



**Review and Evaluation of Proposed Legislation Entitled:
An Act Relative to Increasing Coverage for
Infertility Treatments
Senate Bill 485**

**Provided for
The Joint Financial Services Committee**

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Executive Summary

This report was prepared by the Division of Health Care Finance and Policy (DHCFP) pursuant to the provisions of M.G.L. c. 3 § 38C requiring DHCFP to review and evaluate the impact of a mandated benefit bill referred to the agency by a legislative committee. The Joint Financial Services Committee referred Senate 485 “An Act Relative to Increasing Coverage for Infertility Treatments” to DHCFP for review.

Please note that the following phrases are used throughout this paper to describe the two groups of women who are affected by Senate Bill 485 (S. 485):

- “Women over 35” is used to describe women over the age of 35. This term encompasses women who are at an advanced reproductive age, considered as such because they are over the age of 35 with steadily declining rates of fertility and increasing rates of miscarriage.
- “Women who miscarry” is used to describe women with the ability to conceive but are unable to carry a pregnancy to live birth. As used in this report, this term also encompasses women diagnosed with recurrent pregnancy loss (RPL), defined by having two or more failed pregnancies.¹

Overview of Current Law and Proposed Mandate

S. 485 would increase coverage for infertility treatments by changing the definition of infertility, as it exists under current law. These changes would bring Massachusetts in line with the definition approved in 2008 by the American Society of Reproductive Medicine (ASRM).²

The existing law defines “infertility” as the inability to conceive or produce conception during a period of one year.

S. 485 would provide access to coverage for infertility for “women over 35” and “women who miscarry” more quickly than they are provided today by most health insurers through two changes:

- The first change shortens the waiting period for coverage for infertility from 12 months to six months for women over 35. This change would allow women over 35 who are unable to conceive or produce conception during a period of six months to qualify for coverage.
- The second change requires insurers to include in the calculation of the 12-month or six-month period, depending on the woman’s age, the period of time she attempted to conceive prior to achieving a pregnancy that resulted in miscarriage. Currently, certain carriers may require women to attempt to achieve pregnancy on their own for an additional 12 months after a miscarriage, thereby restarting the clock after a miscarriage.

See Box 1 for a definition of infertility as approved by the ASRM, the current law, and the proposed law.³

Box 1: Definitions of Infertility

The intent of S. 485 is to bring the Massachusetts infertility benefit law in line with this most recently adopted definition developed by ASRM.

American Society for Reproductive Medicine (ASRM): “Infertility is a disease, defined by the failure to achieve a successful pregnancy rate after 12 months or more of regular unprotected intercourse. Earlier evaluation and treatment may be justified based on medical history and physical findings and is warranted after six months for women over age 35 years.”

Summary of Massachusetts State Law and Proposed Mandate: Current law defines infertility as “the condition of a presumably healthy individual who is unable to conceive or produce conception during a period of one year.” The current law applies to all ages evenly.

S. 485 defines infertility as “the condition of a presumably healthy individual who is unable to conceive or produce conception during a period of one year, if the female is age 35 or younger or during a period of six months if the female is over age 35. For purposes of meeting the criteria for infertility in this section, if a person conceives but is unable to carry that pregnancy to live birth, the period of time she attempted to conceive prior to achieving that pregnancy shall be included in the calculation of the one-year or six-month period, as applicable.”

Numerous other definitions exist with significant variation among states, and between insurers and providers. Key differences among definitions include: how long a woman should try to conceive “on her own” before coverage, and how miscarriage affects the waiting period.

The proposed bill would apply to the fully insured, commercial market to which the existing mandate applies. The existing mandate, which was enacted in 1987, applies to health insurers that cover pregnancy-related benefits to provide coverage for all medically necessary expenses of diagnosis and treatment of infertility.⁴ That market includes fully insured plans offered by commercial insurers, Health Maintenance Organizations (HMOs), and Blue Cross Blue Shield plans.

Currently health insurers differ in how they apply the definition of infertility under the existing mandate. Some insurers apply a one-year waiting period across all ages; other insurers have shorter waiting period (i.e., six months) for women of a more advanced reproductive age. Another difference exists among insurers between those that require women who miscarry to restart the waiting period if they miscarry, and those insurers that do not restart the clock.

Methodology

DHCFP prepared this review and evaluation of S. 485 by conducting interviews with stakeholders, including legislative staff; speaking with the experts in the fields of reproductive endocrinology and counseling on the psychosocial effects of infertility; interviewing insurers in the Commonwealth; reviewing the relevant literature on age-related infertility and miscarriage; and conducting an actuarial analysis of the fiscal impact of S. 485 (see Appendix).

DHCFP’s analysis focused on how the costs and use of infertility treatments would be affected by S. 485. The analysis was based on an understanding of the following: how health plan medical

policies influence treatment patterns and member behavior and how usage rates of available fertility treatment options (e.g. intrauterine insemination or in vitro fertilization) would likely change for women over 35 and women who miscarry if S. 485 were to be enacted.

Three different impact scenarios were developed – low, middle, and high – to present a range of the possible impact of the proposed mandate on premiums and total health plan expenditures. Summary-level data from Massachusetts health plans was used to assess the reasonableness of estimates developed.

Results

In 2009, the projected increase in spending that would result from S. 485 ranges from 0.04% to 0.31% of premiums or \$4.4 million to \$33.1 million. The impact on per member per month (PMPM) premiums ranges from \$0.16 to \$1.20.

The five-year impact results are displayed in Exhibit 1. In 2009, three scenarios – low, middle, and high – were modeled resulting in estimated increased total spending (including both claims spending and administrative expenses). These three scenarios were then trended forward five years using annual trend rates of 6.3%, 7.3%, and 8.3%, respectively.

Exhibit 1: Estimated Cost Impact of S. 485 on Fully Insured Health Care Premiums (2009-2013)

	2009	2010	2011	2012	2013	All 5 Years
Fully Insured Enrollment	2,300,000	2,300,000	2,300,000	2,300,000	2,300,000	
Low Scenario						
Annual Impact Claims (000s)	\$3,948	\$4,198	\$4,463	\$4,745	\$5,045	\$22,400
Annual Impact Administration (000s)	\$439	\$466	\$496	\$528	\$561	\$2,489
Annual Impact Total (000s)	\$4,387	\$4,664	\$4,959	\$5,273	\$5,606	\$24,889
Premium Impact (PMPM)	\$0.16	\$0.17	\$0.18	\$0.19	\$0.20	
Middle Scenario						
Annual Impact Claims (000s)	\$13,203	\$14,276	\$15,322	\$16,444	\$17,648	\$76,992
Annual Impact Administration (000s)	\$2,175	\$2,228	\$2,391	\$2,566	\$2,754	\$12,016
Annual Impact Total (000s)	\$15,378	\$16,504	\$17,713	\$19,010	\$20,402	\$89,008
Premium Impact (PMPM)	\$0.56	\$0.60	\$0.64	\$0.69	\$0.74	
High Scenario						
Annual Impact Claims (000s)	\$26,652	\$28,870	\$31,273	\$33,876	\$36,696	\$157,367
Annual Impact Administration (000s)	\$6,415	\$6,949	\$7,527	\$8,154	\$8,832	\$37,877
Annual Impact Total (000s)	\$33,067	\$35,819	\$38,800	\$42,030	\$45,528	\$195,244
Premium Impact (PMPM)	\$1.20	\$1.30	\$1.41	\$1.52	\$1.65	

Introduction

Massachusetts currently has the most comprehensive mandate law for the coverage of infertility services in the nation. This law, which was enacted in 1987, requires all health insurers to provide coverage for all medically-necessary expenses of diagnosis and treatments of infertility, if the insurer covers pregnancy-related benefits.

The law defines infertility as “the condition of a presumably healthy individual who is unable to conceive or produce conception during a period of one year.”⁵

S. 485 would make two changes to the existing definition of infertility: (1) The first change would shorten the waiting period for coverage from 12 months to six months for women over 35; and (2) The second change would require insurers to include in the calculation of the 12-month or six-month period, depending on the woman’s age, the period of time she attempted to conceive prior to achieving a pregnancy that resulted in miscarriage. Coverage among Massachusetts insurers is currently inconsistent around the waiting periods for women of advanced reproductive age and for women who miscarry. The enactment of S. 485 would bring Massachusetts in line with the definition approved in 2008 by the American Society of Reproductive Medicine (ASRM) and bring a level of consistency to health plan coverage policies related to waiting periods by age and treatment of miscarriage.

This introductory section summarizes the scope of the current Massachusetts law and describes how private insurance coverage for infertility would change under the proposed mandate.

Summary of Current Coverage and Law

Current Massachusetts law mandates that health insurers provide coverage for all medically necessary expenses of diagnosis and treatments of infertility, if the insurer covers pregnancy-related benefits. Infertility is defined as “the condition of a presumably healthy individual who is unable to conceive or produce conception during a period of one year.”

All six insurers that DHCFP surveyed provide coverage for medically necessary expenses of diagnosis and treatments of infertility. Coverage is most consistent around the requirements for in vitro fertilization (IVF), with most insurers requiring that least costly treatment options, such as intrauterine insemination (IUI), be attempted prior to moving to IVF, when appropriate. (If the cause of infertility were severe male factor infertility, for example, IUI would be an inappropriate first-stage treatment option.) Coverage among Massachusetts insurers is least consistent around the waiting periods for women of advanced reproductive age and for women who miscarry, with an effective waiting period across insurers ranging from six months to over two years.

Summary of Proposed Mandate

S. 485 proposes to amend the definition of infertility in two ways that will grant two groups of women, “women over 35” and “women who miscarry” with access to coverage sooner than they can often receive under existing law.

