State-Mandated Health Insurance Benefits and Health Insurance Costs in Massachusetts

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Prepared by
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Executive Summary

M.G.L. Chapter 3 §38C requires that the Massachusetts Center for Health Information and Analysis (CHIA) issue a comprehensive report at least once every four years on the cost and public health impact of all existing mandated health insurance benefits. Compass Health Analytics, Inc. (Compass) has been engaged to prepare the 2016 report.

This is the third comprehensive review of health benefit mandates. The first comprehensive review was published in 2008 as required under Chapter 58 of the Laws of 2006.[1] The second comprehensive review, published in January 2013, was the first review prepared under M.G.L. Chapter 3 §38C.[2]

The study provides a general review of the efficacy of the benefits described in the mandates. However, the cost estimates apply only to the population with health insurance subject to Massachusetts state health benefit plan mandate laws: individuals covered by fully-insured commercial products regulated by the Massachusetts Division of Insurance. In addition, the Group Insurance Commission (GIC), which provides benefits to public employees in Massachusetts, voluntarily complies with state benefit mandates.[i] Costs associated with mandated benefits are a subset of the total health care costs for this population. Excluded from the cost estimates in this study are costs associated with self-insured plans (other than those offered through the GIC), which are not regulated by The Division of Insurance and not subject to the benefit mandate laws. The cost implications and clinical efficacy of 39 mandates are assessed in this report; the cost results are displayed in Table E1.

The first result column in Table E1 displays total required direct costs, or RDCs, which measure the total 2014 claim costs for services described in the mandate laws. RDCs are estimated to be $1.9 billion in medical expenses after elimination of overlaps in cost between mandates ($2.1 billion including administrative costs). However, RDCs are not a measure of the marginal impact of the mandates. RDCs include both costs for services that would be provided voluntarily in the absence of the mandates and marginal costs resulting from the imposition of the mandate laws. The second, third, and fourth results columns display lower and upper bound estimates of mandate marginal costs; marginal costs represent the estimated expenses for services provided in the presence of the mandates that would not have been provided in their absence.

[i] The majority of the GIC's covered members are in self-insured plans; a subset of the mandates applies to the GIC's members by statute (both fully-insured and self-insured), in addition to the overall fully-insured population. Based on the understanding that all self-insured GIC plans voluntarily offer all Massachusetts state mandated benefits, to the extent possible, all GIC plans are treated as part of the mandate-covered group throughout this analysis.

The mandates at the bottom of Table E1 labeled "Mandates Judged to Have Zero Marginal Cost" were deemed so by the largest Massachusetts health insurance carriers participating in the study, with the exceptions of the contraception and mental health mandates. The contraception and mental health mandates were treated as potential marginal cost mandates in the previous comprehensive reviews. However, since the 2009 analysis period covered by the previous review, the benefits required by both mandates have been superseded by federal statutes,[3] thus erasing any incremental effect of these Massachusetts state health benefit plan mandates. All zero marginal cost mandates have $0 lower (and upper) bound marginal cost estimates (see the second through sixth result columns). Many of the mandates in the "potential marginal direct cost" section in Table E1 were shown to have costs at higher levels in the self-insured population than in the fully-insured population. We assign these to a zero cost lower-bound rather than treating them as having negative cost or savings (e.g., diabetes related services and supplies). The other mandates in Table E1 have non-zero marginal costs relative to self-insured plans (e.g., infertility treatment).[ii]

[ii] As discussed in the body of the report, measurement for some zero marginal cost mandates was not feasible. These mandates are shown as having no cost in the required direct cost column of Table E1.

Table E1
Summary of Estimated Costs for Massachusetts Mandated Benefits as of 2014
Dollars in Millions (000,000s)

	Required Direct Cost Claims Estimate	Lower Bound Marginal Claims Estimate	Lower Bound Estimate with Admin Exp	Upper Bound Estimate with Admin Exp	Lower Bound Percent of Premium	Upper Bound Percent of Premium
Unduplicated Total All Mandates	$ 1,912.96	$ 46.94	$ 52.74	$ 796.81	0.43%	6.45%
Mandates with Potential Marginal Direct Cost						
Service Mandates						
Autism Spectrum Disorders Services	$ 39.54	$ 15.25	$ 17.13	$ 44.42	0.14%	0.36%
Chiropractic Services	$ 2.68	$ 0.94	$ 1.06	$ 3.01	0.01%	0.02%
Child Hearing Aids	$ 6.89	$ -	$ -	$ 7.74	0.00%	0.06%
Cleft Palate and Lip	$ 3.30	$ 0.10	$ 0.12	$ 3.70	0.00%	0.03%
Diabetes-related Services and Supplies	$ 175.79	$ -	$ -	$ 197.52	0.00%	1.60%
Early Intervention Services	$ 25.72	$ 2.78	$ 3.12	$ 28.90	0.03%	0.23%
Home Health Care	$ 257.25	$ -	$ -	$ 289.04	0.00%	2.34%
Hormone Replacement Therapy (HRT)	$ 11.56	$ 0.74	$ 0.83	$ 12.99	0.01%	0.11%
Human Leukocyte Antigen Testing	$ 0.02	$ -	$ -	$ 0.02	0.00%	0.00%
Hypodermic Syringes or Needles	$ 1.08	$ -	$ -	$ 1.22	0.00%	0.01%
Infertility Treatment	$ 104.73	$ 12.67	$ 14.24	$ 117.67	0.12%	0.95%
Low Protein Food Products for Inherited Amino Acid and Organic Acid Diseases (PKU)	$ 1.53	$ 0.08	$ 0.09	$ 1.71	0.00%	0.01%
Nonprescription Enteral Formulas	$ 0.92	$ -	$ -	$ 1.04	0.00%	0.01%
Oral Cancer Drugs	$ 1.38	$ 0.49	$ 0.55	$ 1.55	0.00%	0.01%
Prosthetic Limbs and Associated Services	$ 3.87	$ -	$ -	$ 4.35	0.00%	0.04%
Scalp Hair Prostheses for Cancer Patients	$ 0.41	$ -	$ -	$ 0.46	0.00%	0.00%
Speech, Hearing and Language Disorders	$ 7.12	$ -	$ -	$ 8.00	0.00%	0.06%
Provider Mandates						
Certified Nurse Midwives	$ 1.62	$ -	$ -	$ 1.83	0.00%	0.01%
Certified Registered Nurse Anesthetists	$ 22.09	$ -	$ -	$ 24.83	0.00%	0.20%
Chiropractors	$ 7.97	$ 0.81	$ 0.91	$ 8.96	0.01%	0.07%
Dentists	$ 1.39	$ -	$ -	$ 1.56	0.00%	0.01%
Nurse Practitioners	$ 44.63	$ 9.31	$ 10.46	$ 50.15	0.08%	0.41%
Optometrists	$ 6.23	$ -	$ -	$ 7.00	0.00%	0.06%
Physician Assistants	$ 41.01	$ 2.01	$ 2.26	$ 46.07	0.02%	0.37%
Podiatrists	$ 16.38	$ 0.81	$ 0.91	$ 18.41	0.01%	0.15%
Mandates Judged to Have Zero Marginal Cost						
Bone Marrow Transplants for Treatment of Breast Cancer	$ -	$ -	$ -	$ -	0.00%	0.00%
Cardiac Rehabilitation	$ 2.28	$ -	$ -	$ -	0.00%	0.00%
Clinical Trials (to treat cancer)	$ 2.28	$ -	$ -	$ -	0.00%	0.00%
Contraceptive Services	$ 94.20	$ -	$ -	$ -	0.00%	0.00%
Cytologic Screening	$ 17.54	$ -	$ -	$ -	0.00%	0.00%
Hearing Screening for Newborns	$ 3.32	$ -	$ -	$ -	0.00%	0.00%
Hospice Care	$ 16.49	$ -	$ -	$ -	0.00%	0.00%
Lead Poisoning Screening	$ 1.20	$ -	$ -	$ -	0.00%	0.00%
Mammography	$ 17.69	$ -	$ -	$ -	0.00%	0.00%
Maternity Health Care (including minimum maternity stay)	$ 471.27	$ -	$ -	$ -	0.00%	0.00%
Mental Health Care	$ 455.40	$ -	$ -	$ -	0.00%	0.00%
Preventive Care for Children Up to Age Six	$ 122.14	$ -	$ -	$ -	0.00%	0.00%
Off-Label Uses of Prescription Drugs to Treat Cancer	$ -	$ -	$ -	$ -	0.00%	0.00%
Off-Label Uses of Prescription Drugs to Treat HIV/AIDS	$ -	$ -	$ -	$ -	0.00%	0.00%

The lower bound marginal claims estimate of $46.9 million in the second column represents one measure of the marginal impact of the mandates on claims spending, calculated from per-person spending differences on mandated benefits between the fully-insured population subject to the mandates and the self-insured population not subject to mandates. This $46.9 million difference represents $1.66 per member per month, or 0.43 percent of premium. Stated simply, the additional spending on mandated services in plans subject to the mandates compared to those plans not subject to the mandates represents approximately one half of one percent of premium.

To measure the full impact, insurer administrative costs should be added. In the next two columns of Table E1 the lower bound estimate of $46.9 million becomes $52.7 million with administration, and the $1.9 billion RDC becomes an upper bound estimate of $796.8 million after removing zero marginal cost mandates and adding administrative expense.

The initial range of the marginal direct cost impact of all 39 mandate laws studied, including administrative costs, is therefore between $52.7 million and $796.8 million. However, the true value is not likely to be near either end of this range. The upper bound estimate includes all RDCs except those for mandates judged likely to have zero marginal costs, and so assumes that 100 percent of the RDC for mandates with potential marginal direct cost is marginal, and that carriers would eliminate all mandated benefits completely in the absence of the mandate laws. This is very unlikely to be true or close to true given that $469.4 million of this amount (about 59 percent; these figures are net of mandate overlaps) is composed of two mandates--home health services and diabetes services and supplies--that would likely be provided as cost-effective benefits, even if at somewhat lower levels.

The lower bound marginal cost estimate for each mandate judged to have potential marginal direct costs is derived by comparing the allowed amounts per person approved by insurers for the fully-insured sample to the allowed amounts for the self-insured sample (which is not subject to the mandates). Cases in which the self-insured spending per person is higher are ignored, and the differences, net of mandate overlaps, for the remaining cases in which the fully-insured costs per person are higher are summed to calculate the overall lower bound mandate marginal cost. This lower bound estimate assumes that 100 percent of the spending for the mandates in the self-insured market would occur in the absence of the mandate laws, and that none of the spending is influenced by the mandated spending levels in the fully-insured market. This, too, is very unlikely to be true or close to true, owing to the upward pressure mandates in the fully-insured market place on benefits offered by self-insured plans.

This reasoning supports narrowing the range of the mandate law impact. Table E2 displays medical costs in the fully-insured population for each percent of premium in the $60 million to $800 million range. While the scope of this study does not allow a direct empirical basis for narrowing the range, the actual direct cost impact is likely to be somewhere in the middle part of the range. As self-insured employers must compete in the labor market with fully-insured employers whose health insurance policies must include the mandated benefits, self-insured benefits are likely to be significantly influenced by the presence of the mandate laws and the laws' effect on benefit structures at competing employers. While there are potential effects that could cause the lower bound to be over-estimated, on net it is likely that the 0.43 percent of premium in fully-insured cost levels over and above self-insured cost levels significantly understates the true impact. At the same time, federal benefit requirements would remain even if state mandates were repealed, and it is unlikely that popular and/or cost-effective benefits like diabetes care would be completely removed from policies if the mandate laws were not in place, making 6.45 percent of premium (which assumes *all* costs of the 25 potential marginal cost mandates are marginal) a certain overstatement of the impact. Based on the foregoing discussion, mid-range estimates in the one to four percent of premium (roughly $125 million to $500 million annually) range, while not directly empirically supported by this analysis, may be a logically inferable estimate of the marginal impact on health care costs directly associated with the covered benefits described in the mandate laws.

Table E2
Cost Implications of Impact Assumptions

Percent of Premium	PMPM	Dollars (millions)
0.5%	$ 2.18	$ 61.81
1.0%	$ 4.36	$ 123.62
2.0%	$ 8.72	$ 247.24
3.0%	$ 13.08	$ 370.85
4.0%	$ 17.44	$ 494.47
5.0%	$ 21.80	$ 618.09
6.0%	$ 26.16	$ 741.71
6.5%	$ 28.34	$ 803.52

We note that, owing in part to general cost inflation but in large part to an expansion of the service codes that carriers have provided as services covered under the mandates, the RDCs in the current study at $1.9 billion are far higher than the $1.2 billion in the 2012 study. However, relative to the 2012 results these additional RDCs had a minimal effect on the upper bound estimate because mental health and contraceptive services coverage are now required by federal law. They also had a minimal impact on the lower bound estimate because self-insured plans also tend to cover both contraceptive services and mental health at or near the levels provided by fully-insured plans, and also cover many of the additional service codes in the carriers' expanded lists.

In addition to the direct cost impacts, there are indirect cost effects, such as avoided hospitalizations as a result of the diabetes mandate, that we are not able to address in this study. Almost 75 percent of the total estimated direct cost stems from three service mandates: home health, infertility, and diabetes services and supplies. The eight provider mandates represent nearly another 20 percent. Consideration of these mandates and their likely indirect cost effects would provide most of the required information on how the direct costs might be added to or reduced by indirect cost effects. It is possible that after consideration of indirect cost effects, the net impact of these five mandates is cost reducing, though we cannot estimate that impact in this study. Finally, there are individual and socially beneficial impacts aside from health care spending that these mandates may, and in many cases certainly do, provide. Benefit mandates are often enacted when such beneficial effects are perceived but something short of government provision of the benefit is the balance point of the political process.[4]

The results section of the report discusses the efficacy and public health benefits of services described in the mandates in detail.

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Introduction and Background

Statutory Basis and Scope

M.G.L. Chapter 3 §38C requires the Center for Health Information and Analysis (CHIA) to issue a comprehensive report at least once every four years on the cost and public health impact of all existing mandated benefits. Compass Health Analytics, Inc. (Compass) was engaged to prepare this analysis. This is the third comprehensive review of health benefit mandates, and the second (following the 2012 report[5]) under the statute cited above; the first comprehensive review was published in 2008 as required under Chapter 58 of the Laws of 2006.[6]

The statute defines a health benefit mandate as one that "mandates health insurance coverage for specific health services, specific diseases or certain providers of health care services." Appendix A lists the mandates addressed in this report, including all mandates studied in the previous two mandate review reports, and adds to that set new mandates passed since the analysis period for the 2012 report. This report addresses mandates in force at the end of 2014. It does not address Chapter 258 of the Acts of 2014 "An Act to increase opportunities for long-term substance abuse recovery," the relevant portions of which were not effective until October 2015, leaving insufficient time for the Act's provisions to have an effect measurable under this report's methodology.

Most mandates in Massachusetts require insurers to cover specific services or to provide benefits to individuals with specific conditions, for those individuals the insurers cover. Another smaller set of mandates requires insurers to cover the services of specific types of providers. Most of these provider-centered mandates are similar in effect, essentially providing that payers must pay practitioners of the specified provider type when the service is covered and when the practitioner's provider type is licensed to provide the covered service. Because all mandates addressed in this review apply to medical insurance policies, as opposed to policies that cover other sets of services, such as dental care, these provider-centered mandates do not address non-medical services. For example, while they require payers to pay dentists for a medical service that either a physician or dentist may perform under their licenses, they do not mandate coverage for services typically covered by dental plans.

Massachusetts statutes place various other requirements on insurers, including ones addressing confidentiality, coverage practices (continuity of coverage, dependent coverage, coordination of benefits, etc.), and limitations on insurers' ability to deny coverage in general to individuals with specified conditions (blind persons, victims of domestic abuse, etc.). The statute charging CHIA with this review does not include within the scope of the review these other types of requirements, and consequently this review does not address them.

As discussed in Appendix B, the most recent comprehensive claim data from the Massachusetts All Payer Claims Database (MA APCD) available during the period Compass performed this analysis were from calendar year 2014 (as paid through June 30, 2015), which sets the timeframe basis for the study. Results presented here include those mandates in force in 2014.

Approach to reviewing mandate efficacy

The goal of this report, in its review of evidence related to the efficacy of the provisions of each benefit mandate, is not to judge their efficacy, but rather to summarize how each is currently regarded by government or professional entities that recommend treatment or by general medical literature. If the efficacy of a mandated service is controversial, this report will describe, but not attempt to resolve, the controversy. The report includes appropriate reference notes for readers who wish to learn more.

For some mandates, the depth the report can reach in analyzing the mandate's impact is limited. In particular, for the analysis of the efficacy of provider-centered mandates, the report describes whether the services are widely covered or whether standard-setting entities, such as Medicare, pay for them. However, a complete assessment of current thought about the clinical effectiveness of an entire profession is beyond the scope of this review.

For mandates with potentially significant public health impact, meaning an effect on the health of individuals other than those covered by the mandated benefit, the report provides information describing the impact, but generally does not attempt to quantify it.[i] This approach is consistent with the treatment of indirect costs in the economic analysis, and further consistent with the treatment of indirect costs in the previous reviews.

Approach to analyzing mandate costs

For calendar year 2014, this study estimates the cost of Massachusetts health insurance benefit mandates in force during that year to premium payers. This section summarizes the methodology for measuring those costs. Appendix B contains a more detailed description of the methodology.

Applicable Population

This study estimates the effect of mandates on health care costs only for people in Massachusetts with health insurance plans subject to health benefit mandate laws; those plans fall into two main groups. First, all mandates in the study apply to fully-insured commercial plans regulated by the Massachusetts Division of Insurance. Second, a subset of the mandates in this study also applies to coverage for public employees provided under the Group Insurance Commission (GIC). The great majority of the GIC coverage is provided on a self-insured basis, with the remainder included

[i] This approach is consistent with the treatment of indirect costs in this report's analysis of mandated benefit costs, and further, consistent with the treatment of indirect costs in the 2012 comprehensive review of mandated benefits.

among the fully-insured plans subject to all the mandates. However, it is Compass's understanding that the GIC voluntarily follows all benefit mandates in its self-insured plans.

State health insurance benefit mandates do not apply to individuals covered under:

- Self-insured policies (except the GIC population for some mandates), as these policies are governed by federal ERISA statutes and not subject to state mandate laws
- Medicare and Medicare Advantage plans, the benefits of which are qualified by Medicare
- Federally-funded plans including the Veterans Administration, TRICARE (covering military personnel and dependents), and the Federal Employee's Health Benefit Plan

This analysis excludes members of fully-insured plans over 64 years of age, and does not address potential effects on Medicare supplement plans (which generally cover patient cost sharing within the Medicare benefit structure) even to the extent they are regulated by state law. Finally, some Massachusetts mandate laws affect MassHealth, which administers the Massachusetts Medicaid program; however, this analysis does not address the potential effect of those mandates on MassHealth expenditures.

The total number of persons estimated to be covered by fully-insured policies in Massachusetts was estimated through a variety of sources. U.S. Census Bureau data on the Massachusetts population and percent covered by employer-sponsored plans and MA APCD eligibility data[7] lead to an estimate of 3.8 million Massachusetts residents under age 65 covered by employer-sponsored plans in 2014, approximately 1.8 million of whom are fully-insured. Compass used Massachusetts Department of Insurance (DOI),[8,9] MA APCD eligibility,[10] and CHIA enrollment trends[11] data to develop an estimate of approximately 139,000 additional individuals under age 65 residing in other states are covered by Massachusetts-issued fully-insured employer-sponsored insurance subject to the mandates. Finally, MA APCD eligibility data[12] yielded an estimate of approximately 170,000 persons under age 65 purchased insurance in the non-group market in 2014. The sum of the employer-sponsored state residents, non-residents, and individually insured produces a total estimate of 2.1 million fully-insured members. Because self-insured GIC plans follow the mandates voluntarily, an additional 261,000 members are added to the covered population (based on GIC annual reports)[13] for a total of 2.4 million individuals. Appendix C contains more details about these population calculations. Unless otherwise noted, throughout this report "fully-insured population" will be understood to include the self-insured GIC members, and "self-insured population" will be understood to not include the self-insured GIC members.

Table 1 summarizes the license types and populations to which the mandates apply. Most mandates apply to plans under all types of state insurance license (indemnity, hospital/medical service corporation, HMO); some, however, apply only to subsets of licenses. To calculate the percent of premium the analysis uses as a member-months denominator the sum of member-months for all license types, since it estimates the per-person costs of the benefits with respect to the overall average fully-insured health insurance premium. However, for the five mandates that apply to less than the entire fully-insured population, estimated claims were included in the numerator only for the sub-groups indicated in Table 1, as these are the only claims related to

benefits required by those mandates. The resulting estimates represent the impact on the average fully-insured premiums, not on the premium for the sub-group(s) to which the mandate applies.

Table 1
2014 Estimates of Populations to Which Mandates Apply

Mandate	Applicable Population	Estimated Statute Membership	Est. Effective Membership (incl. SI GIC)
Certified Nurse Midwives Chiropractors Dentists Optometrists	Indemnity and Blue Cross Blue Shield fully-insured members	479,865	730,715
Chiropractic Services	Blue Cross Blue Shield fully-insured members, *excluding* HMO Blue	165,174	165,174
Infertility Services	All fully-insured Massachusetts-resident members	1,962,021	2,206,099
Certified Registered Nurse Anesthetists Early Intervention Home Health Care HRT Infertility Low Protein Foods Nurse Practitioner Podiatrist Syringe Cardiac Rehab Clinical Trials for Cancer Contraception Cytologic Screening Lead Screening Mammography Off-label Uses of Prescription Drugs - Cancer Off-label Uses of Prescription Drugs - HIV/AIDS Preventive Care to Age 6	All fully-insured members	2,101,336	2,362,745
Autism Services Child Hearing Aids Cleft Palate and Lip Diabetes HLA Testing Limb Prosthesis Mental Health Nonprescription. Enteral Formulas Oral Cancer Drugs Physician Assistants Scalp Hair Prosthesis Speech & Hearing Bone Marrow Transplants for Breast Cancer Hearing Screening for Newborns Hospice Care Maternity Care	All fully-insured members and all GIC members (fully and self-insured)	2,362,745	2,362,745

Sample Population

To develop a cost estimate for each mandate, a sample per-member per-month (PMPM) cost estimate was developed from available data sources and multiplied by the applicable population defined in the preceding section.[ii] The estimated PMPM cost developed from claim data drew upon calendar year 2014 data from CHIA's MA APCD,[14] Release 4.0. CHIA collects and manages data from commercial carriers, third party administrators, and public programs.[15] CHIA works with each carrier to conduct a quality control process on the MA APCD data, and "clears" data through this

[ii] As discussed below in the Results section, for aggregated cost estimates, overlap between mandates is removed when summing total dollars.

process on a carrier-by-carrier basis as this process is complete. This quality-controlled sample comprises approximately 87 percent of total commercial fully-insured primary medical membership under age 65 in the Commonwealth.[iii] Compass relied upon this quality-controlled data sample after verifying basic reasonableness checks on membership and expenses. Compass then joined claims to de-duplicated eligibility data to review match rates and average paid and allowed claims PMPMs by carrier. The average fully-insured and self-insured GIC medical membership subject to the mandates represented in the sample passing this additional quality-control step for 2014 is 1.9 million, or 79 percent of the estimated 2.4 million total average membership for the fully-insured and self-insured GIC population in Massachusetts. Cost estimates contained in this report assume the PMPM costs obtained from the MA APCD sample data are representative of the overall fully-insured under-65 population. For the mandates developed with secondary data sources (discussed in the next section), the underlying utilization, prevalence, and other rates were drawn from Massachusetts data wherever possible. The samples used are discussed in detail in the methodology appendices.

Appendix B provides a more detailed discussion of the cost estimation methodology and Appendix C details the development of Massachusetts population segment estimates.

Definition of Estimated Costs

Costs associated with mandated benefits are a relatively small subset of total health care costs for the affected population; to begin to address by how much mandate laws impact total costs it will be helpful to define terminology for the purpose of this report. The general cost concepts defined below will aid in interpreting the results of the study. In practice, these cost sub-categories are difficult to measure, and no precise measurement of these cost breakouts can be achieved within the scope of this project, although conceptual definition will aid in interpreting the results of the analysis. Two general types of costs may be associated with any mandate:

- **Required direct costs**. These are the costs of services explicitly described in a mandate law, used by covered members, and paid for by the regulated insurance plans, whether or not some or all of the costs would have been incurred in the absence of the mandate through voluntary provision of the benefits. These costs are the primary focus of this study, and are the most easily measurable. Required direct costs (RDCs) are the sum of *base direct costs* and *marginal direct costs.*
    - *Base direct costs* (BDCs) are those costs that would be present even if the mandate law were not in force. Mandate laws may require benefits that would be provided, wholly or in part, voluntarily (by some or all of the market) or that are required by another mandate law (state or federal).

