequently than the general population, it is likely that lack of PSA screening may be leading to higher incidence of late detection of prostate cancer. The downstream cost of late detection in terms of shortening of life and or financial burden for the families, insurers, Medicaid and Medicare could be significant. At the same time, many experts believe that a screening for ALL males over 50, regardless of risk factors etc. may be resulting in unnecessary biopsies and other follow up. The cost associated with false positive and unnecessary treatment has an impact on the cost effectiveness of this mandate.

While people from some demographics may be not getting adequate testing, the sense we got from some of the recent literature and through our conversations with oncologists and urologists is that many are getting PSA testing done as frequently as necessary. The actuarial part of this report discusses some of the relevant data in this regard.

## OSTOMY SUPPLIES

The data collected from the carriers show low cost burden as far as premiums are concerned. The allowed and the paid PMPM were \$0.07 and \$0.06 respectively in 2008. However, at the individual patient level the cost of the ostomy supplies could go beyond the \$1,000 mandate provision. The cost of ostomy supplies can vary due to a number of factors. The three types of ostomy covered by the mandate require different replacement frequencies, type of bags, and number and the type of accessories, which can cause cost variations. Other factors influencing annual cost include procurement channel (mail order supplies are generally cheaper) and the switching among different brands (newer patients may try out several makes to get to the optimal brand; patient weight or size of stoma may change).

During the first phase of this project (when financial burden of increasing the mandate limit from \$1,000 to \$5,000 was considered) the cost burden for patients with an annual cost of \$1,850 was analyzed based on the income level of the patient family. We expanded the \$1850 cost through the use of our I-B model to allow for income as well as benefit structure variations. Our analysis shows that for a patient with a \$50,000 annual family income and no insurance, the cost of ostomy supplies will be 3.7% of their income. However, if that person is insured with a plan having 20% member cost sharing and with the coverage of ostomy supplies at the mandate level of \$1,000, the cost burden is reduced to 2.1%. If that person was enrolled in a “rich plan” with only 10% cost sharing, the mandate would reduce to 1.9%. Depending on the other utilization of health care services, a patient with a high deductible plan may end up paying all of the cost of the supplies for various cost burden scenarios. The marginal cost burden analysis shows that if the mandate limit was to increase, the cost burden does not decrease for the high deductible plans. However, as shown in the chart below, the cost burden decreases at a higher rate as the richness of the plans increases.



Ostomy patients face significant social, clinical and associated financial challenges. Studies show that ostomy patients and their caregivers report significantly higher depression and anxiety levels. Also, the patients report lower overall quality of life, poorer health related quality of life, and poor social and sexual activity compared to patients with no stoma.

Ostomy patients have to go through significant life style changes. Some of the more commonly reported issues include discrimination at work place, fear of flying due to full body scans, usage of Imodium and other contingency medications to be taken before dining outside the home. Some of these issues lead to absenteeism, lack of productivity and even quitting employment and the associated social and financial burdens.

The socioeconomic burden due to some of the ostomy related issues are more severe for certain demographics than others. For instance, lower income or education and other socioeconomic factors could lead to less frequent replacement of pouches, etc which could in turn lead to withdrawal from social situations. Similarly, those with lower income and younger patients are more likely to be provided care by family members thereby reducing income or productivity or both for the family. Young adults are more likely to face higher social and mental burden due to the impact of ostomy on social and physical activities.

## **HEARING AIDS**

The technology, quality and cost of the hearing aid devices has significantly changed since this mandate was enacted in 2001. The behind-the-ear (BTE) devices usually recommended for growing children cost between \$1,200 and \$3,000 for one aid. More than 80% of the patients need aids for both ears. Therefore, people with insurance policies covering this benefit at, or slightly above, the mandated \$1,000 for two years are paying for most of the cost of the hearing aids. The mandate allows for the hearing devices to be considered as durable medical equipment (DME). This may further increase the financial burden depending on the need for other DME and based on the coverage limit for DME in a particular policy.