The proposed mandate makes two changes to the existing definition of infertility: (1) The first change shortens the waiting period for coverage from 12 months to six months for women over 35; and (2) The second change would require insurers to include in the calculation of the 12-month or six-month period, depending on the woman’s age, the period of time she attempted to conceive prior to achieving a pregnancy that resulted in miscarriage.

The proposed mandate changes would apply to the fully insured, commercial market to which the existing mandate applies. The existing mandate, which was enacted in 1987, applies to health insurers that cover pregnancy-related benefits to provide coverage for all medically necessary expenses of diagnosis and treatment of infertility. That market includes fully insured plans offered by commercial insurers, Health Maintenance Organizations (HMOs), and Blue Cross Blue Shield plans. That market excludes other insurers. The proposed mandate does not apply to the self-insured.

While Massachusetts currently has the most comprehensive mandate for infertility coverage in the nation, this analysis assumed that demand for infertility services would still increase as a result of the proposed bill.⁶ That assumption was confirmed in several ways:

- by conferring with experts in the field of reproductive medicine;
- by conducting a bifurcated analysis of claims data from health insurers with differing waiting periods of six and 12 months to examine the impact of those different coverage policies on demand for infertility treatments, and
- by analyzing the data from a large provider of reproductive medicine in Massachusetts on those who “self pay” for infertility treatments.

Many factors will ultimately affect the increase in demand for infertility treatments in response to S. 485. Some of these factors were captured in the analysis, including the age of the woman and requirements set forth in the medical policies by each insurer. Other factors could not be captured, however, including: the age of the man, reasons for infertility, the length of efforts to conceive, the health of the woman, and the preference of the woman and couple to pursue treatment options.⁷

Background

In this section, DHCFFP provides an overview of the prevalence and causes of infertility, a discussion of treatment options for infertility, a synopsis of existing health insurance coverage by insurers in Massachusetts, and a summary of federal activity and mandates in other states.

Infertility: Prevalence and Causes

Infertility is a medical condition with a psychological component that afflicts approximately 12.5 percent of women of reproductive age in the United States, or one in 8 couples.⁸ Women between the ages of 15 and 44 are considered to be of reproductive age.

The disease itself may best be viewed along a continuum, depending upon the severity of the cause. Causes may range in nature from the more mild type caused by “male factor” infertility to more severe types such as diminished ovarian reserve. Recurrent pregnancy loss (RPL), which is defined as two or more consecutive spontaneous miscarriages and a separate diagnosis from infertility, would also be considered to be a severe medical condition.⁹

There are many causes of infertility. Between 80 and 90 percent of the cases of infertility can be explained through diagnosis and testing.¹⁰ About one-third of the cases are attributable to factors affecting women, one-third due to male infertility, and one-third caused by a combination of problems in both partners. Female factors include tubal disease or obstruction, ovarian dysfunction or failure to ovulate, and cervical factors (where the sperm can’t effectively pass the cervix), and uterine abnormalities. Ten to twenty percent of the cases of infertility cannot be explained.

As women advance in their reproductive years, a steady and rapid decline in the number of viable follicles and egg quality creates the number one cause of infertility: age.¹¹ Women of advanced reproductive age face a declining fertility rate compounded by an increase in the rate of spontaneous miscarriage. This occurs as a result of a high incidence of abnormalities in aging oocytes.¹² See Box 2 for more information on the effect of age on fecundity, or the ability to reproduce.¹³

Fertility Treatment Options

In general, a woman is considered “infertile” if she has not achieved a successful pregnancy within a specified period of time of unprotected intercourse. That period of time is typically within one year if she is 35 years of age or younger or within six months if she is 35 or older.¹⁴ After the age-appropriate time period has elapsed, the absence of a pregnancy that results in a live birth would lead a woman to pursue evaluation and treatment for her condition.

The first step in the process is the evaluation of her condition, and that of her partner. The evaluation process includes all or some of the following: a history and physical exam, further testing including a semen analysis, a hysterosalpingogram, as well as other tests to evaluate reproductive

Box 2: Fecundity and Age

According to *Clinical gynecologic endocrinology and infertility*, “fecundity is a function of both the ability to conceive (fertility) and the rate of spontaneous miscarriage.” Conception and miscarriage are part of the same natural process.

Among the general population, the monthly rate of fecundity, or the ability to reproduce, is estimated to be 15-20 percent. Yet, cumulative pregnancy rates after 12 months by age group underscore the role that age plays in reproducing. The data on cumulative pregnancy rates after 12 months by age group demonstrates a decline in rates as the age of the woman increases: 74 percent for those younger than 31, 62 percent for those 31 to 35, and 54 percent for those older than 35 years of age. It follows from this data that the rate of infertility increases for women as they age. It is also worth mentioning that 78-85 percent of pregnancies occur within the first six months of efforts to conceive. A much smaller percentage of pregnancies (15 to 20 percent) occur between six and 12 months.

As women age, not only does the rate of pregnancy decline but the rate of miscarriage increases. The data on the rate of miscarriage by age group demonstrates an increase in rates as the age of the woman increases: between 7 and 15 percent for those younger than 30, 8 to 21 percent for those 30-34, 17 to 28 percent for those 35 to 39, and between 34 and 52 percent for those women who are 40 years of age and older.

As the data on pregnancy and miscarriage indicates, age is the single most important factor for women when they are trying to have a family. It follows that most women will have their greatest chances of having a family when they are younger, with declining chances of getting pregnant when they are older.

functions and hormone levels (e.g., cycle day three Follicle-Stimulating Hormone (FSH) and estradiol tests).¹⁵ The evaluation process might also include a referral to a social worker to address the psychological component of her infertility.

The results of the tests can determine the cause(s) of infertility for 80 to 90 percent of the cases. Again, the causes may be due to female factors (e.g., reduced ovarian reserve, ovulatory dysfunction, uterine factor) or male factor or both. About 15 to 20 percent of couples who are diagnosed with infertility face a combination of factors.¹⁶

In general, a diagnosis of infertility will lead to a discussion of a range of treatment options between patient and doctor. This is the second step in the process. Fertility treatment options range in nature from the use of medicine to surgery to artificial intrauterine insemination (IUI) to assisted reproductive technology (ART), including in vitro fertilization (IVF). IVF is the most effective of all forms of treatment today, as a result of the control that it exerts over the process.¹⁷

In Massachusetts today, treatment protocols established by insurers tend to require that women try one to three IUIs before granting approval for coverage of IVF, with most insurers having a lower IUI requirement for women of advanced reproductive age.

See Box 3 for an outline of fertility treatment options, and their corresponding rates of success and costs.¹⁸

Box 3: Fertility Treatment Options

Today, three basic types of fertility treatment options exist, with a range of costs and success rates. These three options include Ovulation induction (OI), Intrauterine insemination (IUI), and In vitro fertilization (IVF):

- OI is a term for the stimulation of ovulation in the anovulatory patient.
- IUI is a term for the procedure that involves placing sperm inside a woman’s uterus to facilitate fertilization. An IUI may involve medication or not. Ovulation induction and IUI are not considered assisted reproductive technology (ART) procedures, because these treatments do not involve the manipulation of a woman’s eggs and sperm though they may involve the stimulation of egg production.
- IVF is a term for the process of “fertilization by manually combining an egg and sperm in a laboratory dish. When the IVF procedure is successful, the process is combined with a procedure known as embryo transfer to physically place the embryo in the uterus.” IVF also serves as a “platform” for other treatment options including gamete intrafallopian transfer, zygote intrafallopian transfer, embryo cryopreservation, egg or embryo donation, and surrogate birth.

IUI is the most common option for treatment of infertility today. Rates of success, as measured by live birth, are highest for those who are under 25 (26.7 percent) and lowest for women over 40 (8.5 percent).

IVF is the most effective form of treatment today, yet it is the most expensive and involved of all treatment options. Rates per cycle initiated are highest for those under 35 (37.3 percent) and lowest for women age 41 to 42 (11 percent). Those rates are specific to non-donor egg cycles. (Rates for women for donor-egg cycles are different, particularly for those women of advanced reproductive age.)

The cost between IVF and IUI cycles vary considerably. An IVF cycle can run as much as \$10,000 to \$15,000 per cycle, while the cost of an IUI cycle might run around \$1,000, reflecting a mix of type cycles: a “natural” cycle that is unmedicated or a medicated IUI cycle.

Health Insurers

Health Insurers in Massachusetts currently provide coverage for infertility treatments, as mandated by law today. See Box 4 for more information on ART cycles in Massachusetts.¹⁹

Coverage levels can vary across health plans, however. Based upon a review of medical policies available online, DHCFP prepared a chart of the coverage for six health insurers in Massachusetts. All six health insurers reviewed the responses on this chart for accuracy. The following statements generalize the policies of the health insurers and are intended to clarify current health insurance coverage overall with respect to the two major changes introduced by S. 485:

- Insurers show a divide in establishing age-related waiting periods: On the one hand, three of the six insurers require that women wait 12 months before meeting the definition of

infertility, without regard to age. On the other hand, three of the six insurers require that women wait 12 months if the female is age 39 or younger or six months if the female is 40 and older. None set the age benchmark at 35 as is proposed by S. 485.

- Insurers show a mix of responses to miscarriage. All six of the insurers distinguish between pregnancies that occur spontaneously and those that are the result of infertility treatments. If the pregnancy is not spontaneous and is the result of infertility treatments, then all of the six insurers indicated that a miscarriage of a pregnancy from infertility treatments would have no effect on the waiting period. If the pregnancy is spontaneous, however, the policy depends upon the insurer. Two of the six insurers indicated that a miscarriage would not restart the waiting period to determine infertility, with one of those two insurers limiting the policy to only one miscarriage. Three of the six insurers confirm that a miscarriage would restart the waiting period. One of the six insurers indicates having no policy on the issue.