[iii] Total average fully-insured commercial primary medical insurance membership under age 65 reported in the MA APCD is approximately 2 million, or 94 percent of Compass's 2014 fully-insured commercial membership estimate of 2.1 million. Total average under-65 fully-insured and self-insured GIC primary medical insurance membership from the MA APCD is 2.1 million, or 90 percent of Compass's 2.4 million population estimate (not all carriers' GIC accounts can be identified in the MA APCD; these accounts are excluded from the 2.1 million estimate).

  - *Marginal direct costs* (MDCs) are those additional costs beyond the base direct costs that the imposition of the mandate impels.

- **Indirect costs.** Indirect costs are costs that may be added as a result of the related delivered services associated with the mandate (e.g., costs of additional complicated births associated with infertility treatment) or service costs avoided (these would be "negative costs" or cost offsets) as a result of the mandate (e.g., fewer emergency department visits for diabetics due to coverage for diabetes services and supplies).

While we can measure RDCs reasonably, measuring their breakdown into base and marginal direct costs is far more difficult, and measuring indirect costs even more difficult. To measure the true cost impact of a mandate law on regulated insurance product premiums, one would include only marginal costs, which would consist of marginal direct costs and marginal indirect costs (those indirect costs associated with the marginal utilization produced by the mandate law). Since marginal indirect costs may be either positive or negative, the net impact of any one mandated benefit on total costs may be either increasing or decreasing, depending on:

- How much of the direct cost associated with the mandate is marginal (i.e., attributable to the imposition of the mandate)
- Whether indirect costs are positive or negative on net
- The size of those indirect costs relative to the direct costs

Though not within the scope of this study, a well-conducted multivariate statistical analysis using multi-state data would be better able to estimate marginal costs that include both direct and indirect components. Some multivariate econometric studies comparing benefit mandates and cost levels across states have shown that some specific mandated benefits decrease costs on net, while others increase costs on net.[16]

This study provides some information that may be useful in understanding the proportion of the required direct costs that are likely to be marginal for the mandates. The scope of this study does not attempt to measure precisely the amount of RDC that is marginal (which would require multi-state data), and the report does not include evaluation of indirect costs. As a result, it is not possible to ascertain from the information in this study the net impact on health care costs in the Commonwealth associated with the mandate laws, but previous research suggests that total RDCs will greatly overstate the net effect of the mandates, that offsetting indirect cost savings can be larger than direct cost effects (making the net effect of such a mandate to reduce cost), and that the impact of mandate laws on insurance premium levels will not be directly inferable from the RDC estimates contained herein.[17]

This report does, however, compare the fully-insured population RDCs to the RDCs observed in the Massachusetts self-insured sector (not subject to the mandate laws)[iv]; this difference provides one

[iv] Note that the Group Insurance Commission (GIC), which administers health insurance benefits for public employees in the Commonwealth, has both fully-insured and self-insured members. The GIC is specifically included in a number of benefit mandates, and is understood to follow the others voluntarily as a matter of policy. As a result, the GIC membership that can be identified in the data are treated as fully-insured for the purpose of measuring PMPM costs relative to the self-insured market. See Appendix B for more details.

estimate of the marginal cost introduced by the mandate legislation. Previous research has found that benefit levels, including for mandated services, are similar, if not richer, in the self-insured market.[18] Mandate laws may have small effects to the extent these research findings indicate firms offer the benefits voluntarily. However, considering that employers in Massachusetts that self-insure must compete in the labor market with fully-insured firms that must offer the mandated benefit package and public-sector employers offering GIC plans that voluntarily include all mandated health insurance benefits (even when the text of the mandate laws does not reach the self-insured GIC), the benefits in the self-insured firms are likely to be at least somewhat richer than they would be in the absence of the mandate laws. This competitive labor market effect would shrink the cost difference between fully-insured and self-insured plans and understate (or provide a lower bound for) the implied impact of benefit laws on health care costs provided by the difference between fully-insured and self-insured costs.

In the cost estimates displayed in the Results section, these lower-bound estimates are derived from the difference between insurer spending in the fully-insured population for the mandated benefit and the insurer spending in the self-insured population for the same benefit. To reduce the impact that differences in average patient cost sharing between these populations may have on the result, the calculation is performed by computing the percentage by which the fully-insured allowed (before cost sharing) PMPM exceeds the self-insured allowed PMPM, and applying that percentage to the fully-insured paid PMPM. The result is a lower-bound estimate of the impact of the mandate on fully-insured paid expenditures. Where the self-insured allowed PMPM is higher than the fully-insured allowed PMPM, we treat the impact as zero, rather than negative; we assume that if self-insured firms on average have a higher spending level than fully-insured products subject to the mandates, it is not caused by the existence of the mandate. That is:

Lower Bound Marginal Cost = [(FI[v] Allowed – SI Allowed)/FI Allowed]*FI paid RDC, *if FI Allowed – SI Allowed > 0*

Lower Bound Marginal Cost = 0, *otherwise*

An upper-bound claim cost estimate is also provided for each mandate, which includes the entire RDC, except for those mandates judged by the carriers likely to have zero marginal costs. This upper-bound estimate assumes that 100 percent of the RDC for mandates with potential marginal direct cost is marginal, and that carriers would pay zero dollars in claims for the services described by the mandates in the absence of the mandate laws. For most mandates there is good reason to believe the actual marginal cost is far lower, though we do not have a direct method of estimating by how much. For example, home health care services are widely considered to be cost-effective in many contexts. In all likelihood carriers would cover this benefit, if at a somewhat lower level, in the absence of the mandate. As a result, the upper bound estimates are likely to be well above the actual marginal direct cost.

To calculate the total cost of the mandates to the Massachusetts health care system, administrative loading (the additional costs over and above health care claims required to administer the health

[v] In this and other equations and exhibits in this report, the abbreviation "FI" refers to the fully-insured and self-insured GIC population subject to the mandates, and "SI" refers to the non-GIC self-insured comparison population.

plan) must be added to the claims expense measures described above. According to CHIA's September 2016 report on the performance of the Massachusetts health care system, in 2014,[19] average administrative loading (including profit) in the fully-insured commercial market was estimated to be 11 percent. Therefore, to arrive at estimates of fully loaded healthcare premium costs, claims costs were divided by one minus the 11 percent administrative load (1 – 0.11), or 0.89.

Comparing the present study to the 2012 reports shows that RDC results for some mandates have changed significantly; most notably, the RDC estimates for diabetes services and supplies and mental health care show nearly three-fold and two-fold increases, respectively. The main drivers of these and other significant differences, illustrated by selected examples, follow.

- *Carrier Input*
  - For the mental health mandate, the carriers provided an extensive list of procedure and diagnosis codes to be added to the cost model specification, including diagnoses not commonly considered behavioral health diagnoses, such as intellectual disabilities, Alzheimer's disease, and Parkinson's disease.[vi]
  - This was also true for the speech, hearing, and language and the non-prescription enteral formulas mandates, which had many-fold cost increases (but very small absolute RDCs even after the large increases shown in this study).
  - Significant additions were also made to the diabetes services and supplies specification to include new products, such as the new insulin pumps discussed below.
- *Price and service mix changes*
  - A recent study found that the average price of insulin has tripled in the past decade.[20]
  - New, more expensive insulin pumps have also become popular with clinicians and diabetes patients in recent years.[21]
- *Clinical practice and guideline changes*
  - As discussed below, decreased frequency guidelines for mammographic and cytological screening (Pap smear) have been released by U.S. government agencies and medical societies since the previous study period.[22,23]

These changes also affected the self-insured cost estimates; therefore, changes in the lower bound estimates were much more modest. Furthermore, the new Federal requirements for mental health and contraceptive services coverage have mitigated the impact of these changes on the aggregate upper bound estimate.

The mandates in the study were reviewed by the major carriers in Massachusetts to ascertain whether, in their opinion, the RDCs of the mandates would be affected if the mandate were repealed. Those for which the law was judged not to affect measurable cost were deemed "zero marginal direct cost" mandates. In the present study, the MA APCD allowed estimation of the RDCs for four of the original zero marginal direct cost mandates (cardiac rehabilitation, cytological screening, lead poisoning screening, and mammography) with claim data. RDCs for the remaining

[vi] These physical health diagnosis codes combined account for approximately 1 percent of sample paid claim expenses for plans subject to the mandate.

zero marginal direct cost mandates identified by the carriers, where measurable, were calculated using secondary data sources. In addition, in light of federal benefit requirements in the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) and the Patient Protection and Affordable Care Act of 2010 (ACA), Compass has re-classified the mental health and contraceptive services mandates as zero marginal direct cost mandates in the present study.[vii] RDC estimates for these two mandates were prepared with MA APCD data.

The remaining "mandates with potential marginal direct cost" were estimated using the MA APCD. More details about this distinction and the overall methodology can be found in Appendix B. In the presentation of results below, the mandates are organized into potential marginal direct cost and zero marginal cost categories.

Effect of the ACA on the Incremental Cost of the Mandates

As noted above, this analysis measures a mandate's RDC and then uses it to estimate a lower bound for how much of the RDC is due to the Massachusetts benefit mandate by subtracting from it the costs incurred for that benefit in the self-insured population that is not subject to the mandate. For purposes of the lower bound, the self-insured costs stem from coverage carriers would have provided on their own or because of other federal or state legal requirements, including ACA requirements.

If an ACA coverage requirement applies to both fully- and self-insured plans, then that requirement does not interfere with the methodology employed in this analysis; it would not contribute to a difference between the cost of coverage for fully-insured plans and the cost for self-insured plans. Indeed, when most ACA requirements with this broader applicability, such as requirements for preventive care coverage, interact with Massachusetts mandates, the mandates can be assumed to have zero incremental cost. Such is the case with the relationship between the state mandate requiring coverage for hormonal contraceptives and the ACA's broad requirement for coverage for contraception. The body of this analysis identifies these cases.

The ACA creates other requirements, including minimum coverage standards – known as Essential Health benefits (EHBs) – for plans offered on health insurance exchanges, such as the Massachusetts Health Connector, and for some other, but not all, fully-insured plans. The ACA's requirements for EHBs are often stated generally, and expressed more precisely in the offerings of a state "benchmark" plan, which for Massachusetts is a specific HMO Blue plan from Blue Cross/Blue Shield. Identifying the effect of EHBs on the cost of a Massachusetts mandate requires isolating EHBs that arise from federally-sourced requirements from those present only because the state mandate exists.[viii] If a Massachusetts mandate requires coverage for a service which federal law

[vii] The contraceptive services and mental health mandates were treated as "mandates with potential marginal direct cost" in the 2008 and 2012 studies.

[viii] One can argue that because the Massachusetts benchmark plan is itself subject to state mandates, EHB requirements indirectly require all plans subject to EHBs to follow the state mandates that fall within the EHB service categories, and therefore that the cost of these mandates beyond meeting federal requirements, for plans subject to EHBs, is zero. The resolution of this circularity lies in asking "what would EHBs include if the state mandates were not present?" and considering only EHB requirements that appear federal in origin.

(not the state mandate) already deems an EHB, the cost of that service in a plan subject to the EHB requirement would not contribute to the incremental cost of the mandate in that plan.

As noted, ACA requirements that apply to both fully- and self-insured plans do not affect this analysis. But because EHB requirements do not apply to self-insured plans – and indeed do not apply even to all fully-insured plans – the lower bound methodology discussed above might not cleanly isolate the effect of EHB requirements from the effect of a Massachusetts mandate. That is, if a Massachusetts mandate requires coverage for a specific service also required as an EHB, then some of the difference in coverage for the service between plans subject to the EHB and self-insured plans might be due to the federal EHB requirement and not due just to the Massachusetts mandate.

Of Massachusetts mandates not completely eclipsed by the ACA, only a few (related to speech and audiology, early intervention, and possibly hormone replacement therapy, as discussed in the body of this analysis) arguably are preempted by EHB requirements. Because the relevant EHBs are stated only generally and ACA regulations rely on benchmark plans for further specificity, determining if EHBs encompass the services in a given Massachusetts mandate is difficult and in some cases not possible within the scope of this analysis, as is isolating the precise set of members subject to the EHB requirement within the fully-insured population. Furthermore the RDCs for these few mandates do not place them among mandates that contribute a great deal to the overall cost of Massachusetts mandates. Attempting to exclude these costs from the mandates runs the risk of under-estimating the cost impact of the mandates. Therefore in these cases, this analysis assumes the impact is the result of the state-mandated services, and so the analysis will still apply the lower-bound methodology in these cases. By not subtracting these (hard to estimate) costs that might already be required by the ACA's EHB requirements, the cost estimates are either immaterially affected or provide a slightly conservatively high estimate of mandate cost impacts.

Finally, Section 1311 of the Affordable Care Act (ACA)[24] requires states to contribute to the cost of subsidizing health insurance coverage for selected segments of the population to pay for benefits mandated by the state and exceeding EHB requirements. The Massachusetts Division of Insurance and the Commonwealth Health Insurance Connector Authority are responsible for determining any potential state liability under that law.

Results

This section presents results of both the efficacy and cost reviews for mandates with potential marginal direct cost and mandates with zero marginal direct cost, and results combining the two.

Mandates with Potential Marginal Direct Cost: Service-Centered Mandates

Results for the individual mandates requiring coverage for services and/or patient conditions, with potential marginal direct cost, and studied with primary data, follow. Detailed specifications for the cost calculations for these mandates are available from CHIA upon request.

Autism Spectrum Disorders

The autism mandate requires coverage for treatment for Autism spectrum disorders (ASDs) on a "non-discriminatory basis", meaning on the same terms as coverage for medical/surgical conditions. The mandate includes in the treatment of ASDs: habilitative or rehabilitative care, pharmacy care, psychiatric care, psychological care, and therapeutic care. Coverage for psychiatric and psychological care is also required by the mental health mandate. The mandate's primary effect is to require coverage for medically-necessary habilitative care, i.e., "professional, counseling, and guidance services and treatment programs, including applied behavior analysis supervised by a Board Certified Behavior Analyst."[25]

Effect of the mandate on health

ASDs are a group of developmental disabilities characterized by persistent impaired social interaction and communication and by restricted and repetitive patterns of behavior, interests, or activities present in early developmental stages that clinically and significantly impair social, occupational, or other areas of functioning.[26,27] This definition incorporates several previously distinct diagnoses, including autism, Asperger's disorder, childhood disintegrative disorder, and pervasive developmental disorder not otherwise specified.[28]

In general, children with autism are less able to interpret non-verbal social and emotional cues, as they struggle to interpret behaviors such as body language and facial expressions. They also struggle with reciprocal social interaction, exhibit inflexibility in their behaviors, have difficulty coping with change, and engage in restricted and repetitive behaviors.[29] While these behaviors and symptoms may change over time, adults with ASD continue to struggle throughout life with: language, especially perspective, nuance, humor, and implied meanings; self-sufficiency; and social skills.[30] Adults with autism are much less likely to be fully self-supporting, and many develop psychiatric issues such as obsessive-compulsive disorder or affective disorders.[31] ASDs require chronic management and cannot be cured. Outcomes and behaviors for individuals change over time, but most patients remain on the spectrum as adults. ASDs affect a person's mental health, as well as his ability to achieve academically, live independently, obtain and retain employment, and establish and maintain positive social relationships.[32] Additionally, ASD patients may have an increased incidence of seizure and gastrointestinal disorders, as well as sleep disturbances, which must also be addressed through appropriate medical management.[33]

ASD is difficult to diagnose, as it is "a neurodevelopmental disability or phenomenological disorder, not a specific disease."[34] Moreover, while symptoms and signs are usually apparent early in a child's development, the behavior patterns and social deficits may not be identified as ASD until social, occupational, educational, or other developmental milestones are not met.[35] Variations in functional limitations, as well as the pattern of development, also contribute to difficulties with diagnosis.[36] For the general population, the U.S. Preventive Services Task Force (USPSTF) – an independent panel of national experts in prevention and evidence-based medicine that recommends clinical preventive services such as screenings, counseling services, and preventive medications[37] – recently released its report on screening for ASD in children ages 18 to 30 months, concluding "current evidence is insufficient to assess the balance of benefits and harms of screening

for [ASD] in young children for whom no concerns of ASD have been raised by their parents or a clinician."[38]

Prevalence

Even with these difficulties, estimates of the prevalence of ASDs – such as those below from the Autism and Developmental Disabilities Monitoring (ADDM) Network based on health and special education records of children across the United States – have risen dramatically over the last decade:

Prevalence of Autism Spectrum Disorder among Children Aged 8 Years

Report Year	2007[39]	2009[40]	2012[41]	2014[42]
Data Year	2002	2006	2008	2010
Prevalence	1 in 152	1 in 110	1 in 88	1 in 68
Per 1000 children	6.6	9.0	11.3	14.7
Change versus previous	-	36.4%	25.6%	30.1%
Change versus 2002	-	36.4%	71.2%	122.7%

Information for these estimates was collected on eight-year-old children because previous work had shown that most children with ASD have been identified for services by that age. The median age of first ASD diagnosis is approximately 4.5 years, and the prevalence among boys is four to five times higher than among girls.[43] White children are approximately 30 percent more likely to be diagnosed with ASD than are black children, and almost 50 percent more likely than are Hispanic children.[44]

The Centers for Disease Control and Prevention (CDC) is currently studying reasons for this increase, including evaluation of "the geographic area covered, the number and racial/ethnic distribution of children living in these communities, sociodemographic population characteristics, and other factors that might influence the prevalence and characteristics of children with ASD in the population."[45] Other factors may be better awareness or a change in diagnostic practices. The most notable change, according to the CDC, is the number of children identified with ASD who have average or above-average intellectual ability.[46] Overall, the CDC has pointed out that due to its behavioral basis, as well as lack of consistent identification, genetic, or biologic markers, ASD presents challenges to epidemiological investigation.[47]

Treatment

The primary treatment goals for ASD, according to the American Academy of Pediatrics, are to "maximize the child's ultimate functional independence and quality of life by minimizing the core autism spectrum disorder features, facilitating development and learning, promoting socialization, reducing maladaptive behaviors, and educating and supporting families."[48] Interventions, therefore, should be designed to promote development and learning; improve communication, social interaction and reciprocity; diminish repetitive and restricted behaviors; and educate and support families.[49] A wide variety of therapies are available, including: behavior and

communication therapies, pharmacological therapies to treat symptoms, dietary approaches, and complementary and alternative medicine therapies.[50] Additional supports are also used by those diagnosed with autism, and may change over time depending on individual age and need, including educational, vocational, residential, and housing support services.[51]

Behavioral and communication interventions are the primary therapies for ASD. Broadly, they address communication, social, daily-living, play, and leisure skills, as well as academic achievement and maladaptive behaviors. Interventions are structured to help the child acquire the skills and knowledge necessary for independence and personal responsibility in a variety of environments.[52] These types of therapies should provide structure, direction, and organization for the child, and encourage family participation.[53] Models have most often been developed upon a "primary philosophical orientation," frequently categorized as behavior analytic, developmental, or structured teaching.[54]

The most widely used and researched type of behavioral therapy for ASD is applied behavior analysis (ABA).[55] Based on psychology research and its resultant principles of learning, these interventions focus on helping patients learn positive behaviors and decrease negative ones, while developing adaptive strategies to new situations.[56] ABA emphasizes evaluation and measurement of behaviors, leading researchers to most easily apply scientific methods when evaluating these interventions. In fact, "most studies of comprehensive treatment programs that meet minimal scientific standards involve treatment of preschoolers using behavioral approaches."[57]

ABA encompasses a variety of methodologies including Pivotal Response Training (PRT), Early Intensive Behavioral Intervention (EIBI) and Verbal Behavior Intervention (VBI).[58] One popular method, Discrete Trial Training (DTT), teaches behaviors and responses step-by-step. Environments are highly structured and lessons are reduced to their simplest parts, using positive reinforcement for desired behaviors.[59] A similar intervention is TEACCH, or Treatment and Education of Autistic and Related Communication Handicapped Children program, also known as "structured teaching." This intervention focuses on modifying the patient's environment to accommodate the individual's deficits, as well as on improving skills. Visual cues, schedules, routines and structured work and activity systems are part of this method.[60] Research has found that while these methods can teach certain skills, they cannot be generalized for "spontaneous use in natural environments."[61] Other types of behavioral and communication interventions include Developmental, Individual Differences, Relationship-Based Approach (DIR; also called "Floortime") and Picture Exchange Communication System (PECS); likewise, sensory integration, occupational and speech therapies are additional approaches to treatment.[62]

No drugs are currently approved specifically for the treatment of ASD.[63] However, medications are used to treat specific symptoms and "maladaptive behaviors such as aggression, self-injurious behavior, repetitive behaviors (e.g., perseveration, obsessions, compulsions, and stereotypic movements), sleep disturbance, mood lability, irritability, anxiety, hyperactivity, inattention, destructive behavior, or other disruptive behaviors."[64] Although dietary approaches and alternative medicine therapies are widely used, in general, research has not proven their effectiveness;[65] in fact, some therapies, such as intravenous chelation of heavy metals, have been shown to be dangerous.[66]

Evidence exists for the potential effectiveness of early intervention for children with ASDs, making early identification and diagnosis important to treatment outcomes.[67,68,69,70]

The National Professional Development Center on Autism Spectrum Disorder (NPDC-ASD), which evaluated with federal funding specific interventions used in treating ASD, identified 27 evidence-based practices that "have been shown through scientific research to be effective when implemented correctly with students with ASD."[71] The National Guideline Clearing House under the federal Agency for Healthcare Research and Quality (AHRQ) includes 36 guidelines for the diagnosis, treatment, and management of ASD which have likewise been shown through various research studies to be effective.[72] In its report comparing effectiveness of various therapies, AHRQ called for more research but concluded the following based on a review of existing studies:[73]

- Good evidence exists (high confidence; consistent results from good-quality studies):
  - Behavioral interventions:
    - Use of cognitive behavioral therapy is effective in treating anxiety in school-aged children without cognitive or language delays.
  - Medical interventions:
    - Aripiprazole can reduce challenging and repetitive behaviors; it is associated with significant weight gain, sedation, and other side effects
- Moderate evidence exists (findings are supported but further research could change conclusions):
  - Behavioral interventions:
    - Certain child-focused early behavioral and developmental interventions can improve cognitive and language outcomes for some children.
    - Play- and interaction-based interventions improve joint attention skills in young children who were also typically receiving early intervention.
    - Risperidone can reduce challenging and repetitive behaviors; good evidence associates it with significant weight gain, sedation, and other side effects.
- Some evidence exists (very few studies, or existing studies are flawed):
  - Behavioral interventions:
    - Parent-focused early intensive behavioral interventions may improve language skills for some children.
    - Social skills interventions may yield short-term improvements in social interactions and emotion recognition for school-aged children with average reasoning and language skills.
- Evidence is insufficient to understand the effectiveness, benefits, and adverse events from all other medical interventions (including serotonin-reuptake inhibitors and stimulant medications), educational interventions, or any allied health or complementary and alternative medicine (CAM) intervention.

ABA is an entire discipline "concerned with the application of behavioral science in real-world settings such as clinics, schools, and industry with the aim of improving socially important issues such as behavior problems and learning."[74,75] Comprehensive interventions focus on teaching specific skills to improve intellectual, social, and adaptive functioning, while focused interventions are more time-limited and aimed at changing specific behaviors, most often including those

associated with aggression, self-injury, or other challenging behaviors.[76] ABA encompasses a wide array of behavioral interventions; some of these services have been shown to be effective in treating certain symptoms in certain patients with ASD, and are identified more specifically in the previous list as well as in guidelines reviewed by the NPDC-ASD.[77]

Estimate of the cost of the mandate

Regulations on required benefits for 2016 issued pursuant to the ACA (45 CFR §156.115(a)(5)(i)) include in EHBs "habilitative services". They define such services as those that "help a person keep, learn, or improve skills and functioning for daily living (habilitative services). Examples include therapy for a child who is not walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology and other services for people with disabilities in a variety of inpatient and/or outpatient settings." But the specific services included, and whether the definitions would include ABA, are left to the states.[78] This analysis will assume ABA would not be included in the benchmark plan without the autism services mandate. Such services are absent from the benchmark plans of about half the states, suggesting they are not a federal requirement.[79] In addition, the definition of habilitative was even less well fleshed-out in years prior to 2016, which make up the measurement period for this analysis.

The RDC of this mandate was calculated as the sum of paid amounts from all claims reporting an ASD diagnosis and a procedure code indicating, per the carrier specification review, medically necessary ABA. The estimated PMPM RDC paid claim amount was $1.39, with total PMPM cost, after administrative loading, of $1.57 (or 0.36 percent of the Commonwealth total premium). Per member per month self-insured allowed expenses for these services were found to be $0.56 lower than fully-insured PMPM allowed expenses, resulting in a lower bound cost impact estimate, including administrative loading, of $0.60 PMPM, or 0.14 percent of Commonwealth premium. Table 2 below displays a summary of these results and related statistics.