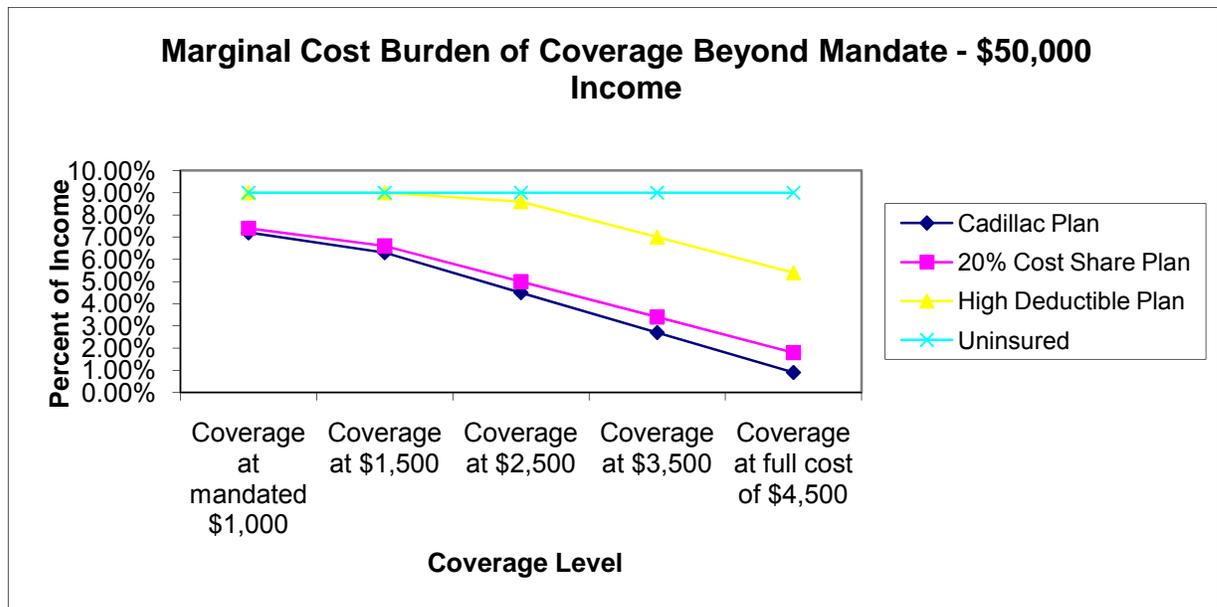
A factor which may be reducing some of the financial burden on the families is that some insurers in CT cover hearing aids at a limit higher than the state mandate. The first phase of the project analyzed the option of raising the mandate coverage age limit from 12 to 18. Using the same assumptions used in that analysis (two devices purchased in the same year at the cost of \$2,250 per aid) cost burden analysis was done on various segments of CT insured (and uninsured) population based on the income and the insurance benefit levels. For low income families and for the uninsured, we assumed that cheaper hearing aids (cost of \$750/aid) are more prevalent. We also assumed that a coverage limit for DME does not impact the mandate, however to the extent it does, there is less than \$1,000 to spend on hearing aids.

Considering the facts that on average lower income families are more likely to be covered under an individual plan and that the cost-sharing for individual plans in CT is roughly twice that of group insurance plans, cost burden as a percentage of disposable income will be even higher for lower income families. For a family at a low income level, the out of pocket cost may be prohibitive. The biennial maximum on this benefit makes the richness of plan less relevant—once the \$1,000 maximum is reached, the cost-sharing is 100%, unless the

plan covers the hearing aid benefit at a higher level than the mandate requires. It is not clear how many fully insured members are covered by plans that have a higher level of hearing coverage than the mandated \$1,000.

For a plan with effective member cost share of 20%, the cost for a family with \$160,000 income is 2.3%, and a \$50,000 family pays 7.4% of its income for hearing devices for a child. Given the demographics of the population targeted by this mandate, most of the young patients covered under this mandate will have fairly low health care cost other than the hearing aids. It is very likely that they may be paying almost all of the cost of the hearing aids after the \$1000 mandated coverage. It is estimated that a \$50,000 annual income family with a high deductible group policy may be paying up to 9.0% of their income to obtain the hearing devices. Even if they are purchasing lower cost devices, they may be paying as much as 3% of their income.

An uninsured family with annual income of \$50,000 may be spending anywhere from 3% to 9% of their income to pay for the hearing aids for a child (assuming cost per device between \$750 and \$2,250). The marginal cost burden of insurance coverage beyond the \$1,000 is shown in the below figure.



As the actuarial analysis part of this report shows, a reported PMPM cost of \$0.01 indicates underutilization of the hearing aids. The literature shows that there is a link between the cost of the hearing devices and underutilization. Koshkin's study reported that in their survey, 28% of respondents cited financial reasons for not using aids.<sup>3</sup> Other studies have shown that the long term economic consequences of uncorrected or non-amplified hearing loss are quite extensive. Labor force participation is lower for people with hearing loss resulting in a loss of productivity which affects society as a whole.<sup>4</sup> 67% of the working-age population with hearing loss is employed versus 75% without hearing loss. Among people age 51 to 61, the median net worth of those with hearing loss is \$65,575 compared to \$102,000 for those without hearing loss, based on 1994 year figures.

## **ORTHODONTIC TREATMENT OF CLEFT PALATE**

Although clefts are considered among the most common major birth defects in the U.S. their incidence is quite low – estimates range from 6 to 10 per ten thousand. IC data shows even lower rate of clefts in CT. Spread across the insured population in CT, the actuarial analysis found the cost of cleft palate covered through the medical benefit to be less than \$0.01.

The cost of treatment for clefts per patient is high and continues through the adolescent years of the patient. Typically, the impacted infant goes through pre-surgical orthodontics when around six months old. Additional orthodontia continues after the first year for preparation for additional surgeries and treatment. The treatment is done by a team of cross specialty providers and can include lip and palate repair, surgeries, orthodontics, and bone grafts. The mandate covers only medically necessary orthodontic processes and appliances and excludes cosmetic surgery.

The orthodontic work related to the treatment of a cleft palate costs in the \$10,000 range though it varies depending on individual cases. We did not have enough data to estimate how that cost is distributed over the years of treatment. However, assuming an annual cost of \$2,000 for the first two or three years of treatment, our model shows that an uninsured family with \$50,000 income could spend about 4% of the income in the year their child goes through a cleft related orthodontics. An insured family with the same income level and undergoing the same medical procedure could end up paying anywhere from 0.4% (for rich plans) to 1.2%. Thus the mandate reduces the family cost burden. If the above family was to be insured through a high deductible plan, its cost share could be as high as 4% depending on the other services counting towards the deductible.

Children with clefts are not reported to have major social or psychological issues thanks to the advancements in the cleft repair and plastic surgery technology. However, there is some socioeconomic and clinical cost of clefts. Children with clefts often require speech therapy in early years and are more likely to have frequent ear infections. Babies with clefts require special feeding bottles and nipples. Patients with cleft may have significant dental problems. Some of these issues put a hidden financial burden on the families.