Box 4: Assisted Reproductive Technology in Massachusetts

According to the Centers for Disease Control and Prevention (CDC), in 2007, there were close to 133,000 ART cycles performed in the United States.

In Massachusetts, there were close to 8,700 cycles, or approximately 6.5 percent of the total cycles nationwide. Close to 40 percent of the cycles in Massachusetts were performed on behalf of women 35 years of age and younger; 60 percent were performed on behalf of women over 35.

The data for Massachusetts reflects information from 7 fertility clinics and individual providers that report ART data to the CDC, including the three largest programs in the state (Boston IVF, Reproductive Science Center, Brigham and Women's ART Center) and the four smaller programs (Fertility Centers of New England, Vincent IVF (MGH), Baystate Reproductive Medicine, the Cardone Reproductive Medicine and Infertility, LLC).

Federal Activity

Administrative and Research Role

There is no federal law that mandates insurers to provide or offer infertility coverage for women. Government insurance programs such as the Federal Employee Health Benefits Program (FEHBP), the Medicaid program and Tricare, the military's health care program, are not required to provide coverage for infertility treatments for women.²⁰

However, the federal government plays a role in the collection of data and research:

- **Data collection:** Through the office of Reproductive Health of the Centers for Disease Control and Prevention (CDC), the federal government maintains the U.S. ART Clinic

Reporting System. This reporting system includes data, by clinic and by age, on all ART cycles nationwide. The reporting system includes all data from clinics and providers that are members of the Society for Assisted Reproductive Technology (SART).²¹

- Research: Through the National Institute of Health, the federal government has assumed a role in funding clinical trials for research purposes.²²

The Family Building Act of 2009

In this 111th session of Congress, which began on January 3, 2009, the “Family Building Act” (H.R. 697) was introduced in the House of Representatives by Representative Weiner (D-NY), and Representatives Filner (D-CA), Nadler (D-NY), Grijalva (D-AZ), Lowey (D-NY), Wasserman Schultz (D-Fla), Schwartz (D-PA), Lee (D-CA), Frank (D-MA), Israel (D-NY), Cohen (D-TN), and Price (D-NC).²³

H.R. 697 would amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986, to require coverage for the treatment of infertility.

More specifically, the Family Building Act of 2009, which is supported by the American Society for Reproductive Medicine, and RESOLVE: the National Infertility Association, would require that health insurers provide coverage of treatment of infertility if they provide coverage for obstetrical services. The legislation defines infertility “as a disease or condition that results in the abnormal function of the reproductive system,” which results in “(A) the inability to conceive after one year of unprotected intercourse, or (B) the inability to carry a pregnancy to live birth.”

The legislation is also very specific about required coverage and limitations on coverage of ART, with requirements around using less costly infertility treatments prior to providing coverage for ART and on the total number of oocyte retrievals.

The Federal Employees Health Benefit Program (FEHBP)

The health insurance program for federal employees provides coverage for cleft lip and cleft palate, including orthodontic treatment after surgery for closure of a cleft palate or cleft lip, or for correction of prognathism or micrognathism, with limits on lifetime benefits per person, and for oral surgical procedures including surgical correction of cleft lip or cleft palate.¹¹

State Activity

The majority of state infertility mandate laws were adopted over 20 years ago, including Massachusetts, while only a few states have enacted laws since that time. To date, 15 states including Massachusetts have adopted infertility laws. The 14 other states are: Arkansas, California, Connecticut, Hawaii, Illinois, Louisiana, Maryland, Montana, New Jersey, New York, Ohio, Rhode Island, Texas and West Virginia.²⁴

Compared to other states, Massachusetts offers women access to the most comprehensive coverage for infertility treatments.²⁵ DHCFP's analysis of the infertility laws nationwide suggests that no two laws are exactly alike. These differences are a likely reflection of how environmental differences such as religion, politics, and insurance markets affect mandate laws. State laws differ in several ways, including type of mandate, definitions, coverage, and in application of the mandate to policies. For example, some states impose the mandate on HMOs only.

All of the states, with the exception of California and Texas, mandate that required health insurers "cover" infertility treatments. California and Texas mandate only that required health insurers "offer" infertility services.

States differ markedly around the eligibility standard for coverage and the generosity of the coverage. At one extreme, the laws in Texas and Hawaii, for example, require evidence of a 5-year history of infertility regardless of age. At the other extreme, New York's definition falls in line with the definition used by the American Society of Reproductive Medicine.

Coverage differs among states too. New York and California specifically exclude coverage for IVF. In other states, laws are written in an open-ended manner, leaving decisions relative to the definitions and coverage up to the health insurer.

Methodological Approach

Overview of Approach

DHCFP engaged two consultants for this project: the actuarial firm Oliver Wyman Actuarial Consulting, Inc. (Oliver Wyman) and independent consultant Ellen Breslin Davidson of EBD Consulting Services, LLC. Oliver Wyman was hired to estimate the financial effect of the passage of S. 485. Ellen Breslin Davidson was hired to write the report, including reviewing and evaluating the legislation and working with Oliver Wyman to provide consultation on the methodology and assumptions for estimating the financial effects of S. 485. The Commonwealth Enterprise Group (CEG) secured the contract with DHCFP under which Ellen Breslin Davidson worked.

The following steps were taken to prepare the review and evaluation of S. 485:

1. Conducted Interviews with Stakeholders.

DHCFP conducted interviews with stakeholders in the Commonwealth to ensure that it was accurately interpreting the proposed change in law, to understand the perceptions about how the law would be interpreted, if enacted, and expectations about its likely impacts. Interviews were completed with legislative staff including Lisa Pelligrino from the office of Representative Ronald Mariano, and Elana Amaral from the office of Senator Thomas McGee, the bill's sponsor. Experts in reproductive medicine were consulted, including Dr. Mark Hornstein, Dr. Samuel Pang, Dr. Marc Fritz, Dr. Sigal Klipstein, as well as experts in the psychosocial implications of infertility. Meetings were also held with health insurers, and advocates from RESOLVE of the Baystate.²⁶

2. Reviewed Literature.

A review of the literature was conducted to determine the context of the proposed mandate, including the federal and state landscape.

3. Prepared and Collected Survey Data from the Health Plans.

DHCFP asked that the health plans review and provide input on a summary of their current coverage policies for infertility treatments.

4. Developed Baseline for Massachusetts.

DHCFP's actuarial firm developed a baseline of costs for those services that are currently covered by health insurance carriers.

5. Applied Assumptions and Sensitivity Analysis to Methodology.

Model parameters were developed to estimate the marginal premium cost of the proposed mandated benefits. Baseline premium costs were added to the marginal premium costs to estimate the total premium cost of the proposed mandate.

Approach for Determining Medical Efficacy

M.G.L. c. 3 § 38C (d) requires DHCFP to assess the medical efficacy of mandating the benefit, including the impact of the benefit on the quality of patient care and the health status of the population, and the results of any research demonstrating the medical efficacy of the treatment or service compared to alternative treatments or services or not providing the treatment or services. To determine the medical efficacy of S. 485, DHCFP conducted a literature review of the research on infertility and consulted with experts in the field of reproductive medicine.

Approach for Determining the Fiscal Impact of the Mandate

Legal Requirements

M.G.L. c. 3 § 38C (d) requires DHCFP to assess nine different measures in estimating the fiscal impact of a mandated benefit:

1. Financial impact of mandating the benefit, including the extent to which the proposed insurance coverage would increase or decrease the cost of the treatment or the service over the next five years;
2. Extent to which the proposed coverage might increase the appropriate or inappropriate use of the treatment or service over the next five years;
3. Extent to which the mandated treatment or services might serve as an alternative to a more expensive or less expensive treatment or service;
4. Extent to which the insurance coverage may affect the number or types of providers of the mandated treatment or service over the next five years;
5. Effects of mandating the benefit on the cost of health care, particularly the premium, administrative expenses and indirect costs of large employers, small employers and non group purchasers;
6. Potential benefits and savings to large employers, small employers, employees and non-group purchasers;
7. Effect of the proposed mandate on cost shifting between private and public payers of health care coverage;
8. Cost to health care consumers of not mandating the benefit in terms of out-of-pocket costs for treatment or delayed treatment; and
9. Effect on the overall cost of the health care delivery system in the Commonwealth.

Estimation Process

The following steps were followed to estimate the fiscal impact of this mandate:

- Estimate the size of the affected insured population;
- Estimate the baseline claims costs for the affected benefits;
- Estimate the utilization and cost if the mandate is passed; and
- Estimate the impact of administrative expenses of the relevant insurers.

Following these steps, estimates were made for a five-year timeframe (2009-2013) for a range of “low case” to “high case” scenarios. Differences between scenarios were driven by two factors:

1. Demand effects of women over 35.

DHCFP analyzed the impact of starting treatment up to six months earlier by comparing the claims data from those insurers with twelve-month waiting periods to those with six-month waiting periods. The results of this demand analysis demonstrate that total PMPM costs were five to 30 percent higher for carriers with six-month waiting periods than those with twelve-month waiting periods. DHCFP’s actuary varied the assumptions across scenarios using a rate of 5, 18, and 30 percent for low, middle and high scenarios, respectively. These assumptions represent the extent to which women over 35 will use IVF and IUI services at higher rates when waiting periods are six months compared to before the mandate.²⁷

2. Demand effects of women who miscarry.

DHCFP analyzed the impact of starting treatment sooner for women diagnosed with RPL who are most likely to face coverage exclusion by insurers today. Estimates of the impact on costs assumed that the 70 to 90 percent of this population is excluded from services today and will use services in the future at the same rate as current users of services.²⁸

For more detailed information on the methodological approach used to calculate the impact of S. 485 (including the approach to calculating administrative costs), refer to the Appendix of this report.