Table 2
Autism Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower
Sample Users	1,672	800	
Sample Units	1,762,930	844,889	
Sample Average Members	1,871,491	1,490,706	
Paid PMPM	$ 1.39	$ 0.87	$ 0.54
Paid PMPM With Admin	$ 1.57	$ 0.98	$ 0.60
Allowed PMPM	$ 1.44	$ 0.89	$ 0.56

	Upper Bound Impact		Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 39,537,136		$ 15,246,865
Contribution to Total Annual Premium	$ 44,423,749		$ 17,131,309
Percent of Total Premium	0.36%		0.14%

*Net amounts do not remove overlap in mandated services between the autism mandate and the early intervention and home health care mandates.

Chiropractic Medicine

The chiropractic services mandate requires coverage for chiropractic services.[80] Note Massachusetts has both chiropractic service and chiropractor (provider-based) mandates. The services referred to in this chiropractic services mandate are provided by chiropractors and other providers, and chiropractors provide both chiropractic and other services. The mandate applies to medical service corporations only. That is, the mandate applies to Blue Cross Blue Shield of Massachusetts, Inc. only (but *not* Blue Cross Blue Shield of Massachusetts HMO Blue, Inc.).

Effect of the mandate on health

Chiropractic is a form of alternative medicine that focuses on the relationship of the body's structure, particularly the spine, to its function. The goal of chiropractic treatment is to enable the body to self-heal by realigning structure, often through spinal manipulation.[81] Spinal manipulation is practiced by a variety of healthcare professionals, including physical therapists; naturopathic, osteopathic and medical physicians; and chiropractors.[82] Manipulation is conducted by applying controlled force to a spinal joint, most often with hands or another device.[83] Treatment goals include pain alleviation and physical function improvement.[84]

Chiropractic care accounted for 77 to 82 percent of total ambulatory visits by US adults to complementary and alternative medicine (CAM) providers between 2002 and 2008.[85] As the most common and established of CAM modalities, some chiropractic care is covered by Medicare and military health insurance plans, as well as by most private insurers and many Medicaid programs. Research has been largely conducted on singular treatment modalities or conditions, and has not focused on the entirety of chiropractic medicine.[86,87] The use of spinal manipulation for acute lower

back pain has also been integrated into the clinical guidelines of the American College of Physicians and the American Pain Society.[88]

According to the National Center for Complementary and Integrative Health, one of the federal National Institutes of Health, spinal manipulation may benefit some people with low-back pain, and may be beneficial as treatment for some headaches, neck pain, upper- and lower-extremity conditions, and disorders associated with whiplash.[89] Spinal manipulation may also result in temporary headaches, tiredness, and discomfort in the part of the body that were treated. Rare reports of complications such as stroke have occurred, but the cause is unclear and research into the safety of spinal manipulation is ongoing.[90]

The research, however, is still unclear, despite the high satisfaction rates of patients receiving chiropractic treatments.[91] Outcomes vary based on the exact condition studied (e.g., acute, subacute, mixed duration, or chronic low-back or neck pain), the benefit sought (e.g., pain or disability relief), the timeframe studied (e.g., immediate, short-term, intermediate, or long-term; during the course or following completion of treatment), and the treatments compared in the study (e.g., no treatment, placebo, pain medication, usual care, physiotherapy, massage, or as an adjunctive therapy).[92] One large meta-analysis that reviewed the conclusions of 25 separate evaluations of spinal manipulations for low back pain or neck pain found mixed results that ranged from significantly effective to not at all effective, depending on the specifics of the research design.[93]

Most research points to mild to moderate short-term benefits of chiropractic services for acute low back pain,[94,95] although these results were sometimes similar to those obtained through other treatments, such as physiotherapy, patient educational materials, oral medications, acupuncture, or steroid injections.[96,97,98,99] Other research found evidence that spinal manipulation provided no clinically meaningful benefit in the treatment of chronic low back pain.[100] The results of a 2010 study into the effectiveness of manipulation/mobilization therapies found evidence of the following:[101]

Effective	Inconclusive	Not Effective
• Acute, subacute and chronic low back pain • Migraine and cervicogenic headache • Cervicogenic dizziness • Extremity joint conditions • Acute/subacute neck pain (thoracic manipulation/mobilization)	• Neck pain (cervical manipulation/ mobilization) • Mid-back pain • Sciatica • Tension-type headache • Coccydynia • Temporomandibular joint disorders • Fibromyalgia • Premenstrual syndrome • Pneumonia (Older adults) • Otitis media (children) • Enuresis (children)	• Asthma (adults and children) • Dysmenorrhea • Stage 1 hypertension

As with many medical interventions, side effects and risks also exist.[102] Studies caution that chiropractic manipulation often leads to mild and transient side effects, including headaches, tiredness, and soreness at the treatment site. [103] Other researchers point out more rare but serious side effects, especially with upper spinal manipulation, such as cerebrovascular accidents, ischemia,

other neurological complications, and possibly stroke, although the cause of these is unclear and more research is needed.[104,105,106,107]

Estimate of the cost of the mandate

The RDC of this mandate was calculated as the sum of paid amounts from all claims with procedure codes indicating chiropractic manipulative treatment.[ix] The estimated PMPM RDC paid claim amount was $1.35, with total PMPM cost, after administrative loading, of $1.52 (or 0.02 percent of the Commonwealth total premium). Per member per month self-insured allowed expenses for these services were found to be $0.80 lower than fully-insured PMPM allowed expenses, resulting in a lower bound cost impact estimate, including administrative loading, of $0.53 PMPM, or 0.01 percent of Commonwealth premium. Table 3 below displays a summary of these results and related statistics.

Table 3
Chiropractic Medicine Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower
Sample Users	11,109	59,043	
Sample Units	135,994	511,776	
Sample Average Members	142,186	990,666	
Paid PMPM	$ 1.35	$ 0.81	$ 0.47
Paid PMPM With Admin	$ 1.52	$ 0.91	$ 0.53
Allowed PMPM	$ 2.28	$ 1.48	$ 0.80

	Upper Bound		Lower Bound
Insured Population	165,174		165,174
Contribution to Total Annual Claims	$ 2,677,008		$ 939,196
Contribution to Total Annual Premium	$ 3,007,874		$ 1,055,277
Percent of Total Premium	0.02%		0.01%

*Net amounts do not remove overlap in mandated services between the chiropractor provider mandate and the chiropractic services mandate.

Cleft lip and Cleft palate

The cleft lip and cleft palate mandate requires coverage for children under age 18 for medically-necessary "medical, dental, oral and facial surgery, surgical management and follow-up care by oral and plastic surgeons, orthodontic treatment and management, preventative and restorative dentistry to ensure good health and adequate dental structures for orthodontic treatment or prosthetic management therapy, speech therapy, audiology and nutrition services… consequent to the treatment of the cleft lip, cleft palate or both."[108]

[ix] CPT codes 98940, 98941, 98942, & 98943.

Effect of the mandate on health

Orofacial clefts, the collective term for cleft lip and cleft palate, are birth defects that occur during pregnancy when a baby's lips or mouth do not properly join.[109] During the fourth to seventh weeks of pregnancy, the body tissue and other cells from the sides of the head grow toward the center to join and make a face, creating features including lips and mouth.[110] If the tissue around the lips does not join completely, an opening known as a cleft lip can result that may range from a small slit to a large gap through the lip into the nose; this may occur on one or both sides, or more rarely, in the middle.[111] During the sixth to ninth weeks of pregnancy, the bone, muscle, and other tissue on the roof of the mouth forms to create a palate; if these do not join completely together, a cleft palate is formed, and can include the front, back, or both parts of the palate.[112] Almost 70 percent of children with orofacial clefts have both cleft palate and cleft lip.[113]

Children with orofacial clefts often have problems with their teeth, feeding, clear speaking, ear infections, and hearing.[114] They are also more likely to be hospitalized during childhood than children without orofacial clefts, with hospitalization rates higher for children with cleft palate present than for children with cleft lip only.[115,116] A recent study also found that children born with orofacial clefts may have poorer academic outcomes in elementary school than their peers, but that more study is needed to confirm results and track outcomes at higher grades. The study does not differentiate the performance of children based on their level of cleft repair.[117]

It is estimated that 6.35 babies per 10,000 are born annually with a cleft palate without cleft lip (1 in 1574), and a total of 10.6 babies per 10,000 are born with a cleft lip with or without a cleft palate (1 in 940).[118,119,120] Comparably, as of 2012, 9.2 babies per 10,000 are born in Massachusetts with an orofacial cleft.[121] Isolated orofacial clefts, occurring without another major birth defect, are one of the most common types of birth defects in the United States, and comprise approximately 75 percent of total cases of children with birth defects.[122]

While the causes of orofacial clefts are unknown, these birth defects are thought to be the result of a combination of genetic and environmental factors. Babies born to mothers with diabetes, who smoke or drink alcohol, or who use certain medications during the first trimester of pregnancy face an increased risk of orofacial clefts.[123,124] A mother's healthy diet in the year before pregnancy reduces the risk of orofacial cleft,[125] as does adequate intake of folic acid.[126]

Treatment of orofacial clefts vary based on the cleft's severity, the child's age, needs, and other birth defects or syndromes that may be present.[127] Surgical repair is recommended within the first year of life for cleft lip, and within the first 18 months for cleft palate (earlier if possible).[128] Additional surgeries are often necessary as the children age, including those to improve breathing, hearing, speech, language development, and appearance.[129] Treatment by otorhinolaryngologists, audiologists, dentists, orthodontists, or speech or language therapists may also be necessary.[130] Some children and families also benefit from peer and other emotional support resources.[131] The American Cleft Palate-Craniofacial Association recommends that children with orofacial clefts receive treatment through specialized cleft and craniofacial teams who can coordinate the variety of services needed throughout infancy, childhood, adolescence, and if necessary, adulthood.[132] Interdisciplinary teams include health professionals from medical, dental, surgical, and allied health

disciplines.[133] According to the national Cleft Palate Foundation, there are four such teams in Massachusetts, with two in Boston, and one each in Springfield and Worcester.[134]

While no study was found evaluating the spectrum of services mandated for treatment of orofacial clefts as a whole, the individual services outlined within the legislation have been proven effective for the specific symptom or condition they address.

Estimate of the cost of the mandate

The RDC of this mandate was calculated as the sum of paid amounts from all claims with a primary or secondary diagnosis of cleft palate or cleft lip[x] for members aged 0-17. The estimated PMPM RDC paid claim amount was $0.12, with a total PMPM cost, after administrative loading, of $0.13 (or 0.03 percent of the Commonwealth total premium). Per member per month self-insured allowed expenses for these services were found to be $0.004 lower than fully-insured PMPM allowed expenses, resulting in a lower bound cost impact estimate, including administrative loading, of $0.004 PMPM, or 0.001 percent of Commonwealth premium. Table 4 below displays a summary of these results and related statistics.

Table 4
Cleft lip and Cleft palate Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower
Sample Users	385	356	
Sample Units	29,083	20,880	
Sample Average Members	1,871,491	1,490,706	
Paid PMPM	$ 0.12	$ 0.11	$ 0.004
Paid PMPM With Admin	$ 0.13	$ 0.13	$ 0.004
Allowed PMPM	$ 0.12	$ 0.12	$ 0.004

	Upper Bound		Lower Bound
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 3,295,170		$ 103,431
Contribution to Total Annual Premium	$ 3,702,438		$ 116,215
Percent of Total Premium	0.03%		0.001%

*Net amounts do not remove overlap in mandated services between the cleft palate and lip mandate and the home health mandate.

Diabetes-related Services and Supplies

The diabetes mandate requires coverage for a wide range of services and supplies related to diabetes treatment, including: blood glucose monitoring gear, urine glucose strips, ketone strips, lancets, insulin, insulin syringes, prescribed diabetes medications that influence blood sugar level,

[x] Any ICD-9 diagnosis code with the first three digits "749." The 2014 analysis period was prior to the ICD-10 cutover.

laboratory tests, insulin pumps, therapeutic shoes and inserts, supplies and equipment approved by the FDA, and outpatient self-management education, including medical nutrition therapy.[135]

Effect of the mandate on health

Diabetes is one of the most serious and widespread illnesses in the U.S., in which it is the seventh-leading cause of death. It affects 9.1 percent of, or 29.1 million, Americans, including 21 million diagnosed and an estimated 8.1 million undiagnosed patients.[136] Over 1.7 million new cases were diagnosed in 2012, and another 37 percent of adults in the U.S., including 51 percent of the over-65 population, have pre-diabetes.[137] Of adults in Massachusetts, 7.7 percent have been diagnosed with diabetes as of 2013,[138] and 5.1 percent have at some point been told they have pre-diabetes, slightly under the national figure of 5.9 percent.[139]

Diabetes mellitus is caused by the body's inability to produce or process insulin, the hormone used by the body to absorb and utilize glucose for energy.[140] The three most common types of diabetes are: type 1diabetes, in which a body is unable to produce insulin; type 2 diabetes, which is a combination of a body's resistance to insulin and insufficient insulin production; and gestational diabetes, a pregnancy complication.[141]

When the body's blood glucose levels rise above normal, metabolic problems occur resulting in serious complications and other illnesses. Diabetes reduces normal life expectancy by up to 15 years, and increases the risk of:[142,143,144]

- Heart disease, stroke, and hypertension: Diabetes increases the risk of heart disease two to four times.
- Kidney failure: In 2011, diabetes was the primary cause of kidney failure in 44 percent of new cases.
- Non-traumatic lower limb amputation: Diabetes patients account for over 60 percent of nontraumatic lower limb amputations, or about 73,000 in 2010.
- Complications of pregnancy, including major birth defects, spontaneous abortion, and excessively large babies, as well as type 2 diabetes in the child.[145]
- Nervous system disease, including impaired sensation in hands or feet, slow digestion, carpal tunnel syndrome, and erectile dysfunction
- Adult-onset blindness and eye problems
- Dental and periodontal (gum) disease
- Biochemical imbalances, including diabetic ketoacidosis and hyperosmolar coma
- Depression

Objectives to curb and control diabetes comprise a significant part of Healthy People 2020, the set of national health promotion and disease prevention goals outlined for the next decade by the U.S. Department of Health and Human Services.[146] Key diabetes objectives include reductions to mortality (all-cause, diabetes-related, and cardiovascular disease-related) and lower extremity amputations in part through the following measures (this list is not exhaustive):[147]

For all those diagnosed with diabetes:

- Improve glycemic and lipid control

- Increase the proportion who control their blood pressure, receive an annual dental exam and urinary microalbumin measurement, and receive formal diabetes education
- Increase the proportion who are diagnosed

For adults diagnosed with diabetes, increase the proportion who:

- Receive annual foot and dilated eye examinations
- Receive at least a semi-annual glycosylated hemoglobin measurement
- Perform blood glucose self-monitoring at least once daily

For those at high risk for diabetes with pre-diabetes, increase the proportion who report:

- Increasing their level of physical activity
- Trying to lose weight
- Reducing the amount of fat or calories in their diet

The supplies and services required under the Massachusetts mandate are necessary to effectively manage diabetes, as outlined in the previous list of evidence-based measures.

Estimate of the cost of the mandate

The RDC of this mandate was calculated as the sum of paid amounts from all claims incurred by target-population members with at least two claims with a primary or secondary diagnosis of diabetes during the calendar 2014 study period for diabetes-related services, devices, or drugs. The estimated PMPM RDC paid claim amount was $6.20, with total PMPM cost, after administrative loading, of $6.97 (or 1.60 percent of the Commonwealth total premium). Self-insured medical costs for these services were found to be *higher* than fully-insured medical costs, resulting in a lower bound impact estimate, including administrative loading, of $0. As noted above, the diabetes services and supplies mandate RDC estimate increased nearly three-fold (267 percent) between the 2012 study and the present study, though the lower-bound estimate is zero in both cases owing to the equally large degree to which self-insured employers pay for these services. This result is driven by code additions to the mandate specifications by the carriers as well as ongoing increases in diabetes prevalence and price and service mix changes since the analysis period (2009) of the previous report.

Table 5 below displays a summary of these results and related statistics.

Table 5
Diabetes-related Services and Supplies Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	55,654	60,696	
Sample Units	49,743,314	30,273,883	
Sample Average Members	1,437,788	1,432,254	
Paid PMPM	$ 6.20	$ 7.36	$ -
Paid PMPM With Admin	$ 6.97	$ 8.27	$ -
Allowed PMPM	$ 7.09	$ 8.21	$ (1.12)

	Upper Bound Impact		Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$175,791,850		$ -
Contribution to Total Annual Premium	$197,518,932		$ -
Percent of Total Premium	1.60%		0.00%

*Net amounts do not remove overlap in mandated services between the diabetes mandate and the home health, nurse practitioner, podiatrist, and hypodermic syringe and needle mandates.

Early Intervention Services

This mandate requires coverage for all "early intervention services" from birth until age three for children with or at risk for specified developmental delays including chromosomal abnormality, neurological condition, metabolic disorder, visual impairments, permanent hearing loss of any degree, and delayed cognitive, physical, communicative, social, or emotional development.[148]

Effect of the mandate on health

Neuroscience shows that early in life, brains grow hierarchically from the simplest to the most complex circuits.[149] Sensory pathways develop first, including vision and hearing, followed by early language skills, and then higher cognitive skills.[150] In the first few years, hundreds of neural connections are made every second; after this initial rapid growth, these connections are reduced so that the brain functions more efficiently. Connections used during this period are reinforced, while those not used are pruned. This means that "[e]arly experiences affect the nature and quality of the brain's developing architecture."[151] Brain architecture is mostly developed during the first three years of life, and the primary mode of this early learning is the interaction between a child, his caregivers, and his family as a unit.[152] For children born at-risk or diagnosed with a developmental delay or disability, these interactions can be compromised, thus impacting lifelong growth and development.

Early intervention is a group of services and supports designed to help children gain basic skills, usually in the first two years of life, including physical, mental, communication, social, and emotional.[153] Services often include physical, occupational and/or speech therapy, family training, nutrition services, case management, referrals, and services for hearing impairment.[154] Each state provides its own set of programs and services to children from birth to age 2 who have been diagnosed with developmental disease or disability, under Part C of Public Law 108-77: Individuals with Disabilities Education Improvement Act (2004), or "IDEA."[155] Some states, including Massachusetts, extend these services to children only at-risk for such delays and disabilities, and continue them until age 3.

Early intervention services have been shown to prevent developmental delay, as measured by placement in special education as well as retention in grade when a child reaches school age.[156] Moreover, it is "deemed essential to prevent mental retardation and poor intellectual development in children whose families do not provide adequate stimulation in the early years of life."[157] Improved outcomes in health, language and communication, cognitive and social/emotional development, as well as academic achievement, labor market success, and a reduction in delinquency, crime, and social welfare program use, have been shown in children who receive high quality early intervention services.[158,159,160]

Estimate of the cost of the mandate

Regulations on required benefits for 2016 issued pursuant to the ACA (45 CFR §156.115(a)(5)(i)) include in EHBs "habilitative services". They define such services as those that "help a person keep, learn, or improve skills and functioning for daily living (habilitative services). Examples include therapy for a child who is not walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology and other services for people with disabilities in a variety of inpatient and/or outpatient settings." But the specific services included, and whether the definitions would include early intervention services, are unclear on the surface and left to the states.[161] For reasons cited in the overview of the methodology, this analysis assumes federal EHB requirements do not address state-mandated early intervention services.

The RDC of this mandate was calculated as the sum of paid amounts from all claims for specifically identified early intervention procedure codes[xi] plus all claims for evaluation and management procedures performed by certified early intervention providers[xii] for members under three years of age in the target population and period. The estimated PMPM RDC paid claim amount was $0.91, with a total PMPM cost, after administrative loading, of $1.02 (or 0.23 percent of the Commonwealth total premium). Per member per month self-insured allowed expenses for these services were found to be $0.10 lower than fully-insured PMPM allowed expenses, including

[xi] HCPCS codes 96153, H0031, H0032, H2012, H2015, H2019, T1015, T1023, T1024, T1025, T1026, and T1027.

[xii] Plans differ in the method used to identify EI providers in their claims systems: Some plans use specific early intervention procedure code modifiers, others use an early intervention provider type code. Compass extracted claims from the MA APCD extract based on carrier-specific rules provided in the carrier specification review.

administrative loading, of $0.11 PMPM, or 0.03 percent of Commonwealth premium. Table 6 below displays a summary of these results.

Table 6
Early Intervention Services Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower
Sample Users	7,070	5,237	
Sample Units	1,123,227	825,078	
Sample Average Members	1,871,491	1,490,706	
Paid PMPM	$ 0.91	$ 0.79	$ 0.10
Paid PMPM With Admin	$ 1.02	$ 0.88	$ 0.11
Allowed PMPM	$ 0.93	$ 0.83	$ 0.10

	Upper Bound Impact		Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 25,716,707		$ 2,780,295
Contribution to Total Annual Premium	$ 28,895,176		$ 3,123,927
Percent of Total Premium	0.23%		0.03%

*Net amounts do not remove overlap in mandated services between the early intervention mandate and the home health, nurse practitioner, and autism mandates.

Hearing Aids for Children

The children's hearing aid mandate requires coverage for any child, age 21 years or younger, for one hearing aid per hearing-impaired ear, up to $2,000 for each hearing aid, every 36 months. Coverage includes all related services prescribed by an audiologist or hearing instrument specialist, including the initial evaluation, fitting and adjustments, and supplies, including ear molds.[162]

Effect of the mandate on health

Hearing loss can occur in a variety of ways when any part of the ear, including the inner, middle, or outer ear, the acoustic nerve, or auditory system, is not functioning properly.[163] Hearing loss may be caused by one or more of many factors, including genetic (approximately 50 percent of cases); maternal infection, pregnancy complications, or head trauma (25 percent); or an unknown cause (25 percent).[164,165] For about 33 percent of babies with genetic hearing loss, the loss is related to another "syndrome" or condition.[166] Approximately 25 percent of children with hearing loss have one or more developmental disabilities.[167]

Hearing loss is categorized in a variety of ways, including:[168]

- Type:
  - Conductive: Something stops sound from reaching the outer or middle ear.
  - Sensorineural: Caused by inner ear or nerve problems.
  - Mixed: Caused by both conductive and sensoineural issues.

  - Auditory Neuropathy Spectrum Disorder: Damage to the inner ear or nerve disrupts the brain's ability to organize sound.
- Degree
  - Mild: May hear some speech; soft sounds are difficult to hear.
  - Moderate: Hears almost no speech at normal level.
  - Severe: Hears no speech at normal level; only some loud sounds are heard.
  - Profound: Hears no speech and only very loud sounds.
- Unilateral or bilateral: One or both ears
- Pre-lingual or post-lingual: Before or after person learned to speak
- Symmetrical or asymmetrical: Same in both ears or different
- Progressive or sudden: Hearing worsens over time or happens quickly
- Fluctuating or stable: Hearing gets better or worse over time or remains the same
- Congenital or acquired (delayed onset): Hearing loss present at birth or appears sometime later

Hearing loss, if left undetected, can hinder a child's development in many ways, leading to "difficulties later in life, including problems with listening and speaking skills, literacy skills, academic performance, and long-term job opportunities."[169]

Estimates of the prevalence of hearing loss in children vary. One study found almost 15 percent of children ages 6 to 19 had low or high hearing loss in one or both ears at 16-decibels,[170] while another summarized parent-reported hearing loss in their children at 20 percent overall.[171] A study of 8 year old children concluded that 1.4 per 1000 suffered bilateral hearing loss at 40 decibels or more.[172] In Massachusetts, recent findings estimate that 12.7 percent of infants screened are found to have hearing loss, or 2.2 per 1000 newborns; these numbers are higher than the national figures of 9.8 percent and 1.5 per 1000.[173] These figures, however, may be low as they do not include late-onset hearing loss or infants not screened at birth.

Hearing loss may be corrected to some degree depending on the type, severity, and cause of the loss.[174] Medications and surgery may be used to correct some conductive hearing loss, especially those caused by infection or malformation of the outer and/or middle ear.[175] For those who may have residual hearing, technology can maximize the hearing that remains.[176] Those with severe to profound hearing loss may benefit from a cochlear implant, a device surgically implanted into the ear to conduct sound directly to the auditory nerve.[177]

For many others with hearing loss of varying causes, a hearing aid can be used, including by infants and children. Hearing aids are designed to amplify and sometimes clarify sounds.[178] The small electronic devices, comprised of a microphone, amplifier, and speaker, are available in in-the-ear, behind-the-ear, or in-the-canal varieties.[179] Sound is received through the microphone, converted to electronic signals, sent to the amplifier that manipulates the power of the signals, and then to the ear through the speaker.[180] Middle-ear implants and bone-anchored hearing aids are also available, but must be surgically implanted; these work differently than other types of hearing aids, helping instead to increase sound vibration transmission to the inner ear.[181]

Studies have found that hearing aids improve communications outcomes for children[182], and the "degree of improved hearing provided by [hearing aids] was associated with better speech and language development in children."[183] Likewise, quality of life indicators improve for hearing-impaired children and their families with use of hearing aids.[184] The age when a child is fit for a device is a significant factor in outcomes regarding communication, including speech perception and production, as well as spoken language.[185] Other factors influencing outcomes for children with hearing loss who were fitted with hearing aids include the presence or absence of other disabilities, severity of hearing loss, gender, and maternal education.[186]

Estimate of the cost of the mandate

The RDC of this mandate was calculated as the sum of paid amounts from all claims with ICD-9 or HCPCS procedure codes indicating a hearing aid-related service or a hearing assessment for a member younger than 22. The estimated PMPM RDC paid claim amount was $0.24, with a total PMPM cost, after administrative loading, of $0.27 (or 0.06 percent of the Commonwealth total premium). Self-insured allowed medial costs per person for chiropractic services were found to be *higher* than fully-insured medical costs, resulting in a lower bound impact estimate, including administrative loading, of $0. Table 7 below displays a summary of these results and related statistics.