The incidence of cleft lip and a combination of cleft lip and cleft palate is twice in male than in female while female have a higher rate of only cleft palates. Clefts are also more prevalent in children of Latino, Native American and Asian descent. Becker et al found in a survey of the children with clefts patients with private insurance coverage were more likely to obtain dental care than those covered under Medicaid or with no insurance.<sup>5</sup> Given the higher incidence of cleft in these ethnic groups, there could be a care gap for them.

It is unusual that an aspect of dental care is required to be covered under a medical plan. In that sense, this mandate shifts the cost of a dental benefit to medical insurers for the special population with cleft palate.

## **HOSPITAL DENTAL**

This mandate covers the non-dental costs incurred in providing dental care under general anesthesia, usually in a hospital setting. General anesthesia is rarely used during dental procedures and is reserved for patients who need to go through a particularly difficult procedure or for patients with special needs. We found very few patients in group and individual plans combined in the data provided by the carriers for the year 2008. Spread across the total insured members, the allowed PMPM was \$0.07 for the group insured.

The medical cost for a hospital encounter could be \$4,000 and above, and therefore the cost puts significant financial burden on the uninsured. We ran our I-B model assuming the services covered under this mandate to cost \$5,000 for an encounter. An uninsured family with \$50,000 income can spend up to 10% of its income for the services covered under this mandate. The cost burden for an insured family with same income could range from 1% (rich plan with 10% member share) to 5.6% for a high deductible plan. If we assume that there would have been no widespread coverage of this service in the absence of the mandate, then this mandate has significantly reduced the cost burden on the targeted patients and families.

Anesthesia is not without adverse reactions and can lead to increase in costs, though according to a study by Messieha et al, the complication rate in special needs patients is low - only 2 out of 363 patients in their study.<sup>6</sup> Moreover, there are increased direct costs, resulting from increased use of pain medications, anxiety medications, anti-nausea medications, additional inpatient admissions, and longer length of stay. Increased indirect or societal costs are also present resulting mostly from the loss of productivity of the parent's work time while in surgery. However, it should be kept in mind that if general anesthesia is not available, the result is either compromised dental care or delayed dental care. Either of these alternatives can result in complications, which are more costly to treat at a later date.

## **DIABETES EQUIPMENT AND SUPPLIES**

The cost of diabetes-related cost for diabetics was \$4.17 PMPM in 2008 according to the carriers' data used for this project. This makes the diabetes treatment mandate among the more expensive ones covered under this phase of the project. However, as mentioned in the actuarial analysis in this report, the cost and clinical effectiveness of proper management of diabetes is so widely accepted that it is hard to estimate the cost impact of this mandate. Most of the insurers today would have wide coverage of diabetes related medical services, devices and equipment and drugs even if the mandate did not exist. Diabetes treatment and cost of treatment, understanding and attitude towards diabetes have also undergone major changes since this mandate came into effect.

Given the broad language for this mandate there are a number of targeted sub-populations which have different levels of financial, clinical and socioeconomic issues. For instance, the cost burden for a Type I diabetic is very different from a Type II diabetic or from a gestational diabetic. Even within the Type II population, which accounts for most of diabetics, the cost burden for a patient who is stable on one or two oral diabetic drugs is very different from a patient with badly controlled glucose levels and resulting cardiovascular or other complications. We ran two of the more common diabetic cases through our model. The first

case was a diabetic patient whose blood sugar level (Hb A1c) is maintained around the recommended level of 6.5 with the help of two oral hyperglycemic medications. We assumed the diabetes related cost for this patient to be around \$1,800 consisting of established generic medications like metformin, cost of test strips, and biannual testing for Hb A1c. The second case was of an insulin dependent patient with suboptimal levels of blood glucose level and either microvascular or macrovascular complications. We assumed annual cost of treatment to be \$14,000 with half of that diabetes related.

Our model for the first case, the healthier patient, shows that an uninsured family with \$50,000 income could spend over 3% of income. An insured family with the same income level and undergoing the same medical procedure could end up paying anywhere from 0.4% (for rich plans) to 0.7% of its income (for a 20% cost share plan). For the sicker, more costly patient, our model shows a significant cost burden. The difference in cost burden for an uninsured and an insured with \$50,000 income could be as much as 25% of the income depending on the richness of the plan for the insured family. Even a family with income of \$160,000 could end up paying about 3%-4% of its income.

The treatment of diabetes has undergone major changes in the last ten to fifteen years and will continue to do so. These changes have had a significant impact on the cost of treatment, a trend which is likely to continue. The broad language of the diabetes testing and treatment mandate will continue to have direct and indirect (sometime even unintended) financial consequences. For instance, there is anecdotal evidence that some health plans have, in the past interpreted this mandate to imply no cost sharing by members for insulin and oral diabetic medications. This means an unintended shift of cost burden within the insurance system.

Several newer oral medications as well as insulins have been recently approved for use. There are several biologicals in the pipeline too. The pharmacoeconomics of these newer therapies is yet to be established. However, given the past history of insurers and health plans interpreting the mandate on the broader side, these more expensive medications have a better chance of being covered than non-diabetic therapies. This is likely to increase the cost of this mandate. The same is true for blood glucose monitors and other equipment.