Summary of Findings

Medical Efficacy

Increasing coverage for infertility treatments would lead to providing an overall more medically-effective treatment approach to “women over 35” and “women who miscarry.” S. 485 would lead to higher rates of live births among these two groups of women, and would very likely lead to an overall improvement in the psychological well being and health of women diagnosed with infertility. The success rate for any individual woman from assisted reproductive technology would be dependent upon the cause of her infertility, among other factors.

In vitro fertilization is known throughout the medical community as “the most successful infertility treatment that can be offered” to patients with a history of fertility problems.²⁹ IVF typically involves four steps:

- Ovulation induction to stimulate the growth of multiple ovarian follicles;
- Oocyte retrieval (egg retrieval), which is performed under vaginal ultrasound guidance;
- Oocyte insemination, which involves placing sperm and eggs in a culture dish under a standard insemination; and (
- Embryo transfer, which is usually performed 72 hours after egg retrieval under abdominal ultrasound guidance. The number of embryos that are ultimately transferred will depend on a variety of factors, including the number and quality of the embryos, the woman’s age, cause of infertility, previous pregnancy history, and other factors. A pregnancy test is performed 10 or more days after the embryo transfer.

Over the decades, success rates have steadily increased for IVF for a number of reasons, including improved ovulation induction medications, refined laboratory techniques, and less traumatic embryo transfer catheters.³⁰ Another type of insemination method – intracytoplasmic sperm injection (ICSI) procedure – is also used over standard methods to improve success rates.

The list of procedures that are coupled with IVF is quite comprehensive, thereby expanding the treatment options for women, and includes: frozen embryo transfer (FET), natural cycle IVF, Gamete intrafallopian transfer (GIFT), tubal embryo transfer (TET), egg donation, gestational surgery, embryo donation, epididymal sperm aspiration. Such laboratory procedures as assisted hatching, blastocyst culture, preimplantation genetic diagnosis (PGD), and oocyte freezing have also served to improve treatment protocols and increase success rates.

Despite these advances, however, age continues to have a significant impact on success rates. The positive outcomes of IVF are greatest for relatively younger women than older women. According to the 2005 data reported by the Centers for Disease Control and Prevention, live birth rates per cycle initiated were 37.3 for under 35, decreasing to 30.2 for ages 35 to 37, 20.2 for ages 38 to 40, and 11 percent for ages 41-42. These results are reported for non-donor cycles. (Egg donation cycles run about 50.8% per embryo transfer.)³¹

The results of another study of more than 6,000 patients undergoing multiple IVF cycles (both fresh and frozen) in a single large center examines the chance of a live birth over an entire treatment course. The study shows that cumulative live birth rates among women 39 years of age or younger who were treated with up to six cycles of IVF appeared to be similar or higher than those reported in general population. The authors constructed an optimistic and conservative analysis of the data to bracket the results. Cumulative live-birth rates were 72 percent with the optimistic analysis and 51 percent with the conservative analysis. Among women younger than 35 years of age, the chance of a live birth ranged from 86 percent to 65 percent; among women 40 years of age and older, rates ranged between 42 percent and 23 percent. Based on these findings, the authors of this study concluded that “IVF may largely overcome infertility in younger women, but it does not reverse the age-dependent decline in fertility.”³²

As the research indicates, live-birth rates decrease with increasing age. It follows that women stand to benefit from S. 485 to the extent that the proposed mandate grants women access to treatment at a younger age by shortening the waiting period for coverage. Women would also have a greater number of chances for a baby by starting at a younger age. Women of advanced reproductive age stand to benefit more from S. 485 than women of younger reproductive age, regardless of the factors that delay their access to coverage today, by starting younger.³³

A recent study of women 40 years of age and older demonstrates the importance of “six months” to women in their later reproductive years, who face a diminishing ovarian reserve and poor embryo quality. In one such observational study of live birth rates and predictors of success in 1-year age increments for women 40 and older, over all cycles, live birth rates were revealed to be 28.4 percent at age 40, declining to 10.5 percent at age 43 and to 1.6 percent at age 44.³⁴ The authors conclude that women have a reasonable chance of a live birth up until the end of the 43rd year.

A shorter waiting period would also be medically efficacious for women diagnosed with infertility from a psychological perspective.³⁵ One particular study involving women preparing for a new course of assisted reproductive treatment indicates that infertility is a medical condition with significant psychological implications. The study found that women diagnosed with infertility have “significantly higher levels of depressive symptoms” and “twice the prevalence of depressive symptoms relative to fertile women,” resulting from their infertility. The rate of psychiatric conditions among “infertile women” was as high as 40.2 percent, largely attributable to generalized anxiety disorder and major depressive disorder.³⁶

Yet, S. 485 also introduces the risk that women with RPL will experience more pregnancy losses. Infertility treatments could lead to an increased number of miscarriages without a proven increase in the live birth rate.³⁷ Such negative consequences, however, may be lower for two mitigating reasons: first, women will have greater access to treatments at a younger age when live birth rates from IVF are highest; and second, women who conceive from IVF have about the same risk of miscarriage as those who spontaneously conceive, meaning that IVF itself will not increase their risk of miscarriage.³⁸

IVF can also introduce complications, such as multiple pregnancies from the implantation of more than one embryo and ovarian hyperstimulation syndrome. Many studies have also examined the

risk of birth defects in children conceived following assisted reproductive technologies. These studies are inconclusive, however, and do not clearly tie the risk to IVF itself.³⁹

Financial Impact of Mandate

1. *DHCFP is required to assess the extent to which the proposed coverage would increase or decrease the cost of the treatment or the service over the next five years.*

As noted above, DHCFP's actuarial consultants, Oliver Wyman Actuarial Consulting, Inc., estimated the fiscal impact of the bill (see Appendix).

- Estimated impacts of S. 485 on Massachusetts health care premiums for fully insured products were calculated assuming that the 2009 premium for a fully insured member is \$4,600.⁴⁰
- Low, middle and high scenarios assumed an increase in demand from both groups of women: (1) women over 35; and (2) women who miscarry. Demand increases were based on prevalence rates of infertility by age and condition paired with utilization rates of current users based on claims-level data from insurers.
- The combination of these assumptions, as well as administrative expense assumptions, produced estimates of the total cost of the mandated benefits. These estimates exclude consideration of other areas of cost, such as increased pregnancies, as well as other areas of savings, such as reduced mental health costs among "infertile" women.
- A range of impact scenarios were applied to baseline premium levels, producing estimated impacts on the premium of \$.16, \$.56, and \$1.20 Per Member Per Month (PMPM) in 2009, to determine the cost increase due to the proposed mandate.
- The PMPMs are multiplied by the fully insured population projection for the corresponding year to arrive at estimated annual impact dollar.

The five-year impact results are displayed in Exhibit 2. In 2009, these scenarios result in estimated increased total spending of approximately \$4.4 million, \$15.4 million, and \$33.1 million.

These results reflect an overall increase in demand for services that is very nearly split equally between the two groups of women affected by S. 485: women over 35 and women who miscarry.

2. *DHCFP is required to assess the extent to which the proposed coverage might increase the appropriate or inappropriate use of the treatment or service over the next five years.*

DHCFP anticipates that a change in the use of treatments and services will take place over the next five years. It is likely that some of this increase will be appropriate and some inappropriate, based on the understanding that treatment protocols are a reflection of established agreement between providers and insurers but the diagnosis of infertility is

**Exhibit 2:
Estimated Cost Impact of S. 485 on Fully Insured Health Care Premiums (2009-2013)**

	2009	2010	2011	2012	2013	All 5 Years
Fully Insured Enrollment	2,300,000	2,300,000	2,300,000	2,300,000	2,300,000	
Low Scenario						
Annual Impact Claims (000s)	\$3,948	\$4,198	\$4,463	\$4,745	\$5,045	\$22,400
Annual Impact Administration (000s)	\$439	\$466	\$496	\$528	\$561	\$2,489
Annual Impact Total (000s)	\$4,387	\$4,664	\$4,959	\$5,273	\$5,606	\$24,889
Premium Impact (PMPM)	\$0.16	\$0.17	\$0.18	\$0.19	\$0.20	
Middle Scenario						
Annual Impact Claims (000s)	\$13,203	\$14,276	\$15,322	\$16,444	\$17,648	\$76,992
Annual Impact Administration (000s)	\$2,175	\$2,228	\$2,391	\$2,566	\$2,754	\$12,016
Annual Impact Total (000s)	\$15,378	\$16,504	\$17,713	\$19,010	\$20,402	\$89,008
Premium Impact (PMPM)	\$0.56	\$0.60	\$0.64	\$0.69	\$0.74	
High Scenario						
Annual Impact Claims (000s)	\$26,652	\$28,870	\$31,273	\$33,876	\$36,696	\$157,367
Annual Impact Administration (000s)	\$6,415	\$6,949	\$7,527	\$8,154	\$8,832	\$37,877
Annual Impact Total (000s)	\$33,067	\$35,819	\$38,800	\$42,030	\$45,528	\$195,244
Premium Impact (PMPM)	\$1.20	\$1.30	\$1.41	\$1.52	\$1.65	

an “emotionally-charged” condition that might lead to treatments that are inappropriate for some women. DHCFP may be able to anticipate less delay in receiving appropriate treatments, and in particular for those who experience spontaneous pregnancy loss, due to the expansion of insurance coverage if the proposed bill were to be enacted.