Over 85 percent of the claims expense volume in Table 7 is comprised of routine hearing assessments rather than hearing aid-specific device, fitting, and service expenses. Assessment services are included in the statutory language for this mandate, and as such Table 7, the summary exhibit, and the aggregated mandate results include assessments include these services, but hearing assessments were mandated elsewhere before passage of this specific mandate, and were not treated as incremental to the mandate in CHIA's prospective analysis of the costs of this mandate.[187]

Therefore, to provide an estimate of the effect of the child hearing aids mandate *per se,* Table 8 presents separate results for the hearing aid-specific procedures, including device and fitting costs required by the mandate.

Table 7
Hearing Aids for Children Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	74,236	63,894	
Sample Units	109,991	94,925	
Sample Average Members	1,871,491	1,490,706	
Paid PMPM	$ 0.24	$ 0.30	$ -
Paid PMPM With Admin	$ 0.27	$ 0.34	$ -
Allowed PMPM	$ 0.30	$ 0.33	$ (0.03)

	Upper Bound Impact	Lower Bound Impact*
Insured Population	2,362,745	2,362,745
Contribution to Total Annual Claims	$ 6,892,940	$ -
Contribution to Total Annual Premium	$ 7,744,876	$ -
Percent of Total Premium	0.06%	0.00%

*Net amounts do not remove overlap in mandated services between the hearing aids for children mandate and the speech, language, and hearing mandate.

Table 8
Hearing Aid-Specific Procedures for Members Less than 22 Years of Age
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	467	395	
Sample Units	1,770	1,356	
Sample Average Members	1,871,491	1,490,706	
Paid PMPM	$ 0.03	$ 0.03	$ 0.003
Paid PMPM With Admin	$ 0.04	$ 0.03	$ 0.004
Allowed PMPM	$ 0.04	$ 0.03	$ 0.004

	Upper Bound Impact	Lower Bound Impact*
Insured Population	2,362,745	2,362,745
Contribution to Total Annual Claims	$ 963,113	$ 92,459
Contribution to Total Annual Premium	$ 1,082,150	$ 103,887
Percent of Total Premium	0.009%	0.001%

The results in Table 8 suggest that the hearing aid device and hearing aid-specific services (i.e., non-assessment) provisions of the hearing aids for children mandate contributed between $0.004 and

$0.04 (between 0.001 and 0.009 percent) to the Commonwealth average fully-insured commercial monthly health care insurance premium.

Home Health Care

The home health care mandate requires coverage for services provided by a home health agency in a patient's residence.[188]

Effect of the mandate on health

Home health care is a term describing a broad range of health care and supportive services provided in the home.[189] Services are most often used by those recovering from illness or injury, the disabled, or those with a chronic or terminal illness who need nursing, medical, social, or therapeutic treatment, and/or assistance with activities of daily living.[190] Home health care is often provided by licensed practical nurses, therapists, or home health aides.[191]

Provision of services in the home may allow for more rapid discharge from inpatient settings, or for a delay in need for long-term nursing home or other institutional care.[192] Use of home health care services continues to grow for a variety of reasons, including the aging of the population, medical advances allowing better disease management, technological advancements, changes to inpatient reimbursement, increasing cost of hospital, nursing home, and other facilities, and patient choice.[193]

Home health care is medically based, and may include:[194] [195]

- Occupational, physical and/or speech therapy and other rehabilitative services
- Skilled nursing
- Case management
- Medical social services and counseling
- Behavioral and mental health counseling
- Medical case management
- Medication management
- Pain management
- Parenteral and enteral nutrition therapy (tube feeding)
- Infusion therapy
- Hospice and palliative care
- Telemedicine
- Vaccination
- Wound care
- Home medical equipment assistance
- Patient and caregiver education
- Home safety instruction and assistance
- Assistance with daily living (including bathing, dressing, and eating)
- Home care support (including housekeeping and cooking)

Given the wide variety of available services, summarizing the clinical effectiveness of home health care is especially challenging. However, research has shown that the provision of well-defined, quality home health care services can provide significant clinical benefits. Some studies have found that home based services can significantly reduce mortality and admissions for non-hospital long-term institutional care,[196,197] while others have documented that those services decrease the rate of decline of functional status.[198] According to the CMS, "[h]ome health care is usually less expensive, more convenient, and just as effective as care…in a hospital or skilled nursing facility (SNF)."[199]

Home healthcare has also been shown to be particularly effective for the care of the terminally ill. Terminally ill patients receiving home health care had fewer hospitalizations, nursing home admissions, and other healthcare visits, were more likely to be able to die at home according to their wishes, and "expressed significantly higher satisfaction" with their care.[200] Moreover, provision of home health services has led to higher quality of life measures for terminally ill patients and their caregivers, and rates of satisfaction with care are higher for both patients and caregivers for both terminal and non-terminal illnesses.[201]

Estimate of the cost of the mandate

The RDC for this mandate was calculated as the sum of paid amounts from all claims for all procedures where the place of service indicated on the claim was the patient's residence. The estimated PMPM RDC paid claim amount was $9.07, with a total PMPM cost, after administrative loading, of $10.19 (or 2.34 percent of the Commonwealth total premium). Self-insured allowed medical expenses for these services were found to be slightly *higher* than fully-insured allowed medical expenses, resulting in a $0 lower bound impact estimate, including administrative loading. Table 9 below displays a summary of these results and related statistics.

Table 9
Home Health Care Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	177,244	145,240	
Sample Units	20,558,276	19,654,385	
Sample Average Members	1,871,491	1,490,706	
Paid PMPM	$ 9.07	$ 9.28	$ -
Paid PMPM With Admin	$ 10.19	$ 10.43	$ -
Allowed PMPM	$ 9.73	$ 9.77	$ (0.04)

	Upper Bound Impact		Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$257,246,649		$ -
Contribution to Total Annual Premium	$289,041,179		$ -
Percent of Total Premium	2.34%		0.00%

*Net amounts do not remove overlap in mandated services between the home health mandate and the autism, cleft palate and lip, diabetes services, early intervention, limb prostheses, low protein foods, nonprescription enterals , nurse practitioner, podiatrist, scalp hair prostheses, and speech, hearing, and language mandates.

Hormone Replacement Therapy (HRT)

The hormone replacement therapy (HRT) mandate requires policies covering outpatient services or outpatient prescription drugs and devices to provide hormone replacement therapy (services and drugs) for peri- and post-menopausal women under the same terms and conditions as other outpatient services/drugs.[202]

Effect of the mandate on health

Menopause is the phase in a woman's life in which menstruation naturally stops, marking the end of her reproductive years.[203] During her reproductive phase, a woman's ovaries produce the hormones estrogen and progesterone to control the menstrual cycle. During the perimenopausal years leading up to menopause, the levels of estrogen begin to decrease, causing some women a variety of mild to severe symptoms.[204]

Fifty to eighty-two percent of US women experience hot flashes, or a sudden feeling of heat that may last seconds to several minutes, causing flushing, chills, clamminess, perspiration, anxiety, sleep disturbances (night sweats), and heart palpitations.[205,206] For 87 percent of these patients, such vasomotor episodes occur daily, and at least ten times per day for 33 percent of patients; the median duration of symptoms varies from 4 to 10 years.[207] Ten to forty percent of patients experience vaginal atrophy, vaginal dryness, and urinary tract changes and infections.[208] Other symptoms include osteoporosis, or the loss of bone density leading to fractures including those of the hip or spine, mood changes, irregular periods, weight gain, and slowed metabolism.[209,210]

To treat the perimenopausal and menopausal symptoms of some patients, estrogen is used as hormone replacement therapy (HRT), or "estrogen therapy" (ET).[211] For those who have never had a hysterectomy and still have a uterus, progestin is added to reduce the risk of endometrial or uterine cancer, in a treatment known as "combined hormone therapy" (CHT).[212,213] While certain symptoms may be treated with a local estrogen-only regimen, combination therapy is administered systemically in the form of pills or a skin patch.[214]

Systemic estrogen, with or without progestin, is the most effective proven treatment for relieving hot flashes and night sweats.[215] Systemic estrogen therapy has been shown to protect against bone loss and prevent hip and spine fracture.[216] Combined therapy may also help to reduce the risk of colon cancer, and systemic or local estrogen therapy is effective in relieving vaginal dryness.[217]

However, hormone therapy is also associated with an increased risk for certain diseases and conditions. Estrogen therapy alone increases the risk of endometrial or uterine cancer, as the treatment causes the lining of the uterus to grow; use of progestin in combination with estrogen decreases this risk.[218] Estrogen therapy is also associated with a small increased risk for gallbladder disease, which may be reduced with non-oral therapy administration.[219,220] Combined therapy is associated with a small increased risk of heart attack; this risk is related to a patient's age, when she begins therapy, and her other medical conditions. However, for women younger than 60 who begin combined therapy within 10 years of menopause, the combined therapy may protect against heart attack.[221] Combined therapy is also associated with a small increased risk for stroke and deep vein thrombosis (DVT), which may be diminished by using non-oral therapy routes.[222] Combined hormone therapy is also associated with a small increased risk of breast cancer, and is not recommended as a first-line treatment for patients with a history of hormone-sensitive breast cancer.[223]

Evidence now exists to support certain non-hormonal treatment of menopausal symptoms, including selective serotonin reuptake inhibitors and selective serotonin/norepinephrine reuptake

inhibitors (SSRI and SNRI, types of anti-depressants),[224] clonidine/Catapres (a drug used to lower blood pressure),[225] and gabapentin/Neurotin (a drug approved to treat seizures)[226] for treatment of hot flashes.[227] However, the only FDA-approved non-hormonal therapies include paroxetine for vasomotor symptoms (hot flashes)[228] and ospemifene for dyspareunia (difficult intercourse),[229] both approved in 2013. Herbal treatments, estriol, and bio-identical hormones are not currently FDA-approved for the treatment of menopausal symptoms.[230]

The use of HRT became very controversial after release of the findings of the landmark 1998 Women's Health Initiative (WHI) clinical trials. These studies, conducted by the National Heart, Lung & Blood Institute, focused on the prevention of heart disease, breast and colorectal cancer, and osteoporosis in postmenopausal women through treatment with hormone therapy, dietary patterns, and calcium/vitamin D supplements.[231] Additional similar studies included the collaborative reanalysis (CR) and the Million Women Study (MWS). Researchers from these studies concluded that, while hormone therapy reduced risks of colorectal cancer and fractures from osteoporosis, it potentially increased risks for coronary heart disease, breast cancer, venous thromboembolism, stroke, cholecystitis, dementia, and lower global cognitive function.[232] Critics of the studies' designs and generalizability questioned these results,[233,234,235,236,237] yet many patients and clinicians failed to differentiate when comparing the risk and rewards of using HRT for treatment of menopausal symptoms versus its use for chronic disease prevention in postmenopausal women. This confusion led many clinicians and patients to abruptly end HRT, which caused "a significant and sudden reduction in quality of life," and led patients to seek alternative treatments that had not been studied for safety and efficacy when used for menopausal symptoms.[238]

The current recommendations of the American College of Obstetricians and Gynecologists related to the treatment of menopausal vasomotor and vaginal symptoms direct patients and providers to discuss the individual's benefits and risks from HRT. In general, patients should use the lowest effective dose for the shortest time possible to treat menopausal symptoms, and should be reevaluated yearly to continuously assess benefits and risks of treatment. Additionally, the treatment guidelines published by the Endocrine Society recommend screening for breast cancer and cardiovascular risk before initiating HRT.[239]

Researchers who retrospectively examined the impact of the WHI results on HRT use concluded:

> [Q]uestions about the long-term health consequences of HRT remain. The women in the WHI were older and taking higher doses of estrogen than women using HRT today. In addition, a number of other hormonal options are available, yet their comparative risks and benefits are unknown. These include different types of hormones — conjugated and synthetic estrogens, phytoestrogens, synthetic progestin, and natural progesterone — and modes of delivery — oral tablets, transdermal patches, local creams, and intrauterine devices. Without further study, deciding on the best treatment plan will continue to involve an amount of guesswork.[240]

Current guidelines explicitly recommend against the use of HRT to prevent postmenopausal chronic conditions, including coronary heart disease,[241] breast cancer, or dementia.[242] The USPSTF recommends against the use of HRT only when used for the prevention of chronic medical conditions, stating:

> This recommendation applies only to postmenopausal women who are considering hormone therapy for the primary prevention of chronic medical conditions. This is not a recommendation about the use of hormone therapy to treat menopausal symptoms, such as hot flashes or vaginal dryness; the USPSTF did not review the evidence related to this possible indication because it falls outside of the mission and scope of the USPSTF. This recommendation also does not apply to women younger than 50 years who have had surgical menopause.[243]

Estimate of the cost of the mandate

Regulations issued pursuant to the ACA (45 CFR 156.122) require EHBs to include at least one drug in each USP category and/or class. The effect of this regulation is to require carriers to include an estrogen/progestin in their formularies, although the regulations do not address HRT directly. This analysis will not address the argument that, by requiring carriers to include the drugs in their formularies, the federal regulation also requires them to pay for every FDA-approved use of the drug; i.e., this analysis will not assume the regulation requires carriers to pay claims for those drugs specifically for treating symptoms of menopause in peri-and post-menopausal women.

RDC for this mandate was calculated as the sum of paid amounts from all claims for specific hormone replacement therapy procedures and pharmaceuticals as well as Evaluation and Management (E&M) procedures with a diagnosis (in any of the top five diagnosis columns) associated with menopause-related hormone regulation. The estimated PMPM RDC paid claim amount was $0.41, with a total PMPM cost, after administrative loading, of $0.46 (or 0.11 percent of the Commonwealth total premium). Per member per month self-insured allowed expenses for this mandate were found to be $0.04 lower than fully-insured PMPM allowed expenses, resulting in a lower bound expense estimate, including administrative loading, of $0.03 PMPM, or 0.01 percent of Commonwealth premium. Table 10 below displays a summary of these results and related statistics.

Table 10
Hormone Replacement Therapy Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	& Lower Bound PMPMs
Sample Users	19,386	9,780	
Sample Units	3,051,706	1,522,383	
Sample Average Members	1,437,788	1,432,254	
Paid PMPM	$ 0.41	$ 0.41	$ 0.03
Paid PMPM With Admin	$ 0.46	$ 0.46	$ 0.03
Allowed PMPM	$ 0.58	$ 0.54	$ 0.04

	Upper Bound Impact		Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 11,563,949		$ 740,590
Contribution to Total Annual Premium	$ 12,993,201		$ 832,123
Percent of Total Premium	0.11%		0.01%

*No significant overlaps were found between this and other mandates.

Human Leukocyte Antigen Testing

The human leukocyte antigen (HLA) testing mandate requires coverage for HLA or histo-compatibility locus antigen testing necessary to establish the suitability of a bone marrow transplant donor.[244]

Effect of the mandate on health

HLA testing is used to identify good matches for patients in need of tissue grafts or organ transplant, and may be used to diagnose some autoimmune disorders, monitor certain medication treatments, and determine parent/child biological relationships.[245] Such transplants include hematopoietic (blood) stem cell transplants (HSCT), which, for many diseases, is part of standard treatment, and others for which HSCT has become a viable option and may be the only available cure.[246] These diseases include leukemia and certain lymphoma, metabolic, blood, autoimmune, and genetic disorders.[247] Transplants are intended to replace unhealthy with healthy blood-forming cells, and can come from one of three sources: bone marrow transplant (BMT), umbilical cord blood, or, most commonly, peripheral blood.[248,249] The two types of HSCTs include autologous, in which a patient's own cells are used for transplant, or allogeneic, which uses donor cells.[250] This mandate specifically refers to bone marrow transplant, and does not include umbilical cord or the more common peripheral blood transplants in its language.

HLAs are proteins found in most cells and serve as immunologic markers which the body uses to identify which cells belong to a patient and which do not.[251] For allogeneic donations, the best matches for BMTs are siblings who have identical markers.[252] However, sibling matches account for only 30 percent of BMTs, leaving 70 percent of patients in need of an unrelated donation.[253,254]

Due to growth in overall numbers and population diversity in the National Marrow Donor registry (Be The Match™), most patients who will benefit from HCT will have a suitable, if not optimal, donor.[255]

The better the HLA match between patient and donor, the better a patient's chances for survival.[256] While many HLA markers exist, only a small number are critical to HSCT outcomes. The National Marrow Donor Program (NMDP) currently requires a minimum number of matches from a series of eight HLA markers[257] (two A, two B, two C and two DRB1) for a transplant to be received from its donor registry; ideal donors match the patient on eight of the eight markers.[258] In 2011, the overall survival rate for patients with related donor transplants was 79 percent, versus 69 percent for unrelated donors; this latter rate is rising as clinical practices have changed, and HLA typing and matching have improved.[259] Mismatched HLA puts a patient at risk for acute and chronic graft-versus-host disease, graft rejection, and treatment related mortality.[260] However, according to the NMDP, an imperfect match does not contraindicate transplantation; instead, "[i]f a mismatch is unavoidable, a…mismatched donor can be used with acceptable risks of transplant-related mortality."[261]

Testing for the HLA-C marker is not specifically outlined in the Massachusetts mandate; however, the language of the mandate does require "coverage for the cost of human leukocyte antigen testing or histocompatibility locus antigen testing that is necessary to establish bone marrow transplant donor suitability."[262] The mandate also includes reference to M.G.L. Chapter 111 Section 218 which provide that HLA testing must "conform to medical eligibility requirements and other test protocols established by the…national marrow donor program registry" which now includes the use of high resolution DNA testing for HLA-A, B, C and DRB1 markers.[263] This analysis presumes that the mandate covers testing under the current guidelines in place with the NMDP for BMTs.

Estimate of the cost of the mandate

RDC for this mandate was calculated as the sum of paid amounts from all claims with a procedure code indicating HLA testing[xiii] (per the carrier specification review) and a primary diagnosis indicating tissue donation.[xiv] The estimated PMPM RDC paid claim amount was $0.001, with a total PMPM cost, after administrative loading, of $0.001 (or 0.0002 percent of the Commonwealth total premium). Self-insured allowed medical expenses for these services were found to be slightly *higher* than fully-insured allowed medical expenses, resulting in a $0 lower bound impact estimate, including administrative loading. Table 11 below displays a summary of these results and related statistics.

[xiii] CPT codes 81377, 81383, 86812, 86813, 86816, 86817, 86821, 86822, 86825, 86826, 86828, 86829, 86830, 86831, 86832, 86833, 86834, 86835, 86812, 86813, 86816, or 86817.
[xiv] ICD-9 diagnosis codes V59.3, V59.9, or V70.8.

Table 11
Human Leukocyte Antigen Testing
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	230	224	
Sample Units	442	423	
Sample Average Members	1,871,491	1,490,706	
Paid PMPM	$ 0.001	$ 0.001	$ -
Paid PMPM With Admin	$ 0.001	$ 0.001	$ -
Allowed PMPM	$ 0.001	$ 0.001	$ (0.00)

	Upper Bound Impact		Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 18,339		$ -
Contribution to Total Annual Premium	$ 20,606		$ -
Percent of Total Premium	0.0002%		0.00%

*No significant overlaps were found between this and other mandates.

Hypodermic Syringes or Needles

This mandate requires coverage for medically necessary hypodermic syringes or needles.[264] The statutory sections requiring coverage for syringes and needles were enacted as part of a law addressing a broad set of issues relating to preventing transmission of blood-borne diseases, including needle distribution programs for users of illegal drugs. However, the mandate language included in this review is limited to medically necessary use of needles covered by insurers. While theoretically that might encompass illegal drug injection, addressing scenarios where illegal use might be involved, likely or not, is beyond the scope of this review.

Effect of the mandate on health

Many medications are self-administered by injection, requiring the use of sterile hypodermic needles or syringes. A wide range of illnesses are treated with patient-delivered injectable therapies, including multiple sclerosis,[265] infertility,[266] pernicious anemia,[267] iron deficiency,[268] cancer,[269] diabetes,[270] and HIV/AIDS[271] among others. Often these drugs must be injected, as the specific medication would be destroyed in the digestive process or is not tolerated orally.[272] Injectable drugs can also deliver a particular dosage of a drug over a long period of time, up to several months.[273] One disadvantage of injection, particularly self-injection, is the risk of infection; patients also may have a fear of needles or may be unable or unwilling to self-administer the drug by injection, making treatment adherence an issue.[274,275,276] Conversely, the ability for a patient to self-administer may improve compliance by eliminating the time and expense associated with additional clinical visits for these injections; patient selection, training and counseling, and simplicity of medication/syringe preparation may improve adherence.[277,278] The availability of newer technologies, such as pre-filled injectable pens, for some conditions may reduce the use of

hypodermic needles and syringes for self-administration; some studies conclude that patients find use of pens easier, more convenient and less stressful,[279] while use of the devices increases the accuracy of the medication dose. [280]

Estimate of the cost of the mandate

The RDC of this mandate was calculated as the sum of paid amounts from all claims with syringe or needle procedure or national drug codes (NDCs). The estimated PMPM RDC paid claim amount was $0.04, with a total PMPM cost, after administrative loading, of $0.04 (or 0.01 percent of the Commonwealth total premium). Self-insured allowed medical expenses for these services were found to be *higher* than fully-insured allowed medical expenses, resulting in a $0 lower bound impact estimate, including administrative loading. Table 12 below displays a summary of these results and related statistics.

Table 12
Hypodermic Syringes or Needles Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	15,904	9,305	
Sample Units	5,698,157	3,275,925	
Sample Average Members	1,437,788	1,432,254	
Paid PMPM	$ 0.04	$ 0.07	$ -
Paid PMPM With Admin	$ 0.04	$ 0.07	$ -
Allowed PMPM	$ 0.11	$ 0.13	$ (0.02)

	Upper Bound Impact		Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 1,083,290		$ -
Contribution to Total Annual Premium	$ 1,217,180		$ -
Percent of Total Premium	0.01%		0.00%

*Net amounts do not remove overlap in mandated services between the syringe and needle mandate and the diabetes mandate.

Infertility Treatment

The infertility mandate requires coverage for infertility treatments for members covered under plans that include pregnancy-related benefits to the same extent benefits are provided for other pregnancy-related procedures.[281]

Effect of the mandate on health

Infertility describes the inability of a woman or man to conceive a child, or a woman's ability to carry a pregnancy to term; it is clinically defined as the inability to become pregnant after one year of trying for a woman of normal childbearing age (or six months for a woman over age 35).[282] An

estimated 10.9 percent of women age 15 to 44 have an impaired ability to get pregnant, or to carry a baby to term (impaired fecundity).[283] Between 2006 and 2010, 17 percent of women age 25 to 44 or their partners had ever used infertility services, a decrease from the 1995 level of 20 percent.[284]

Research shows that the causes of infertility are approximately evenly divided between conditions affecting the woman, conditions affecting the man, and unknown causes.[285] A large number of specific conditions are described within those categories. For women, the most common cause is problems with ovulation, but many other physical, genetic, or environmental causes exist.[286] For men, the most common causes of infertility are problems with sperm (production, function, or delivery), behavior and lifestyle factors, and environmental exposures.[287]

A large number of treatments are available for infertility, and choosing among them depends on a variety of factors, including: the age and health of the parents; the causes, severity and duration of infertility; side effects; and treatment preferences.[288] Generally, however, treatments can be categorized as behavioral changes, medication, surgery, intrauterine insemination, or assisted reproduction techniques (ART).[289,290] Medications are most often used either to induce ovulation, or for "controlled ovarian hyperstimulation" (COH), where follicles are stimulated to grow, mature, and ovulate.[291] This can then be followed by artificial insemination or intrauterine insemination if necessary. COH is also part of ART, which are more complex and invasive techniques in which eggs are manipulated and fertilized outside of the body. Multiple fertilized eggs are then returned to a uterus for implantation, or are frozen for later use. Medication or surgery therapies are used in 85 to 90 percent of treated infertility cases; in-vitro fertilization (IVF) and other ART "account for less than 3 [percent] of infertility services."[292]

The effectiveness of infertility treatment is difficult to summarize as the factors leading to their use vary for each patient. Likewise, many treatments have not been evaluated through high-quality studies, and the definition of successful treatment is not standard.[293,294] One study summarized, "there is little convincing evidence on which to base treatment strategies for the majority of infertile couples. More high-quality data on the relative superiority of each treatment option, and associated adverse events, are needed."[295] Testing and treatment practices of infertility specialists continue to vary widely and evolve, while the age of couples seeking treatment continues to rise.[296]

One large study reviewed research findings regarding ovulation induction, COH and in-vitro fertilization, and analyzed short-term outcomes of pregnancy, live birth, multiple gestation, and complications, as well as long-term outcomes of pregnancy and post-pregnancy complications for mothers and children.[297] The authors found that high-quality evidence was lacking in the majority of the studies to support the choice of specific interventions.[298] However, there was evidence that pregnancy and live birth rates were improved with application of certain specific techniques.[299] Other studies have found that ART treatments, most frequently IVF and intracytoplasmic sperm injection (ICSI),[300] result in "reasonably high pregnancy rates;"[301] this success is prompting more patients to seek ART treatments sooner for their infertility.[302]

However, major risks are associated with ART, most notably multi-fetal and especially higher-order (triplets or more) gestations. More than 30 percent of pregnancies resulting from ART are twins or higher-order multiple gestations;[303] the complications of multiple gestations are well-documented.