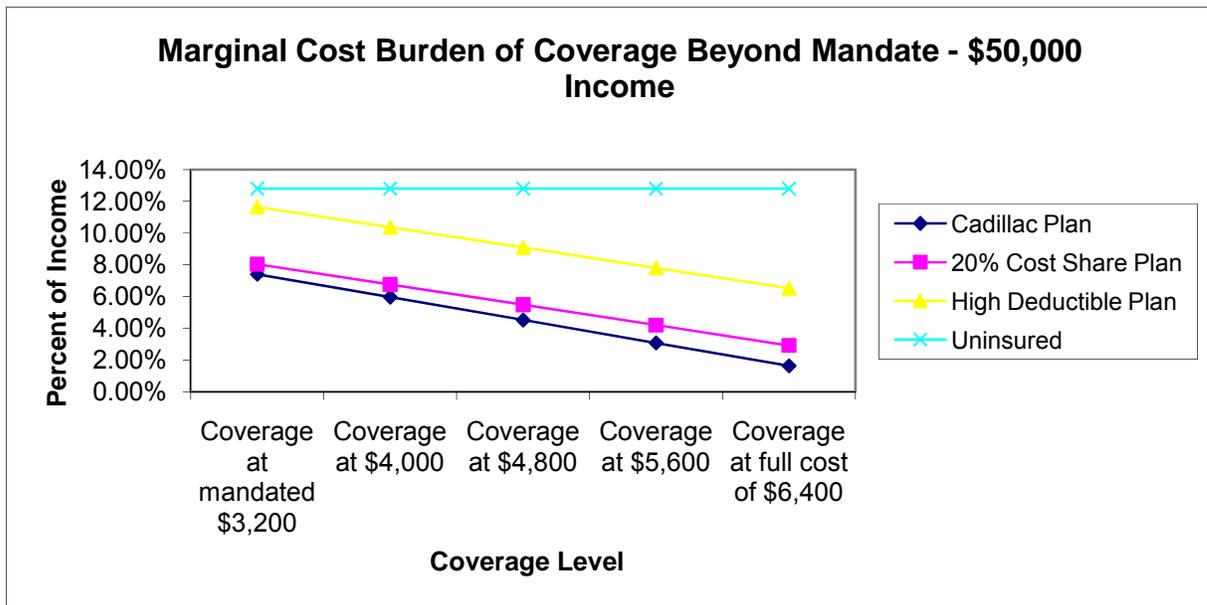
## **BIRTH TO THREE PROGRAM**

This mandate covers a number of developmental disabilities caused by mental and/or physical impairments. These disabilities impact all demographics except Autism Spectrum Disorder (ASD) which occurs more in the male population. ASD incidence has been on the rise and whether this rise is due to better awareness and diagnosis or due to something else is still being studied. The total economic and societal cost of these disabilities is very high.

The cost of care for developmental-needs infants and toddlers can be divided into three components. The first component, direct medical expenditures, can be up to six times higher than that for a person without a developmental disability. This part of the care cost is borne by the family, insurer and the government depending on the type and level of the insurance coverage. The second part is the indirect cost of care borne mostly by the family. An example of this cost is the loss of caregiver's income due to absence from work, voluntary or involuntary loss of employment, etc. The third component is the cost of what

has been described earlier in this report as the “habilitative” services. This cost is mostly covered by the various levels of government as well as charity and other private organizations. The Birth to Three mandate requires insurance companies to cover part of this cost component. The State has mandated coverage, with maximum dollar limits, to provide for the early detection, diagnosis and treatment of developmental disabilities. The insurer is required to pay up to \$3,200 annually. The parents pay a small fraction of the cost based on income and family size. The rest of the cost is covered by state and federal money. According to the data collected from CT carriers, the 2008 cost for these carriers was \$0.15 PMPM.

For 2010, the mandated limit has been doubled to \$6,400 per year. Similarly, the contribution from the families has been increased by 60%. According to our Income-Benefit model, a commercially insured family of three with an income of \$50,000 and using care up to \$6,400 (assuming insurer covered only mandated \$3,200) would have paid from 7% to 12% of their income depending on the richness of the policy. Under the new scenario (increased mandated coverage plus higher contribution by family) the same family as above will pay from 1.9% to 3.1% of its income for these services. For the family with a high deductible plan the cost would have been between 11%-12% with the \$3,200 limit and could be a little over 7% with the new mandate depending on the type of insurance (group or individual) and other factors. The figure below shows the marginal cost burden.



The impact of the new mandated level is yet to be seen. For financially constrained families, the new higher requirement of monthly contribution may act as a barrier to access to the service. For most families, the additional burden will be more than offset by the higher mandated coverage of up to \$6,400.

Prior to the enactment of this mandate, the cost of habilitative services was not borne by private insurers. This mandate shifts some of the cost for this care from families and the

public sector to insurers. It is believed that children who receive Birth to Three services require less special attention upon subsequently entering the school system.