3. *DHCFP is required to assess the extent to which the mandated treatment or services might serve as an alternative to a more expensive or less expensive treatment or service.*

DHCFP expects that by getting women into treatment sooner, certain women, such as those who currently miscarry, will actually require less costly treatments than they would require today. DHCFP does not anticipate that the mandated services will serve as an alternative to less expensive treatment or service for women over the age of 35 but very likely will result in the provision of more expensive treatments.

4. *DHCFP is required to assess the extent to which the insurance coverage may affect the number or types of providers of the mandated treatment or service over the next five years.*

Insurance coverage is not likely to affect the number or types of providers of the mandated treatment or service over the next five years.

5. *DHCFP is required to assess the effects of mandating the benefit on the cost of health care, particularly the premium, administrative expenses and indirect costs of large employers, small employers and non-group purchasers.*

S. 485 will lead to an increase in health plan administrative costs. Exhibit 2 includes administrative cost estimates.

6. *DHCFP is required to assess the potential benefits and savings to large and small employers, employees, and non-group purchasers.*

It is likely that this mandate would produce savings, but some of those savings have not been included in this report. Savings might result from the following factors: a reduction in the use of mental health services, and a potential reduction in the higher costs of pregnancy and delivery associated with multiple births. For instance, the research literature indicates that states with mandates have lower rates of multiple births than states that do not.⁴¹ Lower rates of multiples would translate into lower maternity costs from less complicated pregnancies and deliveries, for example. Overall, however, IVF has higher rates of multiples than IUI.

There are also additional costs that have not been included in the analysis, including the cost of additional pregnancies. It is expected that the net effect will be an increase in costs.

7. *DHCFP is required to assess the effect of the proposed mandate on cost shifting between private and public payers of health care coverage.*

The proposed mandate applies to commercial insurance carriers, Health Maintenance Organizations (HMOs), and Blue Cross Blue Shield plans. DHCFP can expect a shift from self-pay to health insurers.

8. *DHCFP is required to assess the cost to health care consumers of not mandating the benefit in terms of out-of-pocket costs for treatment or delayed treatment.*

It is reasonable to suggest that certain consumers would lower their out-of-pocket costs should S. 485 be enacted, since a certain percentage of women pay out-of-pocket to access assisted reproductive technologies that may either be currently denied or deferred by insurers.

9. *DHCFP is required to assess the effects on the overall cost of the health care delivery system in the Commonwealth.*

Should S. 485 be enacted, the overall cost of the health care delivery system in the Commonwealth will change. Some of this overall cost increase is a result of a shift in costs from individuals and couples to health insurers, but that cannot be quantified with the data available.

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Appendix: Actuarial Review of Massachusetts Senate Bill 485, An Act Relative to Increasing Coverage for Infertility Treatments

July 30, 2009

**Actuarial Review of Massachusetts Senate
Bill 485 An Act Relative to Increasing
Coverage for Infertility Treatments**

Massachusetts Division of Health Care
Finance and Policy

OLIVER WYMAN

Dianna K. Welch, FSA, MAAA



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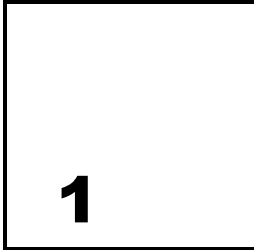
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Appendix A

Appendix B

Appendix C



Introduction and Executive Summary

Introduction

Pursuant to M.G.L. c.3 §38c, when reporting favorably on a mandated benefit bill, joint committees of the general court and the house and senate committees on ways and means are required to include a review and evaluation of the bill conducted by the Massachusetts Division of Health Care Finance and Policy (the Division).

The Division has contracted with Oliver Wyman Actuarial Consulting, Inc. (Oliver Wyman) to perform an actuarial review of Senate Bill 485 An Act Relative to Increasing Coverage for Infertility Treatments. Our analysis includes only the impact on the fully-insured, commercial market. This market includes fully-insured plans offered by commercial insurers, Health Maintenance Organizations (HMOs), and Blue Cross and Blue Shield Plans. It does not include Medicare Supplement or Medicare Advantage plans, Division of Medical Assistance, Commonwealth Care plans, the Group Insurance Commission, or individual products offered prior to July 1, 2007.

We have prepared this report for the sole use of the Division for the purpose described above, and we do not authorize parties other than the Division to use the information contained herein. Any party other than the Division who chooses to use or rely on the information presented in this report does so without our authorization. This report is not intended to be a legal interpretation of the bill as written.

Executive Summary

Senate Bill 485 (S. 485) would expand upon currently mandated coverage for infertility diagnosis and treatment. The current mandate defines infertility as the condition of a presumably healthy individual who is unable to conceive or produce conception during a period of one year. This bill would expand coverage by defining infertility as the inability to conceive or produce conception during a period of twelve months if the woman is age 35 or younger, or six months if the woman is over age 35. In addition, if a person conceives but is unable to carry the pregnancy to live birth, then the period of time she attempted to conceive prior to achieving that pregnancy will be included in the calculation of the twelve month or six month period. The full text of the bill is in Appendix A. The existing mandate that applies to commercial insurers, and HMOs by reference to the commercial insurer statute, can be found in Appendix B. The existing mandate that applies to Blue Cross and Blue Shield plans contains similar language to that shown in Appendix B.

We estimated the financial impact of the mandate on total and marginal costs. The total cost estimate reflects the full cost of the covered benefits mandated by the bill based on our assumptions of cost and utilization levels that would exist under a mandate. However, carriers are already providing many of the services that would be mandated. For those services there is no additional cost associated with the mandate relative to what they are paying currently. The marginal cost estimate reflects only the costs that are expected to be realized in addition to the costs of currently covered benefits for the affected population. Our estimates of the cost impacts of the mandated benefits on the fully-insured commercial market for the five-year projection period from 2009 through 2013 are included in the tables following. Exhibit 1 shows the estimates on a per member per month (PMPM) basis, while Exhibit 2 shows the dollar estimates.

Our estimates reflect only the impact on claims and premium from infertility procedures and prescription drugs. The estimates do not include other indirect cost impacts that could result from the change in infertility treatments. Indirect cost impacts could include, but are not limited to, the following:

- Change in number of pregnancies covered
- Change in costs related to miscarriages
- Change in incidence of more complicated pregnancies with twins or higher order multiples
- Change in mental health costs

We estimate the total impact on premiums of the mandated benefits for the period from 2009 through 2013 to be approximately \$494 million to \$772 million. On a marginal basis, we estimate that the mandate would increase premiums by \$25 million to \$195 million for the period from 2009 through 2013. The total premium cost estimates represent an increase in premium of 0.82% to 1.22%. The marginal cost estimates represent an increase in premium of 0.04% to 0.31%.

Exhibit 1

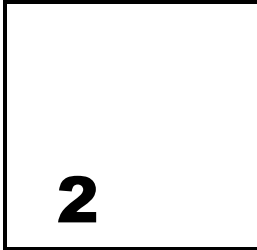
PMPM Claims and Premium due to S. 485 Mandated Benefits

Marginal Cost			<u>2009</u>	<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>
Claims	Low		\$0.14	\$0.15	\$0.16	\$0.17	\$0.18
	Middle		\$0.48	\$0.52	\$0.56	\$0.60	\$0.64
	High		\$0.97	\$1.05	\$1.13	\$1.23	\$1.33
Premium	Low		\$0.16	\$0.17	\$0.18	\$0.19	\$0.20
	Middle		\$0.56	\$0.60	\$0.64	\$0.69	\$0.74
	High		\$1.20	\$1.30	\$1.41	\$1.52	\$1.65
Total Cost			<u>2009</u>	<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>
Claims	Low		\$2.84	\$3.02	\$3.21	\$3.41	\$3.63
	Middle		\$3.26	\$3.49	\$3.75	\$4.02	\$4.32
	High		\$3.82	\$4.14	\$4.48	\$4.85	\$5.26
Premium	Low		\$3.16	\$3.35	\$3.57	\$3.79	\$4.03
	Middle		\$3.76	\$4.04	\$4.33	\$4.65	\$4.99
	High		\$4.74	\$5.13	\$5.56	\$6.02	\$6.52

Exhibit 2

Claims and Premium due to S. 485 Mandated Benefits

Estimate of Commercially Insured Population		2,300,000	2,300,000	2,300,000	2,300,000	2,300,000	
Marginal Cost (in \$000's)		<u>2009</u>	<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2009 - 2013</u>
Claims	Low	\$3,948	\$4,198	\$4,463	\$4,745	\$5,045	\$22,400
	Middle	\$13,302	\$14,276	\$15,322	\$16,444	\$17,648	\$76,992
	High	\$26,652	\$28,870	\$31,273	\$33,876	\$36,696	\$157,367
Premium	Low	\$4,387	\$4,664	\$4,959	\$5,273	\$5,606	\$24,889
	Middle	\$15,378	\$16,504	\$17,713	\$19,010	\$20,402	\$89,008
	High	\$33,067	\$35,819	\$38,800	\$42,030	\$45,528	\$195,244
Total Cost (in \$000's)		<u>2009</u>	<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2009 - 2013</u>
Claims	Low	\$78,377	\$83,333	\$88,602	\$94,205	\$100,162	\$444,679
	Middle	\$89,851	\$96,431	\$103,493	\$111,072	\$119,206	\$520,053
	High	\$105,360	\$114,130	\$123,629	\$133,919	\$145,066	\$622,105
Premium	Low	\$87,085	\$92,592	\$98,447	\$104,672	\$111,291	\$494,088
	Middle	\$103,874	\$111,481	\$119,645	\$128,407	\$137,811	\$601,217
	High	\$130,720	\$141,600	\$153,386	\$166,153	\$179,983	\$771,842



Analysis

Benefits

The benefit that this bill is intended to mandate is diagnosis and treatment of infertility. Many of these services are already covered by insurance carriers in Massachusetts. Currently, diagnosis and treatment of infertility is required to be covered for a presumably healthy individual who is unable to conceive or produce conception during a period of one year, regardless of the age of the female and whether prior conceptions produced a live birth. All commercial carriers, HMOs and Blue Cross and Blue Shield plans must provide this level of coverage. This proposed mandate bill would expand coverage by defining infertility as the condition of a presumably healthy individual who is unable to conceive or produce conception during a period of one year if the female is age 35 or younger or during a period of six months if the female is over age 35. In addition, if a person conceives but is unable to carry that pregnancy to live birth, the period of time she attempted to conceive prior to achieving that pregnancy would be included in the calculation of the twelve month or six month period, as applicable. Currently there are carriers in the market that use a twelve month time period to define infertility regardless of age, while others define infertility as twelve months of inability to conceive if the woman is under age 40 and only six months for women age 40 and older. The carriers' medical policies also vary as to whether pregnancies that end in miscarriage restart the period of time for determining infertility. This bill is intended to require all affected policies to include a six month time period for those aged 36 and older, and to include in the calculation the time attempting to conceive prior to a pregnancy that was unable to continue to live birth.