One study found that more than 50 percent of ART-related newborns are born from a multifetal gestation.[304] For singleton pregnancies, IVF is associated with a slightly-increased risk of birth defects, as well as preterm delivery, perinatal (associated with birth) mortality, and infants small for their gestational age.[305] The mother's risk increases for preeclampsia, gestational diabetes, placenta previa, placental abruption, and cesarean delivery.[306] Beyond these, the major complication of ART for women is ovarian hyperstimulation syndrome.[307] Children born via such treatments are at risk for complications associated with abnormal placentation or implantation, although it is unclear whether this is due to the treatment, the infertility, or both.[308]

Information from the National Institutes of Health found that, for women treated with the medication clomiphene or clomiphine citrate, to stimulate hormones to help eggs mature in the ovaries, 80 percent ovulate; of these, 50 percent are able to achieve a pregnancy or live birth.[309] The drugs bromocriptine or cabergoline reduce the levels of prolactin, which has been shown to stop ovulation, for 90 percent of women with abnormally high levels of prolactin; 85 percent of these women can then ovulate.[310] The success of surgical treatment for infertility caused by diseases of the fallopian types are low and can increase the risk of ectopic pregnancy; on the other hand, surgeries to remove entrometrial patches can double the chances for pregnancy.[311]

Pregnancy rates from ART depend, among other factors, on the age of the mother. The following table summarizes national ART success rates:

2012 National ART Summary Success Rates

	Age of Women					
	<35	35-37	38-40	41-42	43-44	>44
Fresh embryos from non-donor eggs: Percentage of cycles resulting in live births						
Singleton	28.0	23.1	17.5	10.0	4.0	1.6
Triplets or more	0.5	0.2	0.2	0.1	0.0	0.0
All	40.5	31.3	22.2	11.7	4.5	1.8
Frozen embryos from non-donor eggs: Percentage of transfers resulting in live births						
Singleton	31.9	31.2	26.7	22.0	15.3	10.1
Triplets or more	0.4	0.2	0.2	0.1	0.1	0.0
All	42.0	39.3	33.4	25.9	28.2	19.4

Donor eggs: Percentage of transfers resulting in live births		
	Fresh embryos (all ages)	Frozen embryos (all ages)
Singleton	37.2	28.6
All	56.4	46.7

Many professional societies and organizations now recommend that the measurement of the effectiveness of infertility treatment, specifically ART, should be the birth of a single, healthy child.[312] They caution, however, that this goal may not be accepted for many reasons, including "insufficient awareness of the risks and costs associated with multiple pregnancy among the general public and policy makers," limitations in certain aspects of the ART process itself, the cost of

repeated treatment cycles, and competition between fertility specialists based on pregnancy or birth rates per cycle.[313]

Estimate of the cost of the mandate

The infertility mandate requires coverage for infertility treatments for members covered under plans that include pregnancy-related benefits to the same extent benefits are provided for other pregnancy-related procedures. The RDC for this mandate was calculated as the sum of paid amounts from all claims for infertility-related procedure codes and pharmaceuticals, as well as E&M procedures for members with a diagnosis of infertility. The estimated PMPM RDC paid claim amount was $3.96, with a total PMPM cost, after administrative loading, of $4.44 (or 0.95 percent of the Commonwealth total premium). Per member per month self-insured allowed expenses for this mandate were found to be $0.50 lower than fully-insured PMPM allowed expenses, resulting in a lower bound expense estimate, after administrative loading, of $0.54 PMPM, or 0.12 percent of Commonwealth premium. Table 13 below displays a summary of these results and related statistics.

Table 13
Infertility Treatment Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	19,386	9,780	
Sample Units	391,000	194,100	
Sample Average Members	1,162,496	976,376	
Paid PMPM	$ 3.96	$ 3.57	$ 0.48
Paid PMPM With Admin	$ 4.44	$ 4.01	$ 0.54
Allowed PMPM	$ 4.16	$ 3.66	$ 0.50

	Upper Bound Impact		Lower Bound Impact*
Insured Population	2,206,099		2,206,099
Contribution to Total Annual Claims	$104,727,260		$ 12,672,869
Contribution to Total Annual Premium	$117,671,078		$ 14,239,178
Percent of Total Premium	0.95%		0.12%

*No significant overlaps were found between this and other mandates.

Low Protein Foods (LPF)

The low protein foods mandate requires coverage for low protein food products required to treat infants and children with specified metabolic disorders (for inherited amino acid and organic acid diseases) as well as fetuses of pregnant women with phenylketonuria.[314]

Effect of the mandate on health

Phenylketonuria (PKU) is a rare metabolic disorder caused by a defect in the gene that helps to create the liver enzyme needed to break down the amino acid phenylalanine (Phe), which then builds up in the blood and other tissues.[315,316,317] Untreated, PKU can lead to microencephaly, mental retardation, seizures, congenital heart disease, and other significant physical, mental, behavioral, and developmental disorders.[318] Women with untreated PKU during pregnancy may bear children prematurely, or who suffer from birth defects.[319] The prevalence of PKU is approximately 1 in 13,500 to 19,000 births.[320]

In 2012, the National Institutes of Health sponsored a PKU Scientific Review Conference to address new research and outstanding questions regarding the management of PKU, while the Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Center (EPC) conducted an evidence review of the comparative effectiveness of PKU treatment, including diet and pharmacological interventions.[321,322] The result of these collaborative efforts included recognition of the effectiveness of strict dietary control to lower levels of the Phe amino acid in the body, before pregnancy in women and after birth for children with PKU.[323,324]

The low-Phe diet includes medical food and formulas, minimal animal products, and fruits and vegetables high in carbohydrates, and low in saturated and unsaturated fat and cholesterol.[325] This restricted diet may create nutritional deficits in some patients, especially for natural proteins; many patients take amino acid supplements as well as other vitamins and minerals to compensate for these deficiencies.[326] In 2007, the use of sapropterin dihydrochloride (Kuvan) was approved for the treatment of PKU for patients who tolerate and respond to the drug, to be taken in addition to the low-Phe diet.[327,328] Research has shown the drug may help some patients to control Phe concentrations while increasing tolerance of dietary Phe.[329]

To reduce the risk of birth defects and other developmental abnormalities, mothers at risk for PKU during pregnancy must achieve and maintain control of dietary Phe, preferably three months before conception.[330,331] For most children born with PKU identified through newborn screening who are treated early in life and can comply with this low-Phe diet, the outcomes have shown "remarkable success in preventing the devastating brain damage associated with untreated PKU."[332] In fact, those able to achieve and maintain metabolic control "have normal health and development and can likely expect a normal life span."[333] However, the nutritional treatment is difficult to maintain and complicated, while the formulas are often unpalatable and expensive.[334,335] Moreover, the low-Phe diet is not completely effective for all patients, as adherence is difficult and some patients may experience neurocognitive defects and progressive cognitive impairment despite therapy.[336,337] For these reasons, research continues to explore the development of new therapies.[338,339] Overall, however, while the precise level of phenylalanine restriction is unclear, research has shown that the low-Phe diet is effective in reducing blood phenylalanine levels and improving neuropsychological outcomes and intelligence quotient for patients with PKU.[340,341]

Estimate of the cost of the mandate

The LPF mandate covers low protein food products required to treat infants and children with specified metabolic disorders as well as fetuses of pregnant women with PKU. Costs of the mandate

were estimated as the sum of paid amounts from all claims incurred in the study period for procedure codes indicating the purchase of low protein food products. The estimated RDC PMPM paid claim amount was $0.05, with a total PMPM cost, after administrative loading, of $0.06 (or 0.01 percent of the Commonwealth total premium). Per member per month self-insured allowed expenses for this mandate were found to be $0.003 lower than fully-insured PMPM allowed expenses, resulting in a lower bound impact estimate, including administrative loading, of $0.003 PMPM, or 0.001 percent of Commonwealth premium. Table 14 below displays a summary of these results and related statistics.

Table 14
Low Protein Foods Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	359	283	
Sample Units	392,448	299,177	
Sample Average Members	1,871,491	1,490,706	
Paid PMPM	$ 0.05	$ 0.05	$ 0.003
Paid PMPM With Admin	$ 0.06	$ 0.06	$ 0.003
Allowed PMPM	$ 0.06	$ 0.05	$ 0.003

	Upper Bound Impact		Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 1,525,909		$ 78,313
Contribution to Total Annual Premium	$ 1,714,505		$ 87,993
Percent of Total Premium	0.01%		0.001%

*Net amounts do not remove overlap in mandated services between the low protein foods mandate and the nonprescription enteral formulas and home health mandates.

Nonprescription Enteral Formulas

The enteral formula mandate requires "coverage for nonprescription enteral formulas for home use…which are medically necessary for the treatment of mal-absorption caused by Crohn's disease, ulcerative colitis, gastro-esophageal reflux, gastrointestinal motility, chronic intestinal pseudo-obstruction, and inherited diseases of amino acids and organic acids."[342]

Effect of the mandate on health

Enteral nutrition (EN) provides patients with nutrients or food via a tube to the stomach or small intestine when the patient's diet does not meet her/his nutritional needs and results in continued weight loss and prolonged starvation.[343,344] Home enteral nutrition (HEN) is used most often for patients whose intestinal tract is functional, but have some degree of failure in the esophagus or throat; many of these patients have difficulty with swallowing; these include patients with certain neurological problems or head and neck cancers.[345] Other patients for whom HEN is necessary include those with certain gastrointestinal diseases, eating issues caused by dementia or

psychological disorders, or those whose energy demands cannot be met with oral nutrition, such as some AIDS patients.[346,347]

HEN is not without complications, including problems with tubes, gastrointestinal complications, and quality of life impact.[348] One study highlighted the very limited evidence comparing the benefit of EN compared to the complications, quality of life, costs and cost-effectiveness.[349] Research suggests that indications for the use of HEN should be outcome-specific.[350,351] Some studies have found that "EN has been accepted and implemented despite the lack of convincing scientific support of efficacy," and encouraged providers to determine the effectiveness of such therapy by specific patient, disease-state, and its corresponding research and evidence.[352] A recent clinical trial concluded that while HEN improved clinical outcomes, "[i]t was impossible…to determine precisely which factor mattered more: the artificial diet itself or the introduction of complex care."[353,354]

In summary, studies of enteral feeding have shown that, for patients whose oral intake of nutrition is inadequate and who have a functional gastrointestinal tract, EN does increase nutritional intake and thus improve nutritional status;[355,356] for these patients, HEN is a "life-sustaining therapy."[357] Malnutrition is a serious complication of many diseases, and enteral feeding, when appropriately prescribed and used, can minimize complications and be life-saving.[358] Tube feeding helps a patient to increase nutritional intake and avoid starvation and organ failure, and serves to maintain the intestinal tract's integrity and local defense barrier, thereby preventing additional digestive deterioration and the spread of destructive bacteria.[359] According to the American Gastroenterological Association, "[t]ube feeding should be considered when the patient cannot or will not eat, the patient has a functional gut, and a method of access can be safely obtained."[360]

Estimate of the cost of the mandate

The mandate requires "coverage for nonprescription enteral formulas for home use…which are medically necessary for the treatment of mal-absorption caused by Crohn's disease, ulcerative colitis, gastro-esophageal reflux, gastrointestinal motility, chronic intestinal pseudo-obstruction, and inherited diseases of amino acids and organic acids." Therefore, paid amounts from all claims with a procedure code indicating purchase of such formulas and a primary diagnosis of a covered disorder were summed to estimate RDC.

The estimated PMPM RDC paid claim amount was $0.03, with a total PMPM cost, after administrative loading, of $0.04 (or 0.01 percent of the Commonwealth total premium). Self-insured allowed medical expenses for these services were found to be *higher* than fully-insured allowed medical expenses, resulting in a $0 lower bound impact estimate, including administrative loading. Table 15 below displays a summary of these results and related statistics.

Table 15
Nonprescription Enteral Formulas Mandates
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	290	299	
Sample Units	364,972	321,368	
Sample Average Members	1,871,491	1,490,706	
Paid PMPM	$ 0.03	$ 0.04	$ -
Paid PMPM With Admin	$ 0.04	$ 0.05	$ -
Allowed PMPM	$ 0.03	$ 0.05	$ (0.011)

	Upper Bound		Lower Bound
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 924,982		$ -
Contribution to Total Annual Premium	$ 1,039,306		$ -
Percent of Total Premium	0.01%		0.000%

*Net amounts do not remove overlap in mandated services between the nonprescription enteral mandate and the low protein foods and home health mandates.

Oral Chemotherapy Treatment of Cancer

The oral chemo therapy mandate requires coverage for cancer chemotherapy treatment for prescribed, orally administered anticancer medications used to kill or slow the growth of cancerous cells on a basis not less favorable than intravenously-administered or injected cancer medications covered as medical benefits.[361]

Effect of the mandate on health

Chemotherapy is a class of treatments that impede living cells in the human body, with the intention of stopping the rapid growth and reproduction common to cancer cells.[362] In use since the mid-20th century, chemotherapy is most often infused intravenously into a patient, where the therapy disperses throughout the body through the blood and lymphatic symptoms.[363,364] This method is effective for delivering cytotoxic therapies, those intended to kill cells and normally administered in the maximum dose tolerable to a patient. Ordinarily, cytotoxic infusions happen during short intervals of treatment most often separated by long periods of rest; for example, a patient may receive daily chemotherapy for one week followed by no treatment for six weeks, repeating this cycle over several months.[365]

This treatment routine is necessary, as cytotoxic chemotherapy drugs act on all cells, killing or harming both healthy and cancerous cells, or cause other serious illnesses.[366] Serious side effects are common to certain chemotherapy treatments, depending on the toxicity of the drug combination, the type of cancer, and the overall health of the patient.[367] Over time, scientists have created new drugs, combinations, and delivery techniques; new targeted therapies; and approaches to mitigate side effects, all in an effort to improve treatment while minimizing the poisonous effects of chemotherapy on the body.[368] These improvements have been variably successful.

As regimens have developed and improved, the route of treatment administration has continued to evolve. While scientists increasingly focus on targeted agents, oral administration is becoming more common, allowing patients to take chemotherapy drugs by mouth via a pill, liquid, or film.[369] Each year, a larger proportion of newly-approved drugs are oral, some of which are not available as an intravenous equivalent.[370] (To receive FDA approval, drugs must be proven through significant research studies to be safe and effective; therefore, as more oral forms of treatment have received FDA approval, they have been proven effective for their labeled conditions.[371]) While some drugs cannot be delivered by mouth because of digestive irritation and absorption issues, oral delivery has the potential to deliver drugs over a more sustained period in a more convenient way,[372] providing patients with a sense of more control over their disease and treatment.[373] In most cases with oral therapies, patients are able to avoid the sometimes daily medical visits for infusion, but in turn must accept more individual responsibility for treatment.[374]

While patients gain convenience and control, they must comply strictly with instructions on when and how to take medication, monitor for complications, appropriately handle and store medications, and continue follow-up with their healthcare providers.[375] With the shift from office- to home-based treatment, the traditional roles of the patient, oncology treatment professionals, including doctors, nurses and pharmacists, and insurance and delivery management systems, also shift.[376] Compliance and medication errors must be continuously monitored and addressed by the entire team, now including the patient, to assure maximum treatment effectiveness.[377] And with oral delivery, patient outcomes are also impacted by food and drug interactions, which affect the effectiveness and toxicity of the drug.[378,379] Research has found that patients' shift from a passive to a more active treatment role has created a need to provide them more information and support to help them comply with their regimens.[380,381,382,383,384]

Oral therapies, which are often new drugs still under patent protection, are often much more expensive than intravenous treatments. To the extent patients are responsible for the costs of medication, particularly if that cost is very high, that cost might affect their compliance or at least their choice of treatment if infused alternative are available.[385] Prior to implementation of the Massachusetts mandate, self-administered drugs would often have proportionately higher cost sharing than would infused drugs, since the self-administered drugs were typically covered under a pharmacy benefit while infused drugs were typically covered under a medical benefit; the former typically has higher cost sharing.

Estimate of the cost of the mandate

RDC for this mandate was calculated as the decrease in PMPM patient cost sharing (defined as the difference between PMPM allowed expenses and PMPM carrier-paid expenses) expenses for all claims reporting a procedure or NDC code indicating an orally-administered cancer medication between 2012 (prior to implementation of the law) and 2014 (after implementation of the law). The lower bound impact estimate was calculated as the difference between the fully-insured cost sharing PMPM and the self-insured cost sharing PMPM for these medications between 2012 and 2014. The analysis does not adjust for expected changes in average cost-sharing for these products between the two years in the absence of a mandate; such an analysis is outside the scope of this study. To the extent that average patient cost-sharing for these products would have been higher in

2014 than 2012 in the absence of the mandate, the effect of the mandate is understated by this methodology.[xv]

The estimated PMPM RDC paid claim amount was $0.05, with a total PMPM cost, after administrative loading, of $0.05 (or 0.013 percent of the Commonwealth total premium). The fully-insured allowed medical expense PMPM for these services was found to be $0.02 higher than the self-insured allowed medical expense PMPM, resulting in a lower bound impact estimate, including administrative loading, of $0.02 PMPM, or 0.004 percent of Commonwealth premium. Table 16 below displays a summary of these results and related statistics.

Table 16
Oral Chemotherapy Treatment of Cancer Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users, 2014	7,452	4,013	
Sample Units, 2014	1,890,718	1,040,780	
Sample Average Members, 2014	1,437,788	1,432,254	
Decrease in Cost Sharing PMPM, 2012 to 2014	$ 0.05	$ 0.03	$ 0.02
Decreased Cost Sharing with Admin	$ 0.05	$ 0.04	$ 0.02

	Upper Bound Impact		Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 1,378,028		$ 489,691
Contribution to Total Annual Premium	$ 1,548,347		$ 550,214
Percent of Total Premium	0.013%		0.004%

*No significant overlaps were found between this and other mandates.

Prosthetic Devices

The prosthetic device mandate requires coverage for prosthetic devices and repairs under the same terms and conditions that apply to other durable medical equipment covered under the policy; the mandate restricts carriers' use of cost-sharing and coverage limits for prosthetic devices.[386]

Effect of the mandate on health

Prosthetics are artificial replacements used to assist with ambulation and participation in activities of daily living among those with an amputation, or any loss of a limb or part of a limb.[387,388] Amputations are performed for several reasons, most often due to dysvascular diseases such as

[xv] That is, if patient cost sharing is measured at $0.06 PMPM in 2012 and $0.01 PMPM in 2014, but in the absence of the mandate patient cost sharing in 2014 would have been $0.08, $0.06 PMPM - $0.01 PMPM = $0.05 PMPM understates the effect of the mandate, which was actually $0.08 PMPM - $0.01 PMPM = $0.07. Conversely, if for some reason 2014 cost-sharing PMPM would have been lower than 2012 for these products even in the absence of the mandate, $0.05 PMPM would overstate the effect of the mandate.

diabetes and peripheral arterial disease (54 percent), trauma (45 percent), and cancer (under two percent).[389,390] An estimated 2.0 million or more Americans live with limb loss, and over 185,000 amputations occur annually in the United States.[391]

To understand prevalence of individuals with limb loss and incidence rates of new amputations, considering patient age is critical. Over 64 percent of dysvascular disease-related amputations occur among adults 65 and older.[392] As the population ages and the number of individuals diagnosed with diseases such as diabetes continue to rise, annual new cases of amputations are expected to double by 2050.[393] The severity of the conditions that lead to amputation in this older population limits average life expectancy in that group. Five-year mortality for patients whose vascular disease led to amputations is almost 50 percent, higher than the same measure for breast, colon, Hodgkin's lymphoma, and prostate cancers.[394] For patients who need a lower extremity amputation due to diabetes, the five-year mortality rate is up to 74 percent.[395,396]

By 2050, the number of people living with a lost limb, and thus in need of prosthetics and related services, is estimated to triple.[397] This is due to the age of the patients: although only 16 percent of hospital discharges related to amputation are due to trauma, trauma cases account for approximately 45 percent of people living with limb loss, two thirds of whom are adolescents and adults younger than 45.[398]

In general, amputations are categorized as upper limb (arm and hand) and lower limb (leg and foot).[399] Overall, younger patients are more likely to suffer from upper limb loss, and older patients from lower limb loss. Lower limb prosthetics have higher rates of acceptance and daily use, while upper limb prosthetics have higher rates of abandonment.[400] These findings may be attributable to overall intended functions for each prosthetic type. Lower limb prostheses are designed to accomplish gross motor tasks, including weight-bearing, balance, ambulation, and provide more natural cosmetic appearance,[401] functions "well substituted for by the prosthesis."[402] For upper limbs, prosthetics must perform fine motor tasks and balance, in addition to movement and natural cosmetic appearance.[403] Moreover, in the case of thumb amputation, the prosthesis must provide opposition. Generally, fine motor functions are "not well served by a prosthetic device."[404] Acceptance rates and functionality improve while abandonment decreases with early prosthetic fittings, which also decreases risk of phantom pain.[405]

Complications related to limb loss include: psycho-social adjustment; soft tissue and muscle atrophy; skin disorders, including increased moisture, blisters, allergic reactions, irritation and breakdown; joint contracture; soft tissue and bone infections; pain and phantom limb sensations; overuse syndromes in remaining extremities and proximal joints; and heterotopic ossification, or an overgrowth of bone instead of scar tissue.[406,407,408] In the short-term, prosthetic patients are more likely to experience depression and anxiety, as well as social discomfort and body-image anxiety.[409]

Each type of amputation requires a different prosthetic, each with its own rate of effectiveness. Generally, the functionality of the prosthesis is related to: the number of joints preserved and the length of the residual limb;[410] other orthopedic, cardiovascular, neuromuscular, and respiratory conditions; vascular and visual problems; and a patient's emotional and mental health, activity

level, degree of motivation, age, vocation, and support system.[411] Psychosocial factors are also important to understanding quality of life and the ability level of patients, as well as their own self-image and sense of difference.[412,413] As summarized by one study, prosthetic effectiveness revolves around "what people can practically achieve with a prosthetic limb, and the management of personal information and identity."[414] In fact, while most amputees with prosthetics used them extensively and expressed satisfaction with the device's overall performance and quality, a large number were dissatisfied with their own interpersonal skills with the prosthetic, and almost 33 percent were dissatisfied with their comfort.[415] These psychosocial effects are influenced by such factors as time since amputation, social support, satisfaction with prosthesis, personality disposition, active coping attempts, the level of amputation, and the level of pain and phantom limb sensation.[416,417] The needs of a patient with an amputation span the patient's lifetime, and can include, besides an artificial limb, associated services such as fittings, repairs, and upgrades based on needs or improved technology.[418] To the extent changes in coverage required under this mandate improve the quality of devices and treatment available to the patient and consequently the patient's recovery experience, including adjusting to limb loss and to a device, they are likely to lead to a better outcome, that is, greater ongoing functionality, for the patient.

Estimate of the cost of the mandate

The limb prostheses mandate requires coverage for prosthetic devices and repairs under the same terms and conditions that apply to other durable medical equipment covered under the policy and places restrictions on the use of annual or lifetime limits for prosthetic devices. The RDC of this mandate was calculated as the sum of paid amounts from all claims with procedure codes for limb prosthetic devices and repairs. The estimated PMPM RDC paid claim amount was $0.14, with a total PMPM cost, after administrative loading, of $0.15 (or 0.04 percent of the Commonwealth total premium). Self-insured allowed medical expenses for these services were found to be slightly *higher* than fully-insured allowed medical expenses, resulting in a $0 lower bound impact estimate, including administrative loading. Table 17 below displays a summary of these results and related statistics.

Table 17
Prosthetic Devices Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower
Sample Users	397	364	
Sample Units	5,517	5,669	
Sample Average Members	1,871,491	1,490,706	
Paid PMPM	$ 0.14	$ 0.17	$ -
Paid PMPM With Admin	$ 0.15	$ 0.19	$ -
Allowed PMPM	$ 0.15	$ 0.18	$ (0.02)

	Upper Bound Impact		Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 3,868,008		$ -
Contribution to Total Annual Premium	$ 4,346,076		$ -
Percent of Total Premium	0.04%		0.00%

*Net amounts do not remove overlap in mandated services between the limb prosthesis mandate and the home health mandate.