## **LYME DISEASE**

Connecticut has among the highest incidence rate of Lyme disease. There were 4,156 cases of Lyme disease cases in Connecticut for the 2009 with a rate of 122 per 100,000 people. The clinical aspects as well as the data issues in recording the Lyme disease related cost are discussed in the earlier parts of this report. Our estimate is that the cost of treatment of Lyme disease in 2008 was about \$0.45 PMPM. According to a study by the CDC, a Lyme disease patient costs about three thousand in direct and over five thousand in indirect medical cost (in 2000 dollars).<sup>7</sup>

For our cost burden analysis, we assumed a cost of \$3,000. Our model shows that an uninsured family with \$50,000 income could spend 6% in direct medical costs associated with the Lyme disease. An insured family with the same income level and undergoing the same medical procedure could end up paying anywhere from 0.6% (for rich plans) to 1.2% of its income (for a 20% cost share plan). Thus the mandate reduces the family cost by a significant part. If the above family was to be insured through a high deductible plan, its cost share could be as high as 5% depending on the other services counting towards the deductible and whether the family had group or individual insurance plan (individual plans typically have higher deductibles).

There are regional and demographic differences in the incidence of the Lyme disease in CT. The differences have an impact on the financial burden associated with this mandate. Based on the 2009 statistics, the three Eastern/North-Eastern counties (New London, Tolland and Windham) had the highest reported cases per 100,000. These counties also are among the lowest per capita income areas in the state as well as more rural ones. In general, these characteristics – lower income and rural – are associated with population segments less likely to be insured and if insured, having individual plan coverage. That is, the financial burden on the patients is likely to be higher.

In terms of age, the 50 to 69 years old have the highest incidence rate. After infants and young children, this age segment is most vulnerable to infections and more likely to have higher usage of antibiotics even without Lyme disease. That is, these people are likely to have higher resistance to antibiotics and could face the associated clinical and financial issues.

There is substantial controversy surrounding the long-term use of antibiotics to treat the medical condition called Chronic Lyme Disease. To date, no one has died from Lyme disease. It is possible, however, for a person to expire from overuse of antibiotics. To the extent that the mandate might help prevent the latter from occurring, it would help to protect the public health of CT residents.

## COLORECTAL CANCER SCREENING

Tests for colorectal cancer (CRC) for diagnostic and treatment purposes are generally covered by private insurers. This mandate ensures that these tests are covered for screening purposes too. A variety of tests are available ranging from an inexpensive Fecal Occult Blood Test (FOBT) to expensive and invasive colonoscopy. FOBT cost ranges from \$5 to \$15 while a single colonoscopy can cost up to \$1,800.

Our model estimates that an uninsured family with \$50,000 income could spend around 3% of income for a colonoscopy costing \$1,500. An insured family with the same income level and undergoing the same medical procedure could end up paying anywhere from 0.2% (for rich plans) to 0.9% of its income (for a 30% cost share plan). If the above family was to be insured through a high deductible plan, its cost share could be as high as 2% to 3% depending on the other services counting towards the deductible. Practically speaking, the cost burden on the insured targeted population with average risk is not estimated to be prohibitive. The Connecticut Department of Public Health Colorectal Cancer Control Program covers no-cost colonoscopies at 7 health centers for the uninsured and even for persons with private insurance or Medicare who meet certain criteria. The first phase of this project analyzed the financial burden for the small number of patients requiring multiple colonoscopies.

Similar to the cost burden, the available data does not lend itself to accurately measure the effectiveness of the mandate. However, there is some evidence that this mandate is having its intended consequence. States with the screening mandate are shown to have a higher rate of screening. For instance, there are 18 states (CT among them) which had a broad, clinical guidelines based mandate in 2005 that required CRC screening for the 50 and over population. Only 2 of these states had less than 50% of the targeted population who had not had a FOBT, sigmoidoscopy, or colonoscopy.<sup>8,9</sup> Nine states had 50% to 60% of the population go through one of these tests. Another 8 states were between 60% and 70% (CT was in this category). According to a later version of the same survey conducted by the CDC in 2007, there was significant positive movement in the states with the CRC screening mandate. Of the 18, none was in the below 50% tested category, and two had moved from the 50% - 60% group to the 60% - 70% group. Another two states (CT and RI) had moved to the 70% and higher group. According to Kaiser Family Foundation statewide statistics, the percent of age 50 and older who have had a sigmoidoscopy or a colonoscopy by 2008 was 69.5% in CT as compared to the national average of 61.8%. Similarly, the rate of death due to colon cancer in women and men of CT was lower in the five years post mandate as compared to the five pre mandate years.<sup>10</sup>

Despite the fair amount of positive impact of this mandate, there are still significant number of CRC related avoidable deaths in the State indicating that the numbers of CRC screenings in CT are less than optimal. This gap in care puts a significant financial burden on the families, the insurers and the State.

The main issue is that the broad coverage of this mandate causes overutilization of CRC screenings in some instances while non-cost factors have kept the needed screenings low for certain segments of the population. Due to socioeconomic factors, African Americans may have later and less frequent screenings than what is recommended.

## **CANCER, TUMORS, LEUKEMIA, ETC.**

Important outcomes in the treatment of cancer include progression free life-years, time to progression, life-years saved, and quality-adjusted life-years saved. All of these metrics are specific to the type of cancer and stage. They are based on access and availability of treatment and influenced by compliance to screening, treatment, and remission maintenance protocols. They are constrained by ability to pay. There are emotional, as well as, social issues that further impact the quality-of-life in cancer patients. This mandate addresses the medical, as well as, some of the social and emotional aspects of cancer care, such as loss of hair due to treatment and prosthesis replacement. However, the minimum limits ranging from \$300 to \$500 for various products and services are negligible as compared to the current cost of tumor removal or restorative surgeries or chemotherapy. Most of the insurers cover these benefits at a much higher level than the mandated limits.