Process

The first step we took in estimating the impact of this bill was to understand the legislative intent of the bill. We held a conference call with Lisa Pellegrino, Health Policy Analyst, Financial Services Committee; Elana Amaral, Legislative Director for Senator Thomas M. McGee; policy analysts and consultants for the Division; members of

provider groups; and RESOLVE of the Bay State. Through this call and subsequent communications, we were able to gain an understanding of the intent of the bill. The legislative intent in changing the time period for women over 35 is to make the definition of infertility consistent with the definition published by the American Society for Reproductive Medicine (ASRM) as approved by their Board of Directors in February 2008. Their definition of infertility states:

“Infertility is a disease, defined by the failure to achieve a successful pregnancy after 12 months or more of regular unprotected intercourse. Earlier evaluation and treatment may be justified based on medical history and physical findings and is warranted after 6 months for women over age 35 years.”¹

The legislative intent of including in the calculation the period of time spent trying to conceive prior to a pregnancy that is unable to result in live birth is to address concerns about delaying treatment in women whose fertility is quickly declining due to age. It was noted during the conference call that Massachusetts has the highest average age of mother at first birth in the country. While the national average age at first birth was 25.0 in 2006, the average age at first birth was 27.7 in Massachusetts, higher than any other state.² The intent is to make treatment available at a younger age, when treatment may be more successful, and potentially less intensive.

Next, we estimated the financial impact of the bill. This involved estimating the size of the affected population, the targeted population that will utilize the service, the change in covered claims cost relative to current coverage in the market, and the administrative cost associated with the service. Additional detail explaining our analysis for each of these steps is provided in the sections that follow.

Affected Population

The population whose premiums will be affected by this mandate is the commercially insured population. To estimate the size of this population we reviewed the 2008 financial statements of companies filing Health Annual Statements with commercial membership in Massachusetts. However, there are companies that insure commercial members in Massachusetts that do not file Health Annual Statements. We included an estimate of members for companies not filing Health Annual Statements in our total membership estimate. We estimated a commercial insurance population of 2,367,000 as of the end of 2008 using this approach.

We also received enrollment data from the Division, based on carrier reporting of covered residents of Massachusetts. The enrollment data as of December 31, 2008 indicated enrollment of 2,198,000 in fully-insured commercial products. This figure was known to

¹ Practice Committee of the American Society for Reproductive Medicine, “Definitions of infertility and recurrent pregnancy loss”, September 2008. http://www.asrm.org/Media/Practice/Definitions_of_infertility.pdf

² National Vital Statistics Reports, Volume 57, Number 7, January 7, 2009. http://www.cdc.gov/nchs/data/nvsr/nvsr57/nvsr57_07.pdf

be understated due to reporting limitations of one of the carriers. Ultimately, we arrived at an estimate of 2,300,000 based on the two data sources that we reviewed.

Next we estimated the affected population as of 2009-2013 in order to perform our five-year projections. The U.S. Census Bureau has projected Massachusetts population to grow by 10.4% from 2000 to 2030.³ This represents an average annual growth rate of 0.3%. However, the population age 65 or greater is projected to grow at an annual rate of 1.8%. This corresponds to essentially no growth in the under 65 age group. Because the affected population is predominantly under age 65, we are projecting no change in the affected population over the five-year projection period.

Targeted Population

The targeted populations that would utilize the benefits mandated by S. 485 are women or couples that are trying to have a child and either a) the woman is over age 35 and has been unable to conceive for six months, or b) the woman has been unable to carry a pregnancy to live birth. For women who are 35 or younger who have not had a miscarriage, there is no change in coverage relative to currently mandated levels.

Women Over Age 35

For women over age 35 who have not had a miscarriage, the mandate would result in the availability of covered treatments starting up to six months earlier than currently available. For this study we obtained permission from six of the carriers that participated in the study that the Massachusetts Division of Insurance conducted, Trends in Health Claims for Fully-Insured, Health Maintenance Organizations in Massachusetts, 2002-2006⁴ (Trend Study) to use the data provided for that study to support this mandated benefit study. The list of the six participating carriers is in Appendix C. In addition, the participating carriers provided information on their infertility medical policies. As of May 2009, three of the six carriers define infertility as the inability to conceive after 12 months regardless of age. The other three define infertility as the inability to conceive after 12 months for women under age 40, and after 6 months for women age 40 and older. Therefore, the impact of the mandate for those age 40 and older would depend upon the insurance carrier.

³ U.S. Census Bureau, Population Division, Interim State Population Projections, 2005.

⁴ Oliver Wyman, Report to the Health Care Access Bureau of the Massachusetts Division of Insurance, Trends in Health Claims for Fully-Insured, Health Maintenance Organizations in Massachusetts, 2002-2006.

Miscarriage

The mandate would result in earlier availability of treatment for women who have been able to conceive but the pregnancy or pregnancies have resulted in miscarriage. One subset of this group is the population that has a diagnosis of recurrent pregnancy loss (RPL). The ASRM has defined RPL as follows⁵.

“Recurrent pregnancy loss is a disease distinct from infertility, defined by two or more failed pregnancies. When the cause is unknown, each pregnancy loss merits careful review to determine whether specific evaluation may be appropriate. After three or more losses, a thorough evaluation is warranted.”

It is estimated that less than 5% of women will experience two consecutive miscarriages and about 1% of women experience three or more.⁶ Those with RPL may not ever receive coverage for infertility treatment under the existing mandate, if a pregnancy is repeatedly achieved within twelve months and ends in miscarriage. Under the proposed mandate, these women would be able to have covered treatment after six or twelve months of attempting to conceive prior to the pregnancies that ended in miscarriage.

There are several potential causes of RPL. One such cause is a genetic chromosomal cause, such as translocation, which is found in less than 5% of couples that are tested.⁷ These couples may benefit from in vitro fertilization (IVF) with pre-implantation genetic diagnosis (PGD). In IVF procedures performed with PGD, the embryos are tested for the chromosomal abnormality prior to implantation. Most insurers do not currently cover IVF for couples who are able to conceive but miscarry, but would be required to cover it under the proposed mandate.

It is estimated that in 50% to 75% of couples with RPL there is no explanation for the condition.⁸ According to the Mayo Clinic, two losses is still often due to chance and not to an underlying medical cause.⁹ Without treatment, about 60 to 70% of women with RPL have a successful pregnancy on their next attempt.¹⁰

⁵ Practice Committee of the American Society for Reproductive Medicine, “Definitions of infertility and recurrent pregnancy loss”, September 2008. http://www.asrm.org/Media/Practice/Definitions_of_infertility.pdf

⁶ American Society for Reproductive Medicine, Patient’s Fact Sheet, Recurrent Pregnancy Loss, August 2008. http://www.asrm.org/Patients/FactSheets/recurrent_preg_loss.pdf

⁷ Ibid.

⁸ Ibid.

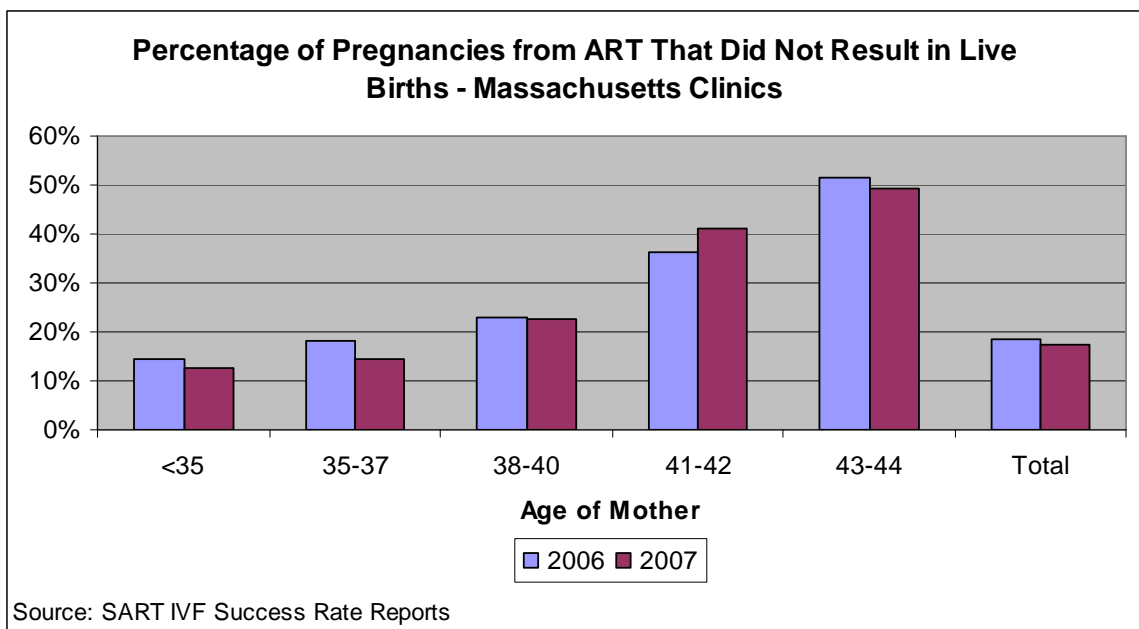
⁹ Mayo Clinic staff, Miscarriage, October 24, 2008. <http://www.mayoclinic.com/health/miscarriage/DS01105>

¹⁰ American Society for Reproductive Medicine, Patient’s Fact Sheet, Recurrent Pregnancy Loss, August 2008. http://www.asrm.org/Patients/FactSheets/recurrent_preg_loss.pdf

Many women experience miscarriage without RPL. About 25% of all recognized pregnancies end in miscarriage.¹¹ In 2006, 27% of assisted reproductive technology (ART) cycles performed nationwide among women who had not previously given birth, were reported by women who had had one or more previous miscarriages.¹² ART is generally synonymous with IVF.