Scalp Hair Prostheses

The scalp prostheses mandate requires policies providing coverage for any other prosthesis to provide coverage for scalp hair prostheses worn for hair loss suffered as a result of the treatment of cancer or leukemia, in an amount not to exceed $350 per year.[419]

Effect of the mandate on health

Hair loss is a side effect of some cancer treatments, including chemotherapy and radiation to the head.[420] These treatments result in "chemotherapy-induced alopecia" (CIA) or damage to the hair follicles leading to the thinning or complete loss of hair. Alopecia is often cited as the "most severe side effect of chemotherapy,"[421] negatively affecting the quality of life for many cancer patients, especially women and children.[422,423] Studies have cited loss of self-confidence, depression,[424] and humiliation as side effects.[425] Likewise, CIA can negatively impact overall quality of life by affecting body image,[426] sexuality, self-esteem, and social functioning.[427] One study found that "[p]atients who fear CIA may sometimes select regimens with less favorable outcomes or may refuse treatment."[428] And while research continues into the management of CIA, methods to prevent the hair loss have not yet proven effective, [429] and no standard of care for treatment exists yet.[430]

Scalp hair prostheses offer some patients the possibility of mitigating the side effects of hair loss, though some studies have shown that "[r]egrowth of hair and other adaptive processes do not normalize or improve the impaired body image and self-concept."[431] These researchers have suggested that the impact of CIA may not be "related exclusively to alopecia," but also to the individual's coping with chemotherapy and how that may be further amplified by alopecia.[432] Others have suggested that treatment providers should emphasize the psychological support for

patients experiencing CIA, and the use of creative measures, including acquisition of scalp prosthesis even before hair loss, to preserve self-image.[433]

Estimate of the cost of the mandate

Scalp hair prostheses offer some patients the possibility of mitigating the side effects of hair loss. The scalp prostheses mandate requires policies providing coverage for any other prosthesis to provide coverage for scalp hair prostheses worn for hair loss suffered as a result of the treatment of cancer or leukemia, in an amount not to exceed $350 per year. The RDC of this mandate was calculated as the sum of paid amounts from all claims with procedure code A9282: "Wig, any type, each." The estimated PMPM RDC paid claim amount was $0.01, with a total PMPM cost, after administrative loading, of $0.02 (or 0.004 percent of the Commonwealth total premium). Non-GIC self-insured allowed medical expenses for these services were found to be slightly *higher* than fully-insured and GIC allowed medical expenses, resulting in a $0 lower bound impact estimate, including administrative loading. Table 18 below displays a summary of these results and related statistics.

Table 18
Scalp Hair Prostheses Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	819	621	
Sample Units	857	654	
Sample Average Members	1,871,491	1,490,706	
Paid PMPM	$ 0.01	$ 0.02	$ -
Paid PMPM With Admin	$ 0.02	$ 0.02	$ -
Allowed PMPM	$ 0.02	$ 0.02	$ (0.00)

	Upper Bound Impact		Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 410,990		$ -
Contribution to Total Annual Premium	$ 461,787		$ -
Percent of Total Premium	0.004%		0.00%

*Net amounts do not remove overlap in mandated services between the scalp hair prosthesis mandate and the home health mandate.

Speech and Audiology Services

This mandate requires coverage for expenses incurred in the medically-necessary diagnosis and treatment of speech, hearing, and language disorders by licensed speech-language pathologists or audiologists.[434]

Effect of the mandate on health

Speech and language disorders and delays are associated with a wide variety of conditions, ranging from chronic illnesses such as cerebral palsy and Parkinson's and Huntington's diseases to acute

events such as brain injuries and strokes. The specific problems vary widely, as do treatment methods and modalities. For children, "[p]rimary speech and language delay/disorder is a common developmental difficulty which, if unresolved, can cause difficulties of both learning and socialisation lasting into adolescence and beyond."[435] In general, "[s]peech and language therapy aims to maximize ability to communicate through speech, gesture, and/or supplementary means, such as communication aids, and to enable [patients] to become independent communicators."[436,437]

Most studies reviewed suggest the effectiveness of treatment for speech, hearing, and language disorders in general; however, one large systematic review found that many of the conclusions are based on "'clinical opinion' rather than on controlled clinical trials."[438] Many investigators cited the need for additional research to be conducted using rigorous scientific methodology, and for the development of more consistent standards of treatment methods and interventions, as well as evidence-based practice guidelines for the variety of conditions requiring speech, hearing, and language therapies.[439, 440, 441, 442, 443,444,445]

Estimate of the cost of the mandate

Regulations on required benefits for 2016 issued pursuant to the ACA (45 CFR §156.115(a)(5)(i)) include in EHBs "habilitative services". They define such services as those that "help a person keep, learn, or improve skills and functioning for daily living (habilitative services). Examples include therapy for a child who is not walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology and other services for people with disabilities in a variety of inpatient and/or outpatient settings." But the specific services included, and whether the definitions would include speech and audiology services, are unclear on the surface and left to the states.[446] For reasons cited in the overview of the methodology, this analysis assumes federal EHB requirements do not address state-mandated speech and audiology services.

Table 19
Speech and Audiology Services
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	14,441	12,063	
Sample Units	48,605	57,072	
Sample Average Members	1,871,491	1,490,706	
Paid PMPM	$ 0.25	$ 0.37	$ -
Paid PMPM With Admin	$ 0.28	$ 0.41	$ -
Allowed PMPM	$ 0.30	$ 0.41	$ (0.11)

	Upper Bound Impact		Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 7,116,174		$ -
Contribution to Total Annual Premium	$ 7,995,701		$ -
Percent of Total Premium	0.06%		0.00%

*Net amounts do not remove overlap in mandated services between the speech and audiology mandate and the children's hearing aids and home health mandates.

This mandate provides for "expenses incurred in the medically necessary diagnosis and treatment of speech, hearing and language disorders by individuals licensed as speech-language pathologists or audiologists." The RDC of this mandate was calculated as the sum of paid amounts from all claims for speech and audiology procedures where the primary diagnosis indicates a covered speech, hearing, or language disorder. The estimated PMPM RDC paid claim amount was $0.25, with a total PMPM cost, after administrative loading, of $0.28 (or 0.06 percent of the Commonwealth total premium). Self-insured allowed medical costs for these services were found to be *higher* than fully-insured allowed costs, resulting in a lower bound impact estimate of $0, including administrative loading. Table 19 above displays a summary of these results and related statistics.

Mandates with Potential Marginal Direct Cost: Provider-Centered Mandates

This study includes eight “provider mandates,” which mandate coverage for specific provider types rather than specific services. An *a priori* assumption that these non-physician providers are cost-effective would be supported by the very small to zero (in fact, negative) lower bound marginal cost estimates for most of these mandates. In many cases, the allowed medical expenses PMPM are higher in the self-insured segment than in the fully insured segment. Based on these results, it would be reasonable to treat these mandates as “zero marginal cost” mandates, though they are treated here as potential-marginal cost mandates (i.e., their RDCs are included in the upper bound estimates).

Categorizing claims by provider type is challenging. In particular, it is generally assumed that the MA APCD does not measure the full volume of services provided by certain allied health professionals, such as advanced practice registered nurses and physician assistants, whose services are generally billed as if performed by the supervising physician in order to maximize reimbursement. However, CHIA is required by M.G.L. Chapter 3 §38C to estimate the cost of these mandates, and the following analysis estimates their costs using all sample claims that could be identified as having been performed by one of the covered practitioners, as the cost of services actually performed by allied health professionals but billed by their supervising physicians is immeasurable within the scope of this study.

In addition, some claims coding schemes identify the service provider as "nurse practitioner or physician assistant." In these cases, Compass grouped ambiguous results under the mandate covering the largest group of members. That is, because the statutory language of the physician assistant mandate includes self-insured GIC products but the nurse practitioner mandate does not, all such ambiguous results were included in the physician assistant mandate sample.

Detailed specifications for the cost calculations for these mandates are available from CHIA upon request.

Certified Nurse Midwives

The certified nurse midwife mandate requires plans to pay for services rendered by certified nurse midwives when the same services are reimbursed when performed by any other practitioner and are within the lawful scope of practice of midwives.[447]

Effect of the mandate on health

Certified nurse-midwives (CNMs) are Advanced Practice Nurses (APRNs) who serve as primary care providers of healthcare to women, providing physical exams, counseling, education, and prenatal, gynecological, labor and delivery, and postpartum care, as well as ordering lab tests and prescribing medications including contraceptives.[448,449] CNMs are legally authorized to practice, and prescribe drugs, in all fifty states, though regulations and regulatory authority vary.[450,451,452] In Massachusetts, CNMs have independent practice and prescribing authority,[453] but are not recognized as primary care providers.[454] Reimbursement in all state Medicaid programs, as well as Medicare, is mandatory for CNMs at 100 percent of the physician reimbursement rates.[455]

CNM services focus primarily on reproductive health and gynecological and obstetrical care, but also may be provided to male partners for treatment of sexually transmitted diseases, and to normal newborns during the first month after birth.[456] In 2013, CNMs and certified midwives attended almost 321,000 births in the United States.[457] Today, approximately 480 CNMs are licensed in Massachusetts,[458,459] and over 11,000 nationwide.[460] As Advanced Practice Nurses, CNMs are also registered nurses or bachelors-prepared nurses who have completed an undergraduate program in nursing as well as, at minimum, a masters-level graduate program in midwifery.[461]

Terms of CNM licensure have historically varied widely by state, especially in the degree of physician oversight required. In 2008, the National Council of State Boards of Nursing (NCSBN) adopted the Consensus Model for Advanced Practice Registered Nurse (APRN) Regulation in an attempt to create consistent regulations and legislation across the United States.[462] The group is attempting to standardize licensure to practice, APRN program accreditation, national certification requirements, and educational requirements.[463]

When comparing care provided during labor and delivery by physicians versus CNMs, a large systematic review found that: CNMs used fewer interventions, including epidurals, induced labor, and episiotomies; perineal lacerations were lower and breastfeeding rates were higher for CNM patients; and infant outcomes including Apgar scores, birth weight, and neonatal intensive care unit admissions did not differ between physicians and CNMs.[464] Researchers have found that CNMs "provide a safe and viable alternative to maternity care in the United States, particularly for low to moderate risk women."[465] Another study of obstetric outcomes in a primary care setting found:[466]

- Low-income, uninsured, and underinsured women who have access to excellent prenatal care with supervised certified nurse-midwives can have obstetric outcomes similar to women having prenatal care with private obstetricians.
- Prenatal care with supervised certified nurse-midwives can reduce the cesarean section rate without compromising infant outcome.
- Utilization of certified nurse-midwives supervised by obstetricians may provide the optimum model for perinatal care, particularly for those women who are at high risk because of social and economic factors and who are currently underserved.

In a study of planned home births, researchers found "that women who have home births attended by CNMs have safety profiles equal to or better than profiles of women who had hospital births in similar populations."[467] These results were also found in a large outcomes study of CNM-attended homebirths which concluded that "[l]ow-risk women in this cohort experienced high rates of physiologic birth and low rates of intervention without an increase in adverse outcomes."[468] A study of spontaneous and episiotomy-caused perineal injury during birth found both severity and prevalence were significantly lower in CNM-attended births.[469]

In a joint statement of policy by the American College of Nurse Midwives and the American College of Obstetricians and Gynecologists, the professional organizations affirmed their shared goal "of safe women's health care in the United States through the promotion of evidence-based models provided by obstetricians-gynecologists, certified nurse-midwives, and certified midwives." Their statement affirmed their commitment to educational standards, certification, and licensure; the need for options and preferences of women in health care; the need for access to affordable professional liability insurance, hospital privileges, equivalent reimbursement, and support services; and outlined how the organizations differ regarding home birth.[470]

Estimate of the cost of the mandate

Table 20
Certified Nurse Midwives Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	605	5,232	
Sample Units	3,227	24,639	
Sample Average Members	142,186	990,666	
Paid PMPM	$ 0.19	$ 0.20	$ -
Paid PMPM With Admin	$ 0.21	$ 0.22	$ -
Allowed PMPM	$ 0.20	$ 0.20	$ (0.01)

	Upper Bound Impact		Lower Bound Impact*
Insured Population	730,715		730,715
Contribution to Total Annual Claims	$ 1,624,290		$ -
Contribution to Total Annual Premium	$ 1,825,045		$ -
Percent of Total Premium	0.01%		0.00%

*No significant overlaps were found between this and other mandates.

The certified nurse midwife mandate requires plans to pay for services rendered by certified nurse midwives when the same services are reimbursed when performed by any other practitioner and are within the lawful scope of practice of midwives. The RDC of this mandate was calculated as the sum of paid amounts from all claims with a certified nurse midwife provider type[xvi] indicator or a procedure code modifier[xvii] indicating the service was performed by a nurse midwife. The estimated PMPM RDC paid claim amount was $0.19, with a total PMPM cost, after administrative loading, of $0.21 (or 0.01 percent of the Commonwealth total premium). Self-insured PMPM allowed expenses for these services were found to be *higher* than fully-insured allowed costs, resulting in a lower bound impact estimate of $0, including administrative loading. Table 20 above displays a summary of these results and related statistics.

Certified Registered Nurse Anesthetists

The certified registered nurse anesthetist mandate requires plans to pay for services rendered by certified registered nurse anesthetists when the same services are reimbursed when performed by any other practitioner and are within the lawful scope of practice of nurse anesthetists.[471]

Effect of the mandate on health

Certified registered nurse anesthetists (CRNAs) are Advanced Practice Registered Nurses (APRNs) licensed to provide anesthesia and related care, as well as pain management and some emergency services.[472] There are more than 40,000 CRNAs practicing in the United States, providing over 40 million anesthetics annually;[473] over 1250 CRNAs are licensed in Massachusetts.[474] According to

[xvi] Provider types vary by carrier. Compass also used NPI taxonomy codes where possible to identify claims provided by the various mandated providers.
[xvii] HCPCS Modifier SB: Nurse midwife.

the American Association of Nurse Anesthetists, "[i]n some states, CRNAs are the sole providers in nearly 100 percent of the rural hospitals," and are the primary anesthesia providers in rural America overall, providing care in trauma stabilization, surgical, obstetrical, and pain management cases.[475]

As APRNs, CRNAs are required to complete a baccalaureate degree program in nursing or other appropriate field, a graduate degree program in nurse anesthesia, and they must pass a national certification exam following graduation.[476] A CRNA must be licensed as a registered nurse (RN), and spend at least one year as an RN in a critical care setting.[477] In Massachusetts, CRNAs are certified to practice as an Advanced Practice Clinical Nurse in their specific clinical category.[478]

The federal Centers for Medicare and Medicaid Services (CMS) currently requires that CNRAs be supervised by a physician, unless the state's own regulations do not require the CRNA to be supervised.[479] States may opt-out of this requirement;[480] since 2001, 17 states have formally opted-out.[481,482] However, there is significant disagreement in the number of remaining states in which CRNAs may operate independently without need for the opt-out filing, with estimates ranging from 18 to 40 states; CRNA independence hinges on the definition of "physician supervision" in state regulations.[483] In 2008, the National Council of State Boards of Nursing (NCSBN) adopted the Consensus Model for Advanced Practice Registered Nurse (APRN) Regulation in an attempt to create consistent regulations and legislation across the United States.[484] The group is attempting to standardize licensure to practice, APRN program accreditation, national certification requirements, and educational requirements.[485]

In Massachusetts, CRNAs do not have independent prescribing authority. Instead, they must have a written agreement outlining physician supervision of their prescriptive practice,[486,487] the physician's name must appear on the prescription, and prescribing practices are regulated for CRNAs by both the state Board of Registration in Nursing and the Board of Medicine.[488] CRNA prescriptive practice is also limited to "the immediate perioperative care of a patient."[489] These regulations make Massachusetts the only New England state without full practice authority for CRNAs (although Maine requires CRNAs to practice under physician or dentist supervision).[490]

In a review of seven years of Medicare data analyzing patient safety outcomes for patients provided anesthesia, researchers found that "the change in CMS policy allowing states to opt out of the physician supervision requirement for certified registered nurse anesthetist reimbursement was not associated with increased risks to patients."[491] Other studies comparing rates of complications for obstetrical anesthesia between CRNAs and anesthesiologists found no difference between the two staffing models.[492,493] In a large study comparing the safety and effectiveness of non-physician anesthetists (NPAs) practicing independently, anesthesiologists, and NPAs supervised or directed by physicians, the researchers found that "[n]o definitive statement can be made about the possible superiority of one type of [anesthesia] care [provider] over another."[494]

Estimate of the cost of the mandate

Table 21
Certified Registered Nurse Anesthetists Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	17,106	26,987	
Sample Units	210,928	331,510	
Sample Average Members	1,049,386	1,209,745	
Paid PMPM	$ 0.78	$ 1.02	$ -
Paid PMPM With Admin	$ 0.88	$ 1.14	$ -
Allowed PMPM	$ 0.82	$ 1.08	$ (0.27)

	Upper Bound Impact		Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 22,094,293		$ -
Contribution to Total Annual Premium	$ 24,825,048		$ -
Percent of Total Premium	0.20%		0.00%

*No significant overlaps were found between this and other mandates.

The certified registered nurse anesthetist mandate requires plans to pay for services rendered by certified registered nurse anesthetists when the same services are reimbursed when performed by any other practitioner and are within the lawful scope of practice of nurse anesthetists. The RDC of this mandate was calculated as the sum of paid amounts from all claims with a registered nurse anesthetist provider type indicator or a procedure code modifier indicating the service was performed by a certified registered nurse anesthetist.[xviii] The estimated RDC PMPM paid claim amount was $0.78, with a total PMPM cost, after administrative loading, of $0.88 (or 0.20 percent of the Commonwealth total premium). Self-insured PMPM allowed medical expenses for these services were found to be *higher* than fully-insured allowed medical costs, resulting in a lower bound impact estimate of $0, including administrative loading. Table 21 above displays a summary of these results and related statistics.

Nurse Practitioners

The nurse practitioner (NP) mandate requires plans to cover services of NPs when those services are reimbursed when performed by any other practitioner and are within the lawful scope of practice of NPs.[495] Also, M.G.L. c. 176R allows NPs to serve as primary care physicians and prohibits carriers from subjecting NPs to reduced coverage limits.[496]

Effect of the mandate on health

Nurse practitioners (NPs) are Advanced Practice Nurses (APNs) who are licensed as Registered Nurses as well as independent practitioners.[497] NPs practice as primary and/or specialty care providers in the full range of health care settings, emphasizing health promotion and disease

[xviii] HCPCS Modifier QX: CRNA service: with medical direction by a physician or QZ: CRNA service: without medical direction by a physician.

prevention in addition to diagnosis, treatment and management of chronic and acute illness.[498] More than 80 percent of nurse practitioners are trained in primary care, most often practicing in family, geriatrics and adults, women's health, and pediatrics.[499] There were over 192,000 licensed NPs practicing in the United States in 2014, including over 7,700 in Massachusetts;[500] over 900 million visits are made annually to NPs.[501] In Massachusetts, an NP is certified to practice as an Advanced Practice Clinical Nurse in a specific clinical category.[502]

As with all APNs, NPs must complete at least four years of undergraduate education and either a master's, post master's, or doctoral-level graduate program for NPs.[503] Nurse Practitioners can be licensed and may prescribe medications in all 50 states,[504,505] although the scope of practice and physician oversight requirements may vary across states.[506,507] In 2008, the National Council of State Boards of Nursing (NCSBN) adopted the Consensus Model for Advanced Practice Registered Nurse (APRN) Regulation in an attempt to create consistent regulations and legislation across the United States.[508] The group is attempting to standardize licensure to practice, APRN program accreditation, national certification requirements, and educational requirements.[509]

In Massachusetts, NPs do not have independent prescribing authority, but "must have a collaborative agreement with a physician or a physician's supervision/delegation in order to prescribe drugs."[510] NPs must have a written agreement in place outlining physician supervision of their prescriptive practice,[511] the physician's name must appear on the prescription, and prescribing practices are regulated for NPs by both the state Board of Registration in Nursing and the Board of Medicine.[512] These regulations make Massachusetts the only New England state without full practice authority, prompting the American Academy of Nurse Practitioners to place it among the 12 "most restrictive of practice environments in the nation."[513,514]

In a review of articles comparing the quality and safety of care provided by NPs to that provided medical doctors (MDs), researchers found that outcomes were comparable or better for all 11 outcomes reviewed, including strong evidence that rates were similar for patient satisfaction with provider/care, functional status, numbers of unexpected ED visits, hospitalization rates, patient blood pressure, blood glucose, serum lipids, patient outcomes for mortality, and self-reported perceived health status.[515] Another review of randomized controlled trials found that while longer term outcomes should be assessed through additional studies, "there were few differences in primary care provided by APNs and physicians; for some measures APN care was superior."[516] Another review found that ANPs could help improve primary care of patients with chronic disease, and that independent specialized nurses:

> …could achieve health outcomes that were similar to those of doctors, reduce hospital visits and improve certain patient outcomes related to diabetes, coronary artery disease, or heart failure. Patients who had nurse-led care were more satisfied and tended to receive more tests and medications. It is unclear whether specialized nurses improve quality of life or doctor workload.[517]

Estimate of the cost of the mandate

The nurse practitioner (NP) mandate requires plans to cover services of nurse practitioners (NPs) when the same services are reimbursed when performed by any other practitioner and are within the lawful scope of practice of nurse practitioners. M.G.L. c. 176R allows NPs to serve as Primary Care Physicians and prohibits NPs from being subject to reduced coverage limits. The RDC of this

mandate was calculated as the sum of paid amounts from all claims with a nurse practitioner provider type indicator or a procedure code modifier indicating the service was performed by a nurse practitioner.[xix] The estimated RDC PMPM paid claim amount was $1.57, with a total PMPM cost, after administrative loading, of $1.77 (or 0.41 percent of the Commonwealth total premium). Per member per month self-insured allowed expenses for this mandate were found to be $0.39 lower than fully-insured PMPM allowed expenses, resulting in a lower bound expense estimate, including administrative loading, of $0.37 PMPM, or 0.08 percent of Commonwealth premium. Table 22 below displays a summary of these results and related statistics.

Table 22
Nurse Practitioners Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	97,794	86,690	
Sample Units	300,640	252,782	
Sample Average Members	1,049,386	1,209,745	
Paid PMPM	$ 1.57	$ 1.30	$ 0.33
Paid PMPM With Admin	$ 1.77	$ 1.46	$ 0.37
Allowed PMPM	$ 1.85	$ 1.47	$ 0.39

	Upper Bound Impact		Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 44,634,265		$ 9,305,274
Contribution to Total Annual Premium	$ 50,150,860		$ 10,455,364
Percent of Total Premium	0.41%		0.08%

*Net amounts do not remove overlap in mandated services between the nurse practitioner mandate and the diabetes, early intervention, and home health mandates.

Physician Assistants

The physician assistant (PA) mandate requires carriers to recognize physician assistants as participating providers and include coverage on a nondiscriminatory basis for care provided by PAs. Such coverage must include benefits for primary care, intermediate care and inpatient care, in a full range of settings, when rendered by a PA who is a participating provider and is practicing within the scope of his or her professional authority. It also allows PAs to serve as primary care physicians.[518]

Effect of the mandate on health

PAs are medical professionals nationally certified and licensed to practice medicine as part of a healthcare delivery team.[519] Depending on their specialty, experience, and the setting in which they practice, PAs diagnose and treat illnesses, assist in surgery, counsel patients on preventive care, and manage the care of hospitalized patients.[520]

[xix] HCPCS Modifier SA: Nurse practitioner rendering service in collaboration with a physician.