At a cost of around \$10 PMPM, this mandate is the most costly among the set of mandates reviewed in this report. As discussed in the actuarial section, we could not isolate the cost associated with the mandate only. The true cost of treatment for a cancer patient can run into several hundred thousand dollars depending on the type and the stage of the cancer and therapy being used. On average, the cost of a patient under going chemotherapy using newer and more expensive oral agents was between \$65,000 and \$75,000 in 2009. The cost of drugs alone was around \$20,000. The out of pocket for commercially insured patients could average around \$1,500 with the top 5% paying over \$35,000. According to the American Society of Clinical Oncology, there was a 20.8% increase in the clinical drug expenditure from 2005 to 2006, largely driven by the novel biological targeted therapies like Avastin and Herceptin. Given these statistics, it is unlikely that patients getting coverage through their insurance plan would receive substantially less coverage in the absence of this mandate.

We do not report results from our Income-Benefit model as the mandates limits for most of the services are very small as compared to the actual cost of treatment and their analysis does not provide any major insight. However, the high plan and member cost associated with cancer related services make the level and type of insurance coverage the biggest factor impacting access to optimal care. CDC data shows that in a survey conducted in 2005, the proportion of under-65 age group who had had a mammogram, Pap test, colorectal cancer screening or PSA was significantly higher for those with private insurance as compared to Medicaid or uninsured. The difference was even more pronounced in comparison to those who had been uninsured for over 12 months. This relationship held across all ethnicities. Not surprisingly, the cancer survival time in months was also significantly higher in the private insured group. These results also held across the type of cancers. The association between the insurance type and cancer survival rate can be explained by later stage of diagnosis, access to and quality of care, adequacy of staging, difference in supportive care, etc.

The low coverage limits set by this mandate imply that the insurance-cancer outcomes relationship above is almost entirely governed by the type and adequacy of policy benefits rather than this mandate. Some benefit aspects of insurance policy which can influence access to cancer related care include the annual and life time maximum limits, member cost-share – copayment or coinsurance, level of copayment and deductibles and out of pocket

maximums, etc. Increasingly, the formulary structure of prescription drugs is becoming a factor. This is due to the emergence of oral agents like Gleevec, which are usually covered in a tier that requires a higher copayment.

Some other insurance-coverage related factors which are going to have major implications for the financial burden and its distribution among stakeholders include the removal of coverage maximums and existing condition requirements through the health reform act, the emergence of specialty pharmacies which provide high degree of disease management and care coordination services, a rich pipeline of biologics and oral medications, and widespread and increasing off label use of cancer medications, etc.

#### **IV. CONCLUSION OF ACTUARIAL REPORT:**

IC examined eleven of the forty-five CT health benefit mandates and calculated their expected costs. This was 6.7% of the cost of an average per member group health insurance premium. Similarly, it was about 6.7% of the per member medical cost for a group contract. As these mandates are written, they add roughly \$20 to the overall per member monthly medical cost of a group plan. They add about \$24 PMPM to the overall per member insurance premium. The language of some of the mandates is broad, however, and covers many medical expenses that carriers were already covering prior to the passage of the cancer and diabetes mandates, for example.

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. The mandates represented about 5.9% of the cost of individual plans.

Some of the mandates have a more positive effect on public health than others. Some affect a small but vulnerable special population; this affected subgroup is so small that their cost is small or *de minimis* when spread to the entire pool of insureds.

The mandates for cancer, diabetes, and colorectal screening, in that order, were the most costly of the 11 mandates. The other 8 mandates all cost less than \$1 PMPM each. All the mandates are required to be covered by CT insurers and, as such, they add to the medical and administrative cost of insurance plans for all fully insured residents of CT.

The costs of the two most expensive mandates, diabetes and cancer, reflect the broad and general nature of the mandate language. Although the original intent of these mandates may have been to avoid the denial of a small percentage of controversial claims associated with diabetes or cancer, as written, these mandates require carriers to cover a broad range of medically necessary claims associated with these two diseases. Thus, the net new cost of each mandate is less than the mandate cost.

In this report, the 11 mandates in set one have been commented on. IC will provide three similar reports for the rest of the mandates covered by sets two, three, and four and a brief final summary report covering all 45 mandates.

#### **LIMITATIONS IN USE OF THE ACTUARIAL REPORT:**

This study was conducted by IC exclusively for the State of CT, specifically and solely as it applies to the evaluation of the first eleven of the forty-five mandates covered by Public Act Number 09-179. This report is not intended for any other application or purpose. This Limitations section applies to the actuarial report. The financial / economic report included in this Set One 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](mailto: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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APPENDIX ONE