The risk of miscarriage increases with age. At age 35, the risk is about 20%. At age 40, it increases to about 40%. At age 45, the risk is about 80%.¹³ We analyzed data published by the Society for Assisted Reproductive Technology (SART).¹⁴ SART publishes success rates for individual fertility clinics. We analyzed the clinics in Massachusetts, and observed the following percentage of pregnancies that were achieved using ART but did not result in live birth.

Exhibit 3



The graph shows the increase in miscarriages by age of the mother. The rates of miscarriage are similar to those reported for the general population, indicating that the use of ART does not decrease the rate of miscarriage. The proposed mandate would, however, make ART treatments a covered option for women who have had one or more miscarriages in six or twelve months of attempting to achieve a successful pregnancy.

¹¹ Ibid.

¹² U.S. Department of Health and Human Services Centers for Disease Control and Prevention, 2006 Assisted Reproductive Technology Success Rates: National Summary and Fertility Clinic Reports. <http://www.cdc.gov/ART/ART2006/508PDF/2006ART.pdf>

¹³ Mayo Clinic staff, Miscarriage, October 24, 2008. <http://www.mayoclinic.com/health/miscarriage/DS01105>

¹⁴ SART, IVF Success Rate Reports. <http://www.sart.org/>

Baseline Claims Costs

The next step of our analysis was to estimate the baseline claims costs, or those already being covered by the carriers. We analyzed the medical policies of the six carriers shown in Appendix C to understand their existing levels of coverage for infertility, and their levels of coverage in 2006, the most recent year for which we have claims data. All of the surveyed carriers are required to provide coverage at currently mandated levels. However, differences in medical policies result in differing levels of coverage. We reviewed the claims data of the carriers to estimate the costs of medical and pharmacy claims that are already being covered by all carriers. We observed an average 2006 claims PMPM of \$2.24 for these services.

Next we trended the claims cost from 2006 to 2009. We trended the claims using an annual cost per service trend of 7.3% for our middle estimate. This trend is our estimate of the average five-year cost per service trend for all medical and prescription drug services from the Trend Study. We do not believe that the prevalence of infertility has increased since 2006. Our review of the SART data showed a decrease in the number of ART cycles performed in 2007 relative to 2006. In addition, we are not aware that treatment protocols have changed that would lead to any change in utilization for those being treated for infertility. Therefore, we used only a cost per service trend, and not a total PMPM trend which includes the impact of cost per service and utilization changes. We trended the claims using annual cost per service trends of 6.3% and 8.3% for our low and high estimates, respectively. Applying these trends resulted in estimated claims PMPMs of \$2.69 to \$2.85 using 2009 payment levels and 2006 coverage levels.

Next, we estimated the 2009 claims PMPM using 2009 coverage levels. The medical policies of some carriers have changed since 2006. We estimate that the changes would have resulted in increased claims of approximately 0.1%, resulting in 2009 PMPMs of \$2.70 to \$2.85. This is the baseline estimate of claims already being covered.

Marginal Cost

To estimate the change in claim costs, we separately analyzed the impact of changing the definition from 12 months to six months for those aged 36 and older, and including the time spent trying to conceive prior to a miscarriage.

Six Month Time Period

During 2006, the most recent year for which we have claims data, some of the participating carriers required a twelve month period regardless of age, while others allowed a six month period for older women. The medical policies were quite similar in other respects. Therefore, we compared utilization rates and claims PMPMs for the carriers with a 12 month period at a given age to carriers with a six month period. We observed lower utilization rates and claims PMPMs for those with the twelve month period. There are several possible reasons for the lower claims costs:

- Some may achieve a successful pregnancy during months seven through twelve and therefore do not need infertility treatment that would have been sought if coverage were available sooner
- Some may decide during months seven through twelve not to pursue pregnancy
- Some may pay out of pocket in order to obtain services sooner; this is more likely to occur when there is a longer time period required

Utilization rates were higher for both IVF and intrauterine insemination (IUI). IUI is a less invasive and less expensive procedure that is often required by carriers to be tried prior to IVF, unless there is an underlying medical issue that would suggest that it would not be effective. Utilization rates for IVF and IUI were significantly higher for those carriers with a six month period. Total claims PMPMs were also higher, though by a smaller percentage. Many services are permitted by insurers prior to the time period being met, such as diagnosis-related services to determine whether there is a known cause of the infertility. Other services do not require prior authorization and therefore can be performed prior to the time period being met as well. Therefore, total medical costs do not increase in proportion with the increase in IVF and IUI utilization. We observed total increased costs of 5% to 30% PMPM when comparing carriers with a six month period to those with a twelve month period. Therefore, we assumed the change in definition would increase costs by 5%, 18%, and 30% for our low, middle, and high scenarios respectively for women aged 36 and older covered by carriers that are not already using the six month period, resulting in increased costs of 2.2% to 13.4% for infertility services.

Miscarriage

To estimate the impact of including the time period spent attempting to achieve a pregnancy that ends in miscarriage, we need to consider which additional treatments will be provided. As previously mentioned, carriers are covering diagnosis costs prior to meeting the definition of infertility. Therefore, diagnosis related costs are assumed to be included in the baseline costs. The increased costs that could arise would be due to increased use of IUI and IVF, which generally require prior authorization. We discussed earlier the potential use of IVF with PGD for those with inherited chromosomal causes. However, this is a very small percentage of the population and the use of PGD is somewhat controversial. The literature that we reviewed did not suggest IUI or IVF as a recommended treatment for those without an inherited chromosomal abnormality. IVF and IUI procedures do not decrease the risk of miscarriage within a given age group. However, providers that we interviewed recommended their use due to age-related benefits. Because both infertility rates and miscarriage rates increase with age, the providers indicated that these procedures can be beneficial by speeding pregnancy and therefore improving success rates because success rates are higher at younger ages. While the purpose of this report is not to determine whether this is medically efficacious, the provider input suggests that we should expect utilization of IVF and IUI to increase under the proposed mandate.

To estimate the magnitude of the increase, we first estimated the percentage of the infertile population that is expected to have RPL. The CDC estimates that 11.8% of women aged 15 to 44 have impaired fecundity, or impaired ability to have children.¹⁵ Estimates of the population with RPL range from approximately 1% to 3% of women, which represents approximately 8% to 25% of the population with impaired fecundity. We are assuming that approximately 10% to 30% of these women are already included in the baseline claims due to an underlying cause that would be covered by the carriers. If the remaining 70% to 90% experience utilization of IVF and IUI similar to others already covered, we would anticipate an increase in costs of 2.5% to 12.2%. This increase results from those carriers that do not already count the time prior to a miscarried pregnancy in the calculation. While not all women with RPL will necessarily want to pursue these treatments at the rate of other infertile women, at the same time there will also be women who have had only one miscarriage who because of their age may choose to pursue more aggressive treatment which has not been separately considered in the cost impact.

Administrative Expense and Profit

Increases in benefits also result in increases in administrative expenses and contributions to surplus or profit. In 2008, Oliver Wyman performed an expense study for the Division of Insurance¹⁶ (Expense Study). This was a five-year study that analyzed expense ratios and loss ratios of the Commonwealth's HMOs and Blue Cross and Blue Shield Plans. The study found that the average loss ratio in Massachusetts for 2002 through 2007 was 86.5%, meaning 13.5% of premium is available for retention items, including administrative expense and contribution to surplus. We used this 13.5% retention ratio to estimate the amount that would be included for retention in premium increases for the mandated benefits. The low and high ends of the ranges were based on the lowest and highest five-year average retention percentages of the health plans included in the analysis.

Results

The following Exhibit shows the results of our analysis.

¹⁵ Centers for Disease Control and Prevention, FastStats: Infertility. <http://www.cdc.gov/nchs/FASTATS/fertile.htm>

¹⁶ Oliver Wyman, Analysis of Administrative Expenses for Health Insurance Companies in Massachusetts, September 2008.

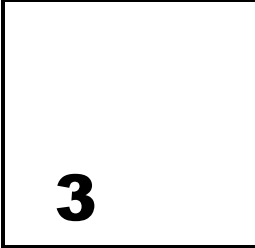
Exhibit 4

Development of Marginal Cost and Total Cost Estimates of S. 485

		<u>Low</u>	<u>Middle</u>	<u>High</u>
Baseline Cost Estimates				
Claims PMPM provided 2006	(A)	\$2.24	\$2.24	\$2.24
Claims trend	(B)	6.3%	7.3%	8.3%
Estimated claims PMPM provided 2009 for 2006 coverage levels	$(C) = A * (1+B) ^ 3$	\$2.69	\$2.77	\$2.85
% change in PMPM based on 2009 coverage levels	(D)	0.1%	0.1%	0.1%
Baseline Claims Cost PMPM	$(E) = C * (1+D)$	\$2.70	\$2.77	\$2.85
Admin & contribution to surplus ratio	(F)	10.0%	13.5%	19.4%
Baseline Premium PMPM (with Admin)	$(G) = E / (1-F)$	\$3.00	\$3.21	\$3.54
Marginal Cost Estimates				
Percentage change in PMPM due to 6 month instead of 12 month wait for those over age 35	(H)	2.2%	7.8%	13.4%
Percentage change in PMPM due to exclusion of miscarriage in time period	(I)	2.5%	6.7%	12.2%
Total percentage change due to S. 485	$(J) = (1+H) * (1+I) - 1$	4.8%	15.0%	27.3%
Marginal Claims Cost PMPM	$(K) = G * J$	\$0.14	\$0.48	\$0.97
Marginal Premium Increase PMPM (with Admin)	$(L) = K / (1-F)$	\$0.16	\$0.56	\$1.20
Total Cost Estimates				
Total Claims Cost PMPM	$(M) = E + K$	\$2.84	\$3.26	\$3.82
Total Premium PMPM (with Admin)	$(N) = G + L$	\$3.16	\$3.76	\$4.74

The total premium cost estimates represent an increase in premium of 0.82% to 1.22% based on an average annual premium per member of roughly \$4,600.¹⁷ The marginal cost estimates represent an increase in premium of 0.04% to 0.31%.

¹⁷ Average commercial group premium per member is from 2008 financial statements of companies filing health statements, trended to 2009 at an annual rate of 5%.



Five-Year Projection

The following two exhibits show the results of our five-year projection. Exhibit 5 shows the impact of the mandate on a PMPM basis. Premiums associated with the covered mandated benefits are estimated to range from \$3.16 PMPM to \$4.74 PMPM in 2009. On a marginal basis we would expect premiums and claims to increase by \$0.16 to \$1.20 PMPM in 2009. Exhibit 6 shows the total impact on the fully-insured commercial market.

Exhibit 5

PMPM Claims and Premium due to S. 485 Mandated Benefits

Marginal Cost			<u>2009</u>	<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>
Claims	Low		\$0.14	\$0.15	\$0.16	\$0.17	\$0.18
	Middle		\$0.48	\$0.52	\$0.56	\$0.60	\$0.64
	High		\$0.97	\$1.05	\$1.13	\$1.23	\$1.33
Premium	Low		\$0.16	\$0.17	\$0.18	\$0.19	\$0.20
	Middle		\$0.56	\$0.60	\$0.64	\$0.69	\$0.74
	High		\$1.20	\$1.30	\$1.41	\$1.52	\$1.65
Total Cost			<u>2009</u>	<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>
Claims	Low		\$2.84	\$3.02	\$3.21	\$3.41	\$3.63
	Middle		\$3.26	\$3.49	\$3.75	\$4.02	\$4.32
	High		\$3.82	\$4.14	\$4.48	\$4.85	\$5.26
Premium	Low		\$3.16	\$3.35	\$3.57	\$3.79	\$4.03
	Middle		\$3.76	\$4.04	\$4.33	\$4.65	\$4.99
	High		\$4.74	\$5.13	\$5.56	\$6.02	\$6.52

Exhibit 6

Claims and Premium due to S. 485 Mandated Benefits

Estimate of Commercially Insured Population		2,300,000	2,300,000	2,300,000	2,300,000	2,300,000	
Marginal Cost (in \$000's)		2009	2010	2011	2012	2013	2009 - 2013
Claims	Low	\$3,948	\$4,198	\$4,463	\$4,745	\$5,045	\$22,400
	Middle	\$13,302	\$14,276	\$15,322	\$16,444	\$17,648	\$76,992
	High	\$26,652	\$28,870	\$31,273	\$33,876	\$36,696	\$157,367
Premium	Low	\$4,387	\$4,664	\$4,959	\$5,273	\$5,606	\$24,889
	Middle	\$15,378	\$16,504	\$17,713	\$19,010	\$20,402	\$89,008
	High	\$33,067	\$35,819	\$38,800	\$42,030	\$45,528	\$195,244
Total Cost (in \$000's)		2009	2010	2011	2012	2013	2009 - 2013
Claims	Low	\$78,377	\$83,333	\$88,602	\$94,205	\$100,162	\$444,679
	Middle	\$89,851	\$96,431	\$103,493	\$111,072	\$119,206	\$520,053
	High	\$105,360	\$114,130	\$123,629	\$133,919	\$145,066	\$622,105
Premium	Low	\$87,085	\$92,592	\$98,447	\$104,672	\$111,291	\$494,088
	Middle	\$103,874	\$111,481	\$119,645	\$128,407	\$137,811	\$601,217
	High	\$130,720	\$141,600	\$153,386	\$166,153	\$179,983	\$771,842

We trended claims and premiums forward at the cost per service trends shown in Exhibit 4. By using the same trend for claims and premium, we are assuming that the loss ratio remains constant. Over the five-year period covered by the Expense Study, the Massachusetts total loss ratio fluctuated from year to year, but remained within 0.6% of the five-year average.

We estimate the total impact on premiums of the mandated benefits for the period from 2009 through 2013 to be approximately \$494 million to \$772 million. On a marginal basis, we estimate that the mandate would increase premiums by \$25 million to \$195 million for the period from 2009 through 2013. The total premium cost estimates represent an increase in premium of 0.82% to 1.22%. The marginal cost estimates represent an increase in premium of 0.04% to 0.31%.



SENATE DOCKET, NO. 1365 FILED ON: 1/14/2009

SENATE No. 485

The Commonwealth of Massachusetts

PRESENTED BY:
Thomas M. McGee

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the passage of the accompanying bill:

An Act relative to increasing coverage for infertility treatments.

PETITION OF:

NAME: _____ DISTRICT/ADDRESS: _____
Thomas M. McGee Third Essex and Middlesex

[SIMILAR MATTER FILED IN PREVIOUS SESSION

SEE SENATE, NO. S00599 OF 2007-2008.]

The Commonwealth of Massachusetts

—————
In the Year Two Thousand and Nine
—————

AN ACT RELATIVE TO INCREASING COVERAGE FOR INFERTILITY TREATMENTS.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. Section 47 H of chapter 175 of the general laws as appearing in the 2000 Official Edition is hereby amended by inserting after the word “year,” in line 23, the following words:- if the female is age 35 or younger or during a period of six months if the female is over age 35. *For* purposes of meeting the criteria for infertility in this section, if a person conceives but is unable to carry that pregnancy to live birth, the period of time she attempted to conceive prior to achieving that pregnancy shall be included in the calculation of the one-year or six-month period, as applicable.

SECTION 2. Section 8k of chapter 176A of the general laws as so appearing is hereby amended by inserting after the word “year,” in line 14, the following words:- if the female is age 35 or younger or during a period of six months if the female is over age 35. *For* purposes of meeting the criteria for infertility in this section, if a person conceives but is unable to carry that pregnancy to live birth, the period of time she attempted to conceive prior to achieving that pregnancy shall be included in the calculation of the one-year or six-month period, as applicable.

SECTION 3. Section 4J of chapter 176B of the general laws as so appearing is hereby amended by inserting after the word “year,” in line 15, the following words”- if the female is age 35 or younger or during a period of six months if the female is over age 35. *For purposes of meeting the criteria for infertility in this section, if a person conceives but is unable to carry that pregnancy to live birth, the period of time she attempted to conceive prior to achieving that pregnancy shall be included in the calculation of the one-year or six-month period, as applicable.*

Appendix B

CHAPTER 175. INSURANCE

PROVISIONS RESPECTING DOMESTIC COMPANIES

Organization

Chapter 175: Section 47H. Infertility, pregnancy-related benefits

Section 47H. Any blanket or general policy of insurance, except a blanket or general policy of insurance which provides supplemental coverage to medicare or other governmental programs, described in subdivisions (A), (C) or (D) of section one hundred and ten which provides hospital expense or surgical expense insurance which includes pregnancy-related benefits and which is issued or subsequently renewed by agreement between the insurer and the policyholder, within or without the commonwealth, while this provision is effective, or any policy of accident and sickness insurance as described in section one hundred and eight which provides hospital expense or surgical expense insurance which includes pregnancy-related benefits and which is delivered or issued for delivery or subsequently renewed by agreement between the insurer and the policyholder in the commonwealth while this provision is effective, or any employees' health and welfare fund which provides hospital expense and surgical expense benefits which includes pregnancy-related benefits and which is promulgated or renewed to any person or group of persons in the commonwealth while this provision is effective shall provide, to the same extent that benefits are provided for other pregnancy-related procedures, coverage for medically necessary expenses of diagnosis and treatment of infertility to persons residing within the commonwealth. For purposes of this section, "infertility" shall mean the condition of a presumably healthy individual who is unable to conceive or produce conception during a period of one year.

Appendix C

**List of Carriers That Provided Permission to Use
Massachusetts Division of Insurance Trend Study Data and
Provided Survey Responses**

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of
Massachusetts HMO Blue, Inc.

Fallon Community Health Plan

Health New England, Inc.

Harvard Pilgrim Health Care, Inc.

Neighborhood Health Plan

Tufts Associated Health Maintenance Organization, Inc.

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Oliver Wyman Actuarial Consulting, Inc.



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GUY CARPENTER OLIVER WYMAN