Most PA training programs last 26 months over 3 academic years, and require approximately 3 years of additional healthcare training and experience.[521] Students fulfill prerequisite courses similar to those required in medical school, and take classes in basic and behavioral sciences as well as clinical medicine.[522] PAs are then required to complete at least 2,000 hours of clinical rotation in family, internal, and emergency medicine, pediatrics, psychiatry, surgery, and obstetrics and gynecology.[523]

To practice in Massachusetts, PAs must complete a bachelor's degree, obtain certification by passing a national exam administered by the National Commission on Certification of PAs, and obtain state licensure from the Massachusetts Board of Registration of Physician Assistants under the Division of Health Professions Licensure in the Department of Health.[524,525,526,527] PAs are also required to complete continuing medical education to remain licensed in the state.[528] There are approximately 92,000 PAs nationally and 2,250 in Massachusetts.[529]

While PAs must by supervised by a physician,[530] they are able to independently prescribe medications in Massachusetts following guidelines developed with the supervising physician.[531] Likewise, for major invasive procedures, PAs must follow written protocols developed in partnership with the supervising physician which specify the level of supervision each service requires.[532]

Studies of the effectiveness of physician assistants often include nurse practitioners as well, and researchers may report outcomes related to both professions without distinguishing between them. Some studies indicate that PAs are effective and generate outcomes in acute care settings equivalent to those generated by medical residents, providing safe care in the emergency department, as well as the intensive care, critical care, and neonatal intensive care units.[533,534,535,536,537] However, one meta-analysis concluded that although research may support use of PAs in acute and intensive care settings, the level of evidence provided is often low.[538] One study of the provision of primary care by PAs showed results similar to care provided by physicians, although this study also included care provided by nurse practitioners.[539]

The PA mandate requires carriers to recognize physician assistants as providers for health maintenance, diagnosis, and treatment of patients, and cover PAs practicing within the scope of their licenses for providing primary, intermediate, and inpatient care in hospitals, clinics, professional offices, home and long-term care settings, mental health or substance abuse programs, or other settings.[540] The mandate deems PAs qualified to be designated as a primary care provider in an insurer network.[541]

Estimate of the cost of the mandate

The RDC of this mandate was calculated as the sum of paid amounts from all claims with a physician assistant provider type indicator or a procedure code modifier indicating the service was performed by either a physician assistant or a nurse practitioner.[xx] The estimated RDC PMPM paid

[xx] HCPCS Modifier AS: Physician assistant, nurse practitioner, or clinical nurse specialist services for assistant at surgery or HCPCS Modifier GF: Non-physician (e.g. nurse practitioner (NP), certified registered nurse

claim amount was $1.45, with a total PMPM cost, after administrative loading, of $1.63 (or 0.37 percent of the Commonwealth total premium). Per member per month self-insured allowed expenses for this mandate were found to be $0.09 lower than fully-insured PMPM allowed expenses, resulting in a lower bound expense estimate, including administrative loading, of $0.08 PMPM, or 0.02 percent of Commonwealth premium. Table 23 below displays a summary of these results and related statistics.

Table 23
Physician Assistants Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	97,790	93,388	
Sample Units	354,607	327,560	
Sample Average Members	1,049,386	1,209,745	
Paid PMPM	$ 1.45	$ 1.46	$ 0.07
Paid PMPM With Admin	$ 1.63	$ 1.64	$ 0.08
Allowed PMPM	$ 1.74	$ 1.65	$ 0.09

	Upper Bound Impact		Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 41,006,587		$ 2,009,567
Contribution to Total Annual Premium	$ 46,074,816		$ 2,257,941
Percent of Total Premium	0.37%		0.02%

*No significant overlaps were found between this and other mandates.

Chiropractors

The chiropractor provider mandate requires coverage by general health insurance corporations for chiropractic services whether performed by a physician or chiropractor, and a related statute (c. 176B § 7) prohibits a medical service corporation from discriminating against chiropractors in providing chiropractic services. Note both chiropractic service (above) and chiropractor provider mandates exist. Chiropractors provide both chiropractic services and non-chiropractic services, and chiropractic services are provided by both chiropractors and other providers.[542]

Effect of the mandate on health

Chiropractors, or doctors of chiropractic, diagnose and treat conditions primarily through manipulation and realignment of the musculoskeletal and nervous systems.[543] The goals of chiropractic care include improved function, pain alleviation, correction of alignment problems, and support to allow the body to naturally heal itself.[544] In theory, by aligning spinal joints, chiropractors improve the function of the body's nervous system and improve overall health.

Chiropractors are required to complete two to four years of undergraduate education followed by four to five years at a chiropractic college, where the curriculum includes at least 4200 hours of

anesthetist (CRNA), certified registered nurse (CRN), clinical nurse specialist (CNS), physician assistant (PA)) services in a critical access hospital).

classroom, laboratory, and clinical experience.[545] For licensure in Massachusetts, graduates of a chiropractic college must pass parts I, II, III, and IV and the physiotherapy section of examinations administered by the National Board of Chiropractic Examiners, as well as the Massachusetts jurisprudence examination administered by the state Board of Registration of Chiropractors.[546] Massachusetts also requires chiropractors to complete 12 hours of continuing education annually to maintain and renew licensure.[547]

Licensed chiropractors are recognized by Medicare for payment as a physician only for manual spinal manipulation treatment of spinal subluxation.[548] Chiropractors are not eligible to order and/or refer for Part B and DMEPOS (durable medical equipment, prosthetics, orthotics, and supplies) Medicare beneficiaries,[549] but may act as a supplier of durable medical equipment.[550]

Limited research is available comparing outcomes among provider types who perform spinal manipulation (e.g. chiropractor versus physician). However, one large meta-analysis that reviewed the results of 39 randomized-controlled trials concluded that "[t]he evidence is insufficient to conclude that benefits of manipulation vary according to the profession of the manipulator (chiropractor vs. other clinician trained in manipulation)."[551] Another study found that, when comparing orthopedic surgeons, primary care providers, and chiropractors, the time to functional recovery, complete recovery, and return to work after treatment for lower back pain was similar between all three provider types.[552] The same study found that costs were lowest for primary care providers, and patient satisfaction highest for chiropractors.[553] A more recent article examining the costs of care between chiropractors and other providers was equivocal in its conclusions and called for additional research.[554]

Estimate of the cost of the mandate

The chiropractor provider mandate, c. 175 § 108D, requires a payer to pay for chiropractic services whether they are performed by a physician or chiropractor, and c. 176B § 7 statute prohibits a Medical Services Corporation from discriminating against chiropractors in providing chiropractic services. Note that there are both chiropractic service and chiropractor (provider-based) mandates. The chiropractors provide both chiropractic services and non-chiropractic services, and chiropractic services are provided by both chiropractors and other providers.

The RDC of this mandate was calculated as the sum of paid amounts from all claims with a chiropractor provider type indicator. The estimated RDC PMPM paid claim amount was $0.91, with a total PMPM cost, after administrative loading, of $1.02 (or 0.07 percent of the Commonwealth total premium). Per member per month self-insured allowed expenses for this mandate were found to be $0.15 lower than fully-insured PMPM allowed expenses, resulting in a lower bound expense estimate, including administrative loading, of $0.10 PMPM, or 0.01 percent of Commonwealth premium. Table 24 below displays a summary of these results and related statistics.

Table 24
Chiropractor Provider Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	4,684	32,762	
Sample Units	72,343	455,012	
Sample Average Members	142,186	990,666	
Paid PMPM	$ 0.91	$ 0.85	$ 0.09
Paid PMPM With Admin	$ 1.02	$ 0.96	$ 0.10
Allowed PMPM	$ 1.46	$ 1.32	$ 0.15

	Upper Bound Impact		Lower Bound Impact*
Insured Population	730,715		730,715
Contribution to Total Annual Claims	$ 7,973,244		$ 810,103
Contribution to Total Annual Premium	$ 8,958,701		$ 910,228
Percent of Total Premium	0.07%		0.01%

*Net amounts do not remove overlap in mandated services between the chiropractic services mandate and the chiropractor provider mandate.

Dentists

This mandate requires a dentist to be considered a physician for purposes of reimbursement for any services covered by the medical policy/contract which dentists are licensed to perform.[555]

Effect of the mandate on health

Dentists are doctors of oral health focused on the diagnosis, treatment, and prevention of diseases of the mouth and maxillofacial area.[556] To practice general dentistry, dentists must complete an undergraduate degree, as well as four years of dental school; residency training is required as well, spanning an additional two to six years depending on specialty.[557]

To obtain a license, dentists must pass Parts I and II of the National Board Dental Examinations written tests which cover basic biomedical sciences, dental anatomy, ethics, and other clinical subjects including patient management.[558,559,560,561] All states also require an additional clinical examination which focuses on performing dental procedures on patients;[562] clinical examinations in Massachusetts are administered by the Commission on Dental Competency Assessments.[563] Applicants for dental licensure in Massachusetts must also pass the Massachusetts Dental Ethics and Jurisprudence Exam.[564] Licensure is available in nine specialties, including: dental public health; endodontics; oral and maxillofacial pathology, radiology, and surgery; orthodontics and dentofacial orthopedics; pediatric dentistry; periodontics; and prosthodontics.[565]

Dentists are recognized as physicians by Medicare when providing medically-necessary services while acting within the scope of the dental license.[566] Dental services – procedures "primarily provided for the care, treatment, removal, or replacement of teeth or structures supporting the teeth" – are generally excluded from Medicare coverage.[567] In contrast, services that may be considered as medical, even when performed by a dentist, include such procedures as extractions in preparation for radiation treatments of abnormal growths and diseases involving the jaw, and oral

examinations prior to kidney or heart transplants or valve replacements.[568] Additionally covered may be procedures related to orofacial medical conditions, sleep apnea, myofacial pain, temporomandibular joint disorders, oral dysfunction, trauma to the teeth or jaws, or medically necessary periodontia, implants, or radiography, as well as screenings for oral cancers.[569]

This analysis uncovered no research on the effectiveness of services provided by dentists compared to the identical services provided by physicians when provided under the scope of their respective licenses.

Estimate of the cost of the mandate

This insurance mandate requires a dentist to be considered a physician for purposes of reimbursement for any services covered by the medical policy/contract which dentists are licensed to perform. The RDC of this mandate was calculated as the sum of paid amounts from all medical claims with a dentist or oral surgeon[xxi] provider type indicator. The estimated RDC PMPM paid claim amount was $0.16, with a total PMPM cost, after administrative loading, of $0.18 (or 0.01 percent of the Commonwealth total premium). Self-insured PMPM allowed medical expenses for these services were found to be significantly *higher* than fully-insured allowed medical costs, resulting in a lower bound impact estimate of $0, including administrative loading. Table 25 below displays a summary of these results and related statistics.[xxii]

Table 25
Dentist Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	616	13,635	
Sample Units	1,537	58,160	
Sample Average Members	142,186	990,666	
Paid PMPM	$ 0.16	$ 0.73	$ -
Paid PMPM With Admin	$ 0.18	$ 0.82	$ -
Allowed PMPM	$ 0.20	$ 0.79	$ (0.59)

	Upper Bound		Lower Bound
Insured Population	730,715		730,715
Contribution to Total Annual Claims	$ 1,388,993		$ -
Contribution to Total Annual Premium	$ 1,560,666		$ -
Percent of Total Premium	0.01%		0.00%

*No significant overlaps were found between this and other mandates.

[xxi] Maxillo-facial surgeon provider types were not included, as maxillo-facial surgeons hold dual licensure as dentists and medical doctors. Cases where the maxillo-facial and oral surgeon provider types could not be distinguished were also excluded.

[xxii] These counterintuitive results may be a result of missing, miscoded, or unknown provider identifiers or provider type information in the underlying carrier sample data, and should not be considered conclusive. Compass's investigation into the results was inconclusive, and an alternative analysis using supplemental data did not significantly improve the results.

Optometrists

The optometrist mandate requires coverage for services of optometrists when those services are reimbursed when performed by medical or osteopathic physicians and within the lawful scope of practice of optometrists.[570]

Effect of the mandate on health

Optometrists, or doctors of optometry, are independent health care professionals who diagnose and treat eye and visual system diseases and disorders.[571] Educational requirements for optometrists include four years of undergraduate education and four years of graduate study at a college of optometry.[572] To practice, optometrists must obtain state licensure, requiring them to pass a set of national examinations administered by the National Board of Examiners in Optometry (NBEO). In Massachusetts, these include five tests, including applied basic science, patient assessment and management (PAM), clinical skills, treatment and management of ocular disease (TMOD), and state jurisprudence.[573,574] Passing these examinations also grants optometrists certification to use or prescribe diagnostic pharmaceutical agents (DPA) and therapeutic pharmaceutical agents (TPA).[575] Licenses must be renewed annually[576] and must include evidence of continuing education.[577]

Medicare considers optometrists to be physicians "with respect to all services the optometrist is authorized to perform under State law or regulation."[578] This review found no published studies quantifying the efficacy of the work of optometrists specifically, comparing the relative quality of services provided by optometrists with differing amounts of education or training, or comparing the relative quality of services provided by optometrists to services provided by other provider types.

The ACA requires non-grandfathered health plans in the individual and small group markets to cover essential health benefits (EHBs) in ten categories of service or items.[579] One EHB category, pediatric services, includes coverage for oral and vision care for children. (For plans effective in 2017, pediatric vision care is provided through a supplementary plan under the Federal Vision Insurance Program (FEDVIP), and covers routine eye exams and eyeglasses for children.[580,581]) However, while coverage for pediatric vision services is required as an EHB, coverage for optometrists per se is not required.[582] Moreover, routine, non-pediatric eye exam services are excluded from EHBs, even though an EHB benchmark plan may cover them.[583] Therefore, the ACA and its EHB requirements do not affect the marginal cost of this mandate.

Estimate of the cost of the mandate

The optometrist mandate requires coverage for services of optometrists when services are reimbursed when performed by medical or osteopathic physicians and are within the lawful scope of practice of optometrists. The RDC of this mandate was calculated as the sum of paid amounts from all claims with an optometrist provider type indicator. The estimated RDC PMPM paid claim amount was $0.71, with a total PMPM cost, after administrative loading, of $0.80 (or 0.06 percent of the Commonwealth total premium). Self-insured PMPM allowed medical expenses for these services were found to be *higher* than fully-insured allowed medical costs, resulting in a lower

bound impact estimate of $0, including administrative loading. Table 26 below displays a summary of these results and related statistics.

Table 26
Optometrists Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	9,153	81,626	
Sample Units	12,543	115,173	
Sample Average Members	142,186	990,666	
Paid PMPM	$ 0.71	$ 0.95	$ -
Paid PMPM With Admin	$ 0.80	$ 1.07	$ -
Allowed PMPM	$ 0.80	$ 1.04	$ (0.24)

	Upper Bound Impact		Lower Bound Impact*
Insured Population	730,715		730,715
Contribution to Total Annual Claims	$ 6,228,813		$ -
Contribution to Total Annual Premium	$ 6,998,666		$ -
Percent of Total Premium	0.06%		0.00%

*No significant overlaps were found between this and other mandates.

Podiatrists

The podiatrist mandate requires coverage for services of podiatrists when those services are reimbursed when performed by medical or osteopathic physicians and within the lawful scope of practice of podiatrists.[584]

Effect of the mandate on health

A podiatrist is a doctor of podiatric medicine (DPM) who diagnoses and treats conditions affecting the lower extremity. According to the American Podiatric Medical Association, podiatrists are foot and ankle specialists qualified to: "perform comprehensive medical history and physical examinations; prescribe drugs and order and perform physical therapy; perform surgeries ranging from basic to complex re-constructive surgery; repair fractures and treat sports–related injuries; prescribe and fit orthotics, durable medical goods, and custom–made shoes; and perform and interpret X–rays and other imaging studies."[585] An estimated 15,000 podiatrists practice in the United States.[586]

To be licensed in Massachusetts, podiatrists are required to complete four years of undergraduate education, four years of graduate education at a podiatric medical college, and three years of residency training in a hospital.[587,588,589] Additionally, podiatrists must pass oral, written, and/or clinical examinations administered by the state,[590] and complete fifteen hours of continuing education annually to renew licensure.[591] Massachusetts, however, is one of four states nationally that includes only the foot and does not include the ankle in the scope of practice for podiatrists.[592]

Medicare considers a podiatrist a physician "only with respect to those functions which he/she is legally authorized to perform in the State."[593] Podiatrists are eligible to order and/or refer for Part

B and Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Medicare beneficiaries.[594] Further, podiatrists may order and refer for Medicare Part A Home Health Agency (HHA) beneficiary services, the only provider type besides doctors of medicine and osteopathy permitted to do so.[595]

While no evidence was found comparing the effectiveness of podiatric care provided by podiatrists to that provided by nurses, allied health professionals, or non-specialist physicians, some evidence exists that interdisciplinary foot care including podiatric care had a positive impact on outcomes for patients with diabetes, including reductions in urgent surgeries, below-knee amputation rates, major amputations, recurrence of foot ulcers, and death in patients with diabetic lower-extremity ulcerations.[596,597,598,599] Other studies have found that for patients waiting for an evaluation by an orthopedic surgeon, podiatrists can provide appropriate triage service, resulting in more timely provision of non-surgical care and better targeted use of orthopedic surgical resources.[600,601]

This review found no published studies quantifying the efficacy of the work of podiatrists specifically (noting the distinction between podiatric care and care by podiatrists), comparing the relative quality of services provided by podiatrists with differing amounts of education or training, or comparing the relative quality of podiatrists services against services provided by other provider types.

Estimate of the cost of the mandate

The podiatrist mandate requires coverage for services of podiatrists when services are reimbursed when performed by medical or osteopathic physicians and are within the lawful scope of practice of podiatrists. The RDC of this mandate was calculated as the sum of paid amounts from all claims with a podiatrist provider type indicator. The estimated RDC PMPM paid claim amount was $0.58, with a total PMPM cost, after administrative loading, of $0.65 (or 0.15 percent of the Commonwealth total premium). Per member per month self-insured allowed expenses for this mandate were found to be $0.04 lower than fully-insured and GIC PMPM allowed expenses, resulting in a lower bound expense estimate, including administrative loading, of $0.03 PMPM, or 0.01 percent of Commonwealth premium. Table 27 below displays a summary of these results and related statistics.

Table 27
Podiatrists Mandate
Contribution to Premium

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	28,137	29,141	
Sample Units	99,823	105,346	
Sample Average Members	1,049,386	1,209,745	
Paid PMPM	$ 0.58	$ 0.62	$ 0.03
Paid PMPM With Admin	$ 0.65	$ 0.70	$ 0.03
Allowed PMPM	$ 0.79	$ 0.75	$ 0.04

	Upper Bound Impact		Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 16,383,060		$ 808,388
Contribution to Total Annual Premium	$ 18,407,933		$ 908,301
Percent of Total Premium	0.15%		0.01%

*Net amounts do not remove overlap in mandated services between the podiatrist mandate and the diabetes and home health mandates.

Aggregated Results of Mandates with Potential Marginal Direct Cost

The aggregated results of the required direct cost measurement for the twenty-five mandates judged to have potential marginal direct cost, with overlap (double-counting) between mandates removed, are summarized in Table 28. The overall RDC was calculated as the sum of paid amounts from all claims extracted for any of the potential marginal direct cost mandates. The estimated RDC PMPM paid claim amount was $25.01, with a total PMPM cost, after administrative loading, of $28.10 (or 6.45 percent of the Commonwealth total premium). The lower bound impact was calculated as the sum of the individual mandate lower bound estimates net of mandate overlaps[xxiii] with each mandate's lower bound impact estimate lower bounded at zero (i.e., a result of higher self-insured allowed expenses for one mandate did not offset higher fully-insured results found for other mandates). The resulting lower bound expense is $1.86 PMPM or 0.43 percent of Commonwealth premium. That is, the additional cost of mandated services in plans subject to the mandates compared to those plans not subject to the mandates represents approximately one half of one percent of premium. Table 28 below displays a summary of these results.

[xxiii] In the overall calculations, each claim extracted in the analysis of any potential marginal direct cost mandate was assigned to one and only one mandate.

Table 28
Unduplicated Combined Potential Marginal Direct Cost Mandate Results
Contribution to Premium

Measures	Upper Bound Impact	Lower Bound Impact*
Insured Population	2,362,745	2,362,745
Paid PMPM	$ 25.01	$ 1.66
Paid PMPM With Admin	$ 28.10	$ 1.86
Contribution to Total Annual Claims	$ 709,161,988	$ 46,942,722
Contribution to Total Annual Premium	$ 796,811,223	$ 52,744,631
Percent of Total Premium	6.45%	0.43%

*Results are net of all mandate overlaps.

Neither the RDC estimate in Table 28 ($796.8 million) nor the lower bound marginal cost estimate of $52.7 million provides an answer to the question of what additional direct costs are caused by the mandate laws, though the mandate impact should be somewhere in this rather wide range. As discussed in more detail below, it is also not likely to be near either of the two extremes produced by the required direct cost and lower bound marginal cost estimates.

In the next section, we address results for the mandates judged likely to have zero marginal cost.

Mandates Judged Likely to have Zero Marginal Cost

The RDC results for each of the mandates analyzed in the secondary cost analysis phase of the project are described below. As discussed above, carrier input and/or analysis of federal mandate requirements supported the position that these mandates are likely to have little or no marginal direct cost – that is, essentially all the costs of these services would be incurred even if the associated state mandate laws were not in effect. The estimates presented below, then, are for RDCs only, as the marginal costs (and therefore lower bound marginal costs) are assumed to be zero. Detailed specifications for the cost calculations for the six zero marginal cost mandates estimated using the Massachusetts MA APCD are available from CHIA upon request.

Bone Marrow Transplant for Breast Cancer

The bone marrow transplant mandate requires coverage for bone marrow transplants for patients with metastatic breast cancer if they meet criteria set by the Department of Public Health.[602]

Effect of the mandate on health

Treatment for high-risk breast cancer has evolved significantly over time, with the development of new interventions as well as publication of additional research findings. At one time, high-dose chemotherapy plus autologous bone marrow transplant (HDC-ABMT) was used as a last resort to treat advanced breast cancer, or breast cancer with a high probability of recurrence, as it reduced the probability of relapse.[603,604]

However, since the mid-1990s, HDC-ABMT has been discredited as a standard treatment regimen due to the serious side effects of the highly toxic chemotherapy, including an increase in treatment-related mortality, and because the treatment did not offer an increased chance of overall survival when compared to standard-dose chemotherapy.[605,606,607,608,609,610,611,612,613,614] The National Comprehensive Cancer Network has excluded HDC-ABMT from its clinical practice guidelines since 1996.[615]

The use of HDC-ABMT for treatment of breast cancer is most often recommended "only…in the context of a clinical trial."[616,617] Some already-concluded and ongoing trials have shown the potential application of this treatment for more narrowly-defined groups of patients[618,619,620] and/or with an adjustment to the previously-used chemotherapy regimen, as the specific treatments may increase the disease-free survival rate for certain patients.[621,622,623] The data are not yet clear, however, and experts continue to press for additional rigorous clinical studies, with several now underway.[624,625,626]

Despite these recommendations, as HDC-ABMT remains an independently mandated benefit, clinical trials have faltered due to the inability to enroll suitable patients, as nine out of ten patients have chosen to receive the therapy outside of the context of a clinical trial, thereby avoiding the possibility of random assignment to a control cohort.[627,628]

Discussion of the cost of the mandate

In light of these recommendations, the BMT mandate appears to be redundant to the separate mandate providing benefits for cancer clinical trials, which is also a zero marginal cost mandate (see the sub-section analyzing the cancer clinical trials mandate below).

Cardiac Rehabilitation

The cardiac rehabilitation mandate requires coverage for multidisciplinary, medically necessary treatment of persons with documented cardiovascular disease.[629]

Effect of the mandate on health

Almost 800,000 Americans die each year from major cardiovascular diseases (CVD), the leading cause of morbidity and mortality in the country, accounting for almost 31 percent of all deaths in the U.S.[630] In a 2015 report on heart disease and stroke statistics, researchers reported that one in three American adults suffers from some form of heart disease, stroke, or other blood vessel disease; each year, 795,000 will suffer a stroke, and 750,000 will suffer a heart attack.[631]

Cardiac rehabilitation (CR) refers to multidisciplinary programs that combine exercise, education, and psychological support in medically-supervised programs designed to improve physical, mental, and social functioning, reduce health risks and disability, and foster compliance, healthy behaviors, and active lifestyles for people with cardiovascular diseases.[632] The goal of CR "is to stabilize, slow, or even reverse the progression of CVD, which in turn reduces the risk of a future cardiac event."[633] Research has shown such programs to be effective in improving coronary heart disease risk factors and health-related quality of life, while reducing clinical events, risk of death, and costs.[634]

Specifically, CR improves exercise tolerance, symptoms, overall psychosocial well-being, and blood lipid levels while reducing mortality, stress, and cigarette smoking.[635,636] These outcomes are similar in both center- or home-based programs, although programs provided at home are associated with a higher level of patient adherence to treatment.[637]

Research so clearly demonstrates the benefit of CR that, in a search for cardiac rehabilitation guidelines issued by U.S.-based organizations, 58 different recommendations and guidelines for use of CR for various conditions are listed on the National Guideline Clearinghouse, a public resource of the U.S. Agency for Healthcare Research and Quality (AHRQ) for evidence-based clinical practice guidelines.[638] Despite this, however, utilization of cardiac rehabilitation programs remains low, "with less than 30 percent of eligible patients participating in a cardiac rehabilitation program after a cardiovascular disease event."[639] Patients cite inconvenient clinic location and hours, insurance cost-sharing and other expenses, and a lack of physician referral as reasons for low compliance rates.[640,641]

Discussion of the cost of the mandate

The cardiac rehabilitation mandate covers the expense of cardiac rehabilitation, i.e., multidisciplinary, medically necessary treatment of persons with documented cardiovascular disease.

For this analysis, the cost of the cardiac rehabilitation mandate reflected in insurance premiums is estimated as the total cost to fully-insured plans subject to the mandate for cardiac rehabilitation procedure codes.[xxiv] The estimated PMPM RDC paid claim amount for the calendar year 2014 study period was $0.08, with a total PMPM cost, after administrative loading, of $0.09 (or 0.02 percent of the Commonwealth total premium). Table 29 below displays a summary of these results and related statistics.

[xxiv] HCPCS code 91797, 93798, G0422, or G0423.

Table 29
Cardiac Rehabilitation Mandate
Required Direct Cost Estimate

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	1,252		
Sample Units	16,215		
Sample Average Members	1,871,491		
Paid PMPM	$ 0.08	N/A	N/A
Paid PMPM With Admin	$ 0.09	N/A	N/A
Allowed PMPM	$ 0.09	N/A	N/A

	Direct Cost		Lower Bound
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 2,279,569		$ -
Contribution to Total Annual Premium	$ 2,561,314		$ -
Percent of Total Premium	0.02%		0.00%

* This mandate was judged by carriers to contribute $0 marginal cost to premiums.
Required direct cost was estimated using the Massachusestts APCD.

Clinical Trials for Treatment of Cancer

The mandate for coverage of clinical trials for treatment of cancer requires coverage for services for patients enrolled in a qualified clinical trial to the same extent that the services would be covered if the patient was not receiving care in a qualified clinical trial. A qualified clinical trial must be cancer-related and must meet other criteria set forth in the law.[642]

Effect of the mandate on health

According to the Coalition of Cancer Cooperative Groups, "[a] clinical trial is a carefully monitored medical research study in which people participate as volunteers to test new methods of prevention, screening, diagnosis, or treatment of a disease."[643] The National Cancer Institute defines the different types of clinical trials to be for treatment, prevention, screening, or quality of life/supportive/palliative care.[644] Clinical trials are categorized into four phases:

- Phase I trials, usually the first to involve humans, typically enroll 15 to 30 people, and seek to determine treatment safety, side effects, and optimal mode of administration.[645]
- Phase II trials, usually enrolling 25 to 100 people, attempt to determine if and how the new treatment affects a certain cancer and may vary dosage levels between treatment groups while continuing to monitor side effects.[646]
- Phase III trials typically enroll from 100 to several thousand participants, and compare the new treatment or use with the current standard, randomizing patients into test groups.[647] Seventy-five percent of patients in clinical trials are part of phase III trials.[648]
- Phase IV trials, if conducted, include several hundred to several thousand people, and assess long-term safety and effectiveness of a treatment that has already been approved by the FDA.[649]

Phase 0 trials are also possible, in which patients face lower risk but will not benefit from the trial; these are used to study how the cancer, body, and treatment interact, and are intended to hasten and streamline the approval process.[650]

The National Cancer Institute cites several possible benefits of participation in clinical trials, including access to new treatment, close monitoring by research staff, and the opportunity to help future patients.[651] Trial participants who are randomized into control groups receive the best known standard treatment, while those in the test groups receive the new treatment intended to improve upon the current standard.[652] The American Cancer Society (ACS) also points out that participation empowers patients to actively decide their cancer treatment, and provides an opportunity to help others and advance research.[653] Participation drawbacks may be that the new treatment is not as effective for an individual as the current standard, or may cause different or more severe side effects than the standard treatment protocol; likewise, clinical trials also may require more testing or clinical appointments than would standard treatment.[654]

A 2013 study on public and patient perspectives of clinical trials found that 87 percent of respondents were "somewhat willing" or "very willing" to participate in clinical trials.[655] Yet ACS reports that the biggest barrier to the completion of trials is that fewer than 5 percent of adults participate in them, with the most common reason being that the patient did not know the studies were an option for them.[656] Of patients aware of their eligibility, only 25 percent reported participating.[657] Participants do report a high rate of satisfaction, especially with the quality of their care; over 75 percent report that they would recommend participation to others.[658] Approximately 60 percent of children under age 15 participate, and this has been credited with the dramatic increase in childhood cancer survival rates in the past few years.[659]

Discussion of the cost of the mandate

The clinical trials for treatment of cancer mandate requires coverage for patient care services for patients enrolled in a qualified clinical trial to the same extent as the services would be covered if the patient was not receiving care in a qualified clinical trial. A qualified clinical trial must be cancer-related and must meet other criteria set forth in the law.

Detailed data do not exist to specifically identify costs associated with clinical trials for the treatment of cancer, but information is available to aid in its estimation. One study estimates that the costs of clinical trials range from 10 percent lower to 23 percent higher compared to standard medical care.[660] Compass obtained 2013 U.S. cancer prevalence rates by 10-year age band[661] and applied these rates to a U.S. Census Bureau estimate of Massachusetts population by single year of age on July 1, 2014,[662] yielding an approximate count of people aged 0-59 in Massachusetts living with cancer in 2014 of 74,160. An additional 70,062 cancer patients were aged 60-69. The Census data on Massachusetts population by single year of age indicate that the proportion of the estimated 2014 Massachusetts population aged 60-69 who were aged 60-64 versus 60-69 was 55.1 percent. Applying this proportion to the estimated Massachusetts cancer cases in the age 60-69 age group and adding the result to the cases in the population aged 0-59 yields a 2014 estimate of 112,740 cancer patients aged 0-64 in Massachusetts in 2014. However, Massachusetts has a higher overall incidence rate for cancers versus the nation as a whole. While the national figure for 2008-

12 was estimated at 453.8 cases per 100,000, the Massachusetts number was approximately 6.5 percent higher at 483.1.[663] Applying a factor based on this higher rate to the preliminary number of cases raises the estimate of cancer cases in Massachusetts under age 65 to 120,019.

In 2010, the American Cancer Society reported that the proportion of adults with cancer who participate in clinical trials was just 5 percent.[664] Allowing for a somewhat higher participation rate of 6 percent in Massachusetts, owing to its density of teaching hospitals, brings the estimate of clinical trial patients in Massachusetts to just over 7,200. U.S. Census Bureau insurance coverage data indicate that 74.7 percent of the under-65 population in Massachusetts was privately-insured in 2014.[665] Compass's insured population membership model estimates that 49.1 percent of the privately-insured have fully-insured medical coverage, resulting in an estimated number of cases of privately-insured under-65 individuals in Massachusetts participating in clinical trials in 2014 of 2,742.

Table 30
Clinical Trials to Treat Cancer Mandate
Required Direct Cost Estimate

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	N/A		
Sample Units	N/A		
Sample Average Members	N/A		
Paid PMPM	$ 0.08	N/A	N/A
Paid PMPM With Admin	$ 0.09	N/A	N/A
Allowed PMPM	N/A	N/A	N/A

	Required Direct Cost		Upper and Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 2,275,297		$ -
Contribution to Total Annual Premium	$ 2,556,513		$ -
Percent of Total Premium	0.02%		0.00%

* This mandate was judged by carriers to contribute $0 marginal cost to premiums.
Required direct cost was estimated using secondary data sources.

The National Institutes of Health estimated the total 2010 U.S. cost of medical care for cancer at $102.8 billion dollars.[666] Applying this amount to a total U.S. 2014 cancer prevalence estimate of 14.1 million[667] yields a cost per case for cancer care of $7,270 annually. For the Massachusetts fully insured population under age 65, the cost of cancer care would then be about $22.8 million in total after trending the 2010 cost estimate forward to 2014. The incremental cost of care in clinical trials for cancer is estimated at 10 percent,[668] although a later article specifically examining NIH-sponsored clinical trials calculated this figure at 6.5 percent.[669] Assuming the more conservative 10 percent estimate, the total cost of cancer clinical trials for the 2.4 million Massachusetts fully-insured under 65 population is $2.3 million, or $0.08 PMPM. With administrative loading, this

figure rises to $0.09, or 0.02 percent of the overall $436 PMPM average 2014 premium. These results are summarized in Table 30 above.

Contraceptive Services

The contraceptive services mandate requires coverage for outpatient contraceptive services (consultations, exams, procedures, etc.) to the same extent as other outpatient services and for prescription contraceptive drugs and devices under the same terms and conditions as other prescription drugs and devices. The mandate provides exclusions for church-affiliated employers.[670]

Effect of the mandate on health

The United States has an estimated 61 million women ages 15-44;[671] of these, 70 percent are sexually active but do not want to become pregnant.[672] Massachusetts has 1.44 million women of reproductive age, of whom 61 percent are sexually active and do not wish to become pregnant.[673] In the United States, more than half of all pregnancies are estimated to be unintended.[674] Family planning is one of the major objectives of Healthy People 2020, the set of evidence-based national health promotion and disease prevention goals outlined for the next decade by the U.S. Department of Health and Human Services.[675] According to Healthy People, "Family planning is one of the 10 great public health achievements of the 20th century. The availability of family planning services allows individuals to achieve desired birth spacing and family size and contributes to improved health outcomes for infants, children, and women."[676]

The benefits of contraception include improved women's health and well-being, reduced maternal mortality, health benefits for mother and child associated with spacing pregnancy, female workforce engagement, and economic self-sufficiency.[677] Additionally, contraceptive use may decrease menstrual period pain and bleeding, and reduce gynecological disorder risks, including those for ovarian and endometrial cancers.[678] The negative consequences of unintended pregnancies are numerous. They include: delays in initiating prenatal care; the increased risk of tobacco and alcohol use and of physical violence during pregnancy; premature birth and low birth weight; reduced likelihood of breastfeeding; poor maternal mental health; and lower relationship quality between mother and child.[679,680] Some studies show that children born from an unintended pregnancy may be more likely to suffer from poor physical and mental health in childhood, and may attain lower educational and behavioral outcomes.[681,682,683,684,685,686,687]

Outcomes are worse for unintended pregnancies in teen mothers; 82 percent of pregnancies among mothers age 15 to 19 are unintended.[688] An adolescent who experiences an unintended pregnancy is less likely to graduate from high school or attain a GED by age 30, and will earn approximately $3500 less per year on average than her peers who delay having children; teen fathers experience similarly lower educational achievement and income.[689,690] Teen mothers, on average, receive twice as much federal aid for twice as long as non-parent teens.[691] Finally, children of teenagers have more behavioral problems and lower cognitive abilities than others, on average; in fact, sons of teen mothers are more likely to be incarcerated, while daughters are more likely to become pregnant as teens.[692]

Furthermore, adequate pre-pregnancy planning allows women to receive appropriate preconception care, the importance of which is becoming increasingly evident. Care provided before pregnancy allows providers to reduce the risks of pregnancy to women, as well as some pre-term births and their associated birth defects.[693]

Contraceptive drugs and devices, used consistently and correctly, and paired with appropriate associated examination and consultation services, can play a significant role in family planning. While 30 percent of women do not need a contraceptive method,[694] 8 percent of women are at risk of unintended pregnancy but are not using contraception.[695] Of the women not using contraception and at risk of unintended pregnancy, larger percentages are under 20 years of age, have never married, and are black.[696]

The remaining 62 percent of women of reproductive age are currently using a contraceptive method.[697] While almost half of women with an unintended pregnancy report using some form of contraception,[698] 67 percent of women at risk of unintended pregnancy use contraception consistently and correctly, and account for only 5 percent of unintended pregnancies.[699] Proper use of the most effective methods of contraception "virtually eliminates" the risk of unintended pregnancy, while using any method reduces the chances by 85 percent.[700]

Slightly more than half of pregnancies in the United States each year are unintended; of these, research shows that 95 percent are in women either not using contraception or using it inconsistently.[701] Most women (64 percent) who use contraception rely on non-permanent methods, while the remainder rely on male or female sterilization.[702]

Success rates depend on either permanency or consistency of use; permanent sterilization methods result in a failure rate of less then 1 percent with typical use, while other methods vary widely, from 1 percent failure rates for implants to 28 percent failure rates for spermicide alone with typical use. However, by preventing unintended pregnancies, "[c]ompared with nonuse, even with a time horizon as short as 1 year, use of any method [of contraception]…results in financial savings and health gains."[703] Table 31 summarizes the estimated number of users of each type of contraception and the expected proportion of pregnancies expected for each.

Table 31
Methods of Birth Control[704,705,706]

Method	Users # (000s)	Users Percent	Number of pregnancies expected per 100 women[707] Perfect use	Typical use
FDA-APPROVED METHODS				
Permanent				
Sterilization Implant for Women (Transcervical Surgical Sterilization Implant)	492[xxv]	1.3[1]	0.05	0.05
Sterilization surgery for men	3,084	8.2	0.10	0.15
Sterilization Surgery for Women, Surgical Implant (Transabdominal Surgical Sterilization)	9,443	25.1	0.5 (tubal only)	0.5 (tubal only)

[xxv] User number combines permanent sterilization implant and removable implantable rod.

Method	Users # (000s)	Users Percent	Number of pregnancies expected per 100 women[707] Perfect use	Number of pregnancies expected per 100 women[707] Typical use
Implant				
Implantable rod	492[1]	1.3[1]	<1	N/A
Intrauterine Device (IUD) w/progestin	3,884	10.3	0.2	0.2
IUD copper			0.6	0.8
Hormonal				
Shot/injection	1,697	4.5	0.2	6
Oral contraceptives/ combined pill, progestin only and extended/continuous use	9,720	25.9	0.3	9
Patch	217	0.6	0.3	9
Vaginal contraceptive ring	759	2.0	0.3	9
Barrier				
Diaphragm w/spermicide	133[xxvi]	0.4[2]	6	12
Sponge w/spermicide			9/20	12/24
Cervical cap w/spermicide			N/A	17/23
Male condom	5,739	15.3	2	18
Female condom	N/A	N/A	5	21
Spermicide alone	N/A	N/A	18	28
Emergency Contraception				
Plan B, Plan B One Step, Next Choice	91	0.2		88 percent[xxvii]
Ella				60-70 percent[3]
OTHER METHODS				
Withdrawal	1,817	4.8	4	22
Fertility awareness-based[xxviii]	509	1.4	0.4-5	24
No method, at-risk of unintended pregnancy	4,175	N/A	85	85
No method, not at risk	19,126	N/A	N/A	N/A

In general, when used correctly and consistently, contraceptives are effective at preventing unintended pregnancies and related negative health impacts on women and children. Contraceptive effectiveness varies by method: permanent sterilization is most effective, and the next most effective contraceptives are long-acting reversible methods. Consistent and effective use of contraception, as well as use of more effective methods, can be improved by reducing cost and other barriers to access, as well as by providing women with access to methods that are medically-appropriate and consistent with their social, cultural, emotional, and sexual lifestyles.

Under the Patient Protection and Affordable Care Act (ACA), non-grandfathered health insurance plans must fully cover the costs of contraceptive methods and counseling for all women, as prescribed by a health care provider.[708] When provided by an in-network provider, these services will require no patient cost-sharing (no deductibles, coinsurances or copayments).[709] Covered methods include at least one type of method within all categories of prescribed contraception

[xxvi] Also includes female condom, foam, suppository, jelly/cream, and other methods.
[xxvii] Prevents pregnancy in percent of women who would have otherwise become pregnant.
[xxviii] Includes cervical mucus methods, body temperature methods, and periodic abstinence.

approved by the Food and Drug Administration (FDA), including sterilization procedures, implanted devices, barrier and hormonal methods, emergency contraception, and education and counseling; over-the-counter contraception, drugs to induce abortions and sterilization surgery for men are not included in this benefit.[710] Health plans sponsored by certain exempt religious organizations may not be covered and may require out-of-pocket payment.[711] Some non-profit religious organizations that certify religious objections do not have to contract, arrange, pay, or refer for contraceptive coverage; for these types of organizations, insurers or third party administrators may make separate payments for contraceptive services to in-network providers without patient cost-sharing.[712]

Estimate of the cost of the mandate

The contraceptive services mandate provides coverage for outpatient contraceptive services (consultations, exams, procedures, etc.) to the same extent as other outpatient services and for prescription contraceptive drugs and devices under the same terms and conditions as other prescription drugs and devices. The mandate provides exclusions for church-affiliated employers.

The federal ACA requires contraception coverage as an essential health benefit (EHB), and, in addition to requiring all of the benefits of the state mandate, requires all compliant plans to cover at least one product from each of the FDA's 18 approved contraception methods at zero cost-sharing. Therefore, this analysis assumes the Massachusetts contraceptive mandate to be redundant to and superseded by the federal ACA; the marginal cost of the state mandate is therefore zero. The contraception provisions of the ACA were required in all new health insurance plans in effect on or after August 1, 2012; accordingly, the Massachusetts contraception mandate was treated as a potential marginal cost mandate in the first two comprehensive reviews.

Required direct costs (RDCs) of this mandate were determined to consist of paid amounts from all claims for female members for outpatient contraceptive procedures and consultations (IUD insertion, etc.), all claims for evaluation and management (identified by the evaluation and management, or E&M, CPT4 codes) with a contraception-related diagnosis, and all pharmacy claims for contraceptive drugs and devices for the target population. The estimated RDC PMPM paid claim amount for the calendar year 2014 study period was $3.32, with a total PMPM cost, after administrative loading, of $3.73 (or 0.86 percent of the Commonwealth total premium). Table 32 below displays a summary of these results and related statistics.

Table 32
Contraception Mandate
Required Direct Cost Estimate

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	164,542		
Sample Units	32,706,555		
Sample Average Members	1,437,788		
Paid PMPM	$ 3.32	N/A	N/A
Paid PMPM With Admin	$ 3.73	N/A	N/A
Allowed PMPM	$ 3.50	N/A	N/A

	Required Direct Cost		FI-SI Allowed & Lower Bound PMPMs
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 94,197,565		$ -
Contribution to Total Annual Premium	$105,839,960		$ -
Percent of Total Premium	0.86%		0.00%

* The requirements of the Massachusetts mandate have been superseded by the ACA.
Required direct cost was estimated using the Massachusestts APCD.

Cytological Screening (Pap Smear)

The cytological screening mandate requires coverage for cytological screening annually for women 18 years and older.[713]

Effect of the mandate on health

According to the American Cancer Society, "[c]ervical cancer incidence and mortality rates have decreased by more than 50% over the past three decades, with most of the reduction attributed to screening with the Papanicolaou (Pap) test, which detects cervical cancer and precancerous lesions."[714,715,716] Further, the survival rate for women with precancerous lesions diagnosed through the Pap test is nearly 100 percent, as cancer is prevented altogether, and women with localized cervical cancer, most often detected early, have a five-year survival rate of 91 percent.[717,718] Yet approximately half of cervical cancers are not diagnosed until later stages, when five-year survival rates are much lower. The five-year survival rate for regional-stage cervical cancer is 57 percent, and is only 16 percent for distant-stage cervical cancer;[719] most women diagnosed at these stages have not had a Pap screening within the five years prior to diagnosis.[720]

While the Pap test has been extremely helpful in identifying precancer and early stage cancer in women who are screened, cervical cancer remains the second most common cancer for women worldwide.[721] Research into the causes and progression of cervical cancer has expanded rapidly in recent years, and these studies have found that almost all cases of cervical cancer are causally related to persistent infection with certain types of human papillomavirus (HPV).[722] HPV is the most common sexually transmitted infection in the US, causing 90 percent of all anal cancers, 60

percent of certain types of oropharyngeal cancers, and 40 percent of vaginal, vulvar, and penile cancers.[723] This new understanding of the causes of these cancers has led to a shift from a strategy mostly focused on screening for pre-cancers and cancers, to approaches that include vaccination against HPV to prevent infection, as well as screening not only for precancers and cancers, but also HPV itself.

Initial infection with HPV is common in young women within their first decade of sexual activity.[724] However, less than 10 percent of these infections persist and, relatively slowly, become precancer, most often between 5 and 10 years after initial infection.[725] From these, a minority of cases progress to invasive cancer; this also most often takes many years or decades, with the risk highest in women 35 to 55 years old.[726]

Given these statistics, agreement is near-universal on the benefits of cytological screening for women, and many U.S. government agencies and medical societies now agree on a single set of recommendations regarding testing methods and intervals released in March 2012. These recommendations call for less-frequent screening, as researchers have found that:

> [S]creening… more often than every 3 years confers little additional benefit, with large increases in harms, including additional procedures and assessment and treatment of transient lesions. Treatment of lesions that would otherwise resolve on their own is harmful because it can lead to procedures with unwanted side effects, including the potential for cervical incompetence and preterm labor. Similarly, the frequency of HPV testing with cytology should not be more often than every 5 years in order to maintain a reasonable balance of benefits and harms similar to that seen with cytology alone every 3 years.[727]

The cytological screening mandate in Massachusetts requires coverage for screening annually for women 18 years and older, a frequency greater than that in the current guidelines.

The USPSTF currently gives the recommendations for women age 21 to 29 and 30 to 64 grades of "A". Under the ACA, non-grandfathered health insurance plans must fully cover the costs of recommended preventive services graded "A" or "B" without patient cost sharing (no deductibles, coinsurances or copayments).[728,729] However, the USPSTF recently released its "Final Research Plan for Cervical Cancer Screening", indicating it will again conduct a systematic review of research to form the basis of an updated recommendation.[730]

Cytological Screening Recommendations[731]

Recommending organizations	General recommendations	Women age		
		21-29	30-64	65+
• American Cancer Society/ American Society for Colposcopy and Cervical Pathology/American Society for Clinical Pathology (ACS/ASCCP/ASCP) (adopted March 2012)[732] • US Preventive Services Task Force/American Academy of Family Physicians (USPSTF/AAFP) (adopted March 2012)[733] • American College of Obstetrics and Gynecology (ACOG) (adopted December 2013)[734]	• No annual screening • No screening for women under age 21 • No screening for HPV for women under age 30 • No screening for women with total hysterectomy • Routine screening should continue for women found to have a high-grade precancerous lesion within past 20 years, regardless of age	• Pap test every 3 years	Preferred: • HPV and Pap test every 5 years Acceptable: • Pap test every 3 years	No more tests if: • No history of cervical intraspithelial neoplasia 2 or higher within the last 20 years –AND– • Adequate testing history within the last 10 years (most recent test within the past 5 years) of either 3 consecutive negative Pap tests or 2 consecutive negative HPV and Pap tests

Discussion of the cost of the mandate

The cytological screen mandate requires coverage for cytological screening (Par smear) annually for women 18 years and older.

For this analysis, the cost of the cytological screening mandate reflected in insurance premiums is estimated as the total cost to fully-insured plans subject to the mandate for cytological screening procedure codes (sample collection and reading and interpretation codes)[xxix] for women aged 18 or older on the date of service. The estimated RDC PMPM paid claim amount for the calendar year 2014 study period was $0.62, with a total PMPM cost, after administrative loading, of $0.69 (or 0.16 percent of the Commonwealth total premium). Table 33 below displays a summary of these results and related statistics.

[xxix] HCPCS codes 88141, 88142, 88143, 88147, 88148, 88155, 88164, 88165, 88174, 88175, P3000, P3001, G0123, G0124, G0141, G0143, G0144, G0145, G0147, G0148, or Q0091.

Table 33
Cytological Screening (Pap Smear) Mandate
Required Direct Cost Estimate

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	230,421		
Sample Units	281,588		
Sample Average Members	1,871,491		
Paid PMPM	$ 0.62	N/A	N/A
Paid PMPM With Admin	$ 0.69	N/A	N/A
Allowed PMPM	$ 0.62	N/A	N/A

	Required Direct Cost		Upper and Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 17,536,272		$ -
Contribution to Total Annual Premium	$ 19,703,676		$ -
Percent of Total Premium	0.16%		0.00%

* This mandate was judged by carriers to contribute $0 marginal cost to premiums.
Required direct cost was estimated using the Massachusestts APCD.

Hearing Screening for Newborns

This mandate requires coverage for hearing screening for newborns.[735]

Effect of the mandate on health

Permanent congenital hearing loss (PCHL) affects approximately 1.5 infants screened per thousand in the United States each year.[736] In Massachusetts, approximately 1300 newborns each year fail a hearing screening before leaving the hospital, and approximately 220 of these are diagnosed with hearing loss after more extensive testing.[737] Hearing loss, if left undetected, can negatively impact a child's development in many ways, resulting in "difficulties later in life, including problems with listening and speaking skills, literacy skills, academic performance, and long-term job opportunities."[738] Research suggests that a child's speech and language development is most intensive during the first three years of life, when the brain is creating the nerve pathways necessary for "understanding auditory information."[739]

Age at diagnosis influences outcomes for children with PCHL: the earlier the detection, the more options and opportunity for treatment, and the better the outcome.[740,741] As research continues to describe the rapid development of the brain before the age of three,[742] and positive outcomes are increasingly associated with early enrollment of hearing-impaired children into treatment programs,[743] it becomes more critical to lower the age of diagnosis to as early as possible, and at no later than at three months of age.[744]

Universal newborn screening leads to earlier detection and treatment of PCHL.[745] Newborn screening is the standard of care nationwide, as recommended by the Joint Committee on Infant

Hearing (JCIH), the U.S. Centers for Disease Control and Prevention, the National Institute on Deafness and Other Communication Disorders at the U.S. National Institutes of Health, and the U.S. Healthy People 2020 initiative, all of which advocate for universal screening for infants before one month of age.[746,747,748,749]

The Joint Committee on Infant Hearing (JCIH) endorses early detection of and intervention for infants with hearing loss, "to maximize linguistic competence and literacy development for children who are deaf or hard of hearing."[750] The group recommends screening for all infants at no later than one month of age, with comprehensive audiological evaluations before three months of age for those who do not pass the