**WEIGHTED AVERAGE COST OF EACH MANDATE  
ACROSS ALL CARRIERS**

		<b>GROUP</b>			
		<b>ALLOWED</b>		<b>PAID</b>	
		<b>2007</b>	<b>2008</b>	<b>2007</b>	<b>2008</b>
<b>MANDATE</b>	<b>DESCRIPTION</b>				
1	Diab Self Mgmt Trng	\$ 0.07	\$ 0.06	\$ 0.06	\$ 0.06
2	PSA	\$ 0.18	\$ 0.19	\$ 0.16	\$ 0.17
3	Ostomy Supplies	\$ 0.07	\$ 0.07	\$ 0.06	\$ 0.06
4	Hearing Aids	\$ 0.01	\$ 0.01	\$ 0.01	\$ 0.01
5	Ortho for Cleft Palate	\$ 0.02	\$ 0.02	\$ 0.02	\$ 0.02
6	Hospital Dental w/ GA	\$ 0.05	\$ 0.07	\$ 0.04	\$ 0.06
7	Diab Test & Trtmnt	\$ 4.47	\$ 4.92	\$ 3.72	\$ 4.17
8	Birth to 3	\$ 0.16	\$ 0.16	\$ 0.14	\$ 0.15
9	Lyme Disease	\$ 0.33	\$ 0.31	\$ 0.27	\$ 0.25
10	CRC Screening	\$ 3.42	\$ 3.54	\$ 2.98	\$ 3.10
11	Tumors, Leukemia, etc	\$ 10.99	\$ 11.13	\$ 9.95	\$ 10.10
<b>TOTAL</b>		<b>\$ 19.76</b>	<b>\$ 20.49</b>	<b>\$ 17.41</b>	<b>\$ 18.13</b>

		<b>INDIVIDUAL</b>			
		<b>ALLOWED</b>		<b>PAID</b>	
		<b>2007</b>	<b>2008</b>	<b>2007</b>	<b>2008</b>
<b>MANDATE</b>	<b>DESCRIPTION</b>				
1	Diab Self Mgmt Trng	\$ 0.02	\$ 0.02	\$ 0.02	\$ 0.02
2	PSA	\$ 0.16	\$ 0.16	\$ 0.09	\$ 0.10
3	Ostomy Supplies	\$ 0.02	\$ 0.02	\$ 0.02	\$ 0.02
4	Hearing Aids	\$ 0.00	\$ 0.01	\$ 0.00	\$ 0.01
5	Ortho for Cleft Palate	\$ 0.06	\$ 0.03	\$ 0.06	\$ 0.03
6	Hospital Dental w/ GA	\$ 0.15	\$ 0.18	\$ 0.14	\$ 0.17
7	Diab Test & Trtmnt	\$ 0.63	\$ 0.59	\$ 0.46	\$ 0.51
8	Birth to 3	\$ 0.24	\$ 0.24	\$ 0.23	\$ 0.23
9	Lyme Disease	\$ 0.44	\$ 0.44	\$ 0.33	\$ 0.31
10	CRC Screening	\$ 1.72	\$ 2.04	\$ 1.20	\$ 1.53
11	Tumors, Leukemia, etc	\$ 7.78	\$ 8.79	\$ 6.49	\$ 7.82
<b>TOTAL</b>		<b>\$ 11.22</b>	<b>\$ 12.52</b>	<b>\$ 9.05</b>	<b>\$ 10.73</b>

**APPENDIX TWO**

**AVERAGE COST SHARING  
ACROSS ALL CARRIERS**

MANDATE	DESCRIPTION	GROUP		INDIVIDUAL	
		2007	2008	2007	2008
1	Diabetes Self Mgt Trng	\$ 0.01	\$ 0.00	\$ 0.00	\$ 0.00
2	PSA	\$ 0.02	\$ 0.02	\$ 0.07	\$ 0.07
3	Ostomy Supplies	\$ 0.01	\$ 0.01	\$ 0.00	\$ 0.00
4	Hearing Aids	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00
5	Ortho for Cleft Palate	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00
6	Hospital Dental w/ GA	\$ 0.00	\$ 0.01	\$ 0.01	\$ 0.02
7	Diab Test & Trtmnt	\$ 0.75	\$ 0.75	\$ 0.17	\$ 0.08
8	Birth to 3	\$ 0.01	\$ 0.01	\$ 0.01	\$ 0.01
9	Lyme Disease	\$ 0.06	\$ 0.06	\$ 0.10	\$ 0.12
10	CRC Screening	\$ 0.44	\$ 0.44	\$ 0.52	\$ 0.51
11	Tumors, Leukemia, etc	\$ 1.04	\$ 1.03	\$ 1.54	\$ 1.26
<b>TOTAL</b>		<b>\$ 2.35</b>	<b>\$ 2.35</b>	<b>\$ 2.43</b>	<b>\$ 2.07</b>

**COST SHARING AS % OF ALLOWED CHARGES**

MANDATE	DESCRIPTION	GROUP		INDIVIDUAL	
		2007	2008	2007	2008
1	Diabetes Self Mgt Trng	13.9%	5.9%	2.2%	5.1%
2	PSA	11.9%	12.5%	42.8%	40.5%
3	Ostomy Supplies	13.9%	15.5%	3.5%	3.6%
4	Hearing Aids	5.6%	9.5%	88.3%	1.0%
5	Ortho for Cleft Palate	5.1%	8.4%	7.4%	6.3%
6	Hospital Dental w/ GA	8.0%	9.9%	6.5%	8.9%
7	Diab Test & Trtmnt	16.8%	15.3%	26.8%	13.7%
8	Birth to 3	9.3%	7.2%	3.5%	5.9%
9	Lyme Disease	18.1%	19.5%	23.8%	27.9%
10	CRC Screening	12.9%	12.6%	30.2%	25.0%
11	Tumors, Leukemia, etc	9.4%	9.3%	13.3%	9.6%

## APPENDIX THREE

### 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 insurance plans. For a broader discussion of how group plans compare to the individual plans, please see the actuarial report.

#### Diabetic Self Management Training

Model was not used for this mandate

#### Prostate Screening - PSA Test

Assumptions:

- 1 Average cost per patient is \$31

INCOME	BENEFIT →	Member	Member	Member	HD Plan	Uninsured
		Share 10%	Share 20%	Share 30%		
↓ 50,000		0.01%	0.01%	0.02%	0.06%	0.06%
80,000		0.00%	0.01%	0.01%	0.04%	0.04%
160,000		0.00%	0.00%	0.01%	0.02%	0.02%

#### Ostomy Supplies

Assumptions:

- 1 For Patients with \$1850 Cost (Phase 1 describes this possibility).
- 2 Payer covers cost beyond mandate

INCOME	BENEFIT →	Member	Member	Member	HD Plan	Uninsured
		Share 10%	Share 20%	Share 30%		
↓ 50,000		1.90%	2.10%	2.30%	3.70%	3.70%
80,000		1.19%	1.31%	1.44%	2.31%	2.31%
160,000		0.59%	0.66%	0.72%	1.16%	1.16%

## Hearing Aids

### Assumptions:

- 1 The patient bought two hearing aids in the same plan year @\$2,250/unit
- 2 Also looked at impact for uninsured if they buy cheaper units @\$750/unit
- 3 Any other DME did not impact the availability of \$1,000 coverage

BENEFIT →

INCOME		Member Share 10%	Member Share 20%	Member Share 30%	HD Plan	Uninsured	Uninsured (Cheaper \$750/Unit)
↓	50,000	7.20%	7.40%	7.60%	9.00%	9.00%	3.00%
	80,000	4.50%	4.63%	4.75%	5.63%	5.63%	1.88%
	160,000	2.25%	2.31%	2.38%	2.81%	2.81%	0.94%

## Orthodontic Services for Cleft Palate

### Assumptions:

- 1 The cost of care is spread over a number of years and varies by age of patient. The annual cost burden calculation is done for first 2-3 years when the major surgery/repair is done.
- 2 surgery/repair is done.
- 3 We assumed \$2,000/year expenditure.

BENEFIT →

INCOME		Member Share 10%	Member Share 20%	Member Share 30%	HD Plan	Uninsured
↓	50,000	0.40%	0.80%	1.20%	4.00%	4.00%
	80,000	0.25%	0.50%	0.75%	2.50%	2.50%
	160,000	0.13%	0.25%	0.38%	1.25%	1.25%

## Hospital Dental

### Assumptions:

- 1 We have assumed that medical cost of an encounter is \$5,000.

BENEFIT →

INCOME		Member Share 10%	Member Share 20%	Member Share 30%	HD Plan	Uninsured
↓	50,000	1.00%	2.00%	3.00%	5.60%	10.00%
	80,000	0.63%	1.25%	1.88%	3.50%	6.25%
	160,000	0.31%	0.63%	0.94%	1.75%	3.13%

## Diabetes Testing & Treatment

Assumptions:

- 1 The cost of care for the patient with controlled sugar level is assumed to be \$1,800

INCOME	BENEFIT →	Member	Member	Member	HD Plan	Uninsured
		Share 10%	Share 20%	Share 30%		
↓ 50,000		0.36%	0.72%	1.08%	3.60%	3.60%
80,000		0.23%	0.45%	0.68%	2.25%	2.25%
160,000		0.11%	0.23%	0.34%	1.13%	1.13%

Assumptions:

- 1 The cost of care for the sicker patient is assumed to be \$14,000

INCOME	BENEFIT →	Member	Member	Member	HD Plan	Uninsured
		Share 10%	Share 20%	Share 30%		
↓ 50,000		2.80%	5.60%	8.40%	9.20%	28.00%
80,000		1.75%	3.50%	5.25%	5.75%	17.50%
160,000		0.88%	1.75%	2.63%	2.88%	8.75%

## Birth to Three

Assumptions:

- 1 The cost of mandate covered care is assumed to be \$6,400 -- equal to the new max for the mandate.
- 2 For a family with income of \$50,000 with monthly payment to State of \$15 for the program, there is an additional \$180 annual cost plus the \$3,200 of the uncovered cost.

INCOME	BENEFIT →	Member	Member	Member	HD Plan	Uninsured
		Share 10%	Share 20%	Share 30%		
↓ 50,000		7.40%	8.04%	8.68%	11.64%	
80,000		5.03%	5.03%	5.43%	7.28%	
160,000		2.51%	2.51%	2.71%	3.64%	

## Lyme Disease

Assumptions:

- 1 The cost of medical care is assumed to be \$3000

INCOME	BENEFIT →	Member	Member	Member	HD Plan	Uninsured
		Share 10%	Share 20%	Share 30%		
↓	50,000	0.60%	1.20%	1.80%	4.80%	6.00%
	80,000	0.38%	0.75%	1.13%	3.00%	3.75%
	160,000	0.19%	0.38%	0.56%	1.50%	1.88%

## Colorectal Cancer Screening

Assumptions:

- 1 The cost of a colonoscopy is assumed to be \$1,500

INCOME	BENEFIT →	Member	Member	Member	HD Plan	Uninsured
		Share 10%	Share 20%	Share 30%		
↓	50,000	0.30%	0.60%	0.90%	3.00%	3.00%
	80,000	0.19%	0.38%	0.56%	1.88%	1.88%
	160,000	0.09%	0.19%	0.28%	0.94%	0.94%

## Cancer, Tumor etc.

Model was not used for this mandate



# Appendix III

## Index of Health Insurance Mandates



# INDEX OF MANDATES

<b>Volume I</b>	
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

<b>Volume II</b>	
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

<b>Volume III</b>	
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

<b>Volume IV</b>	
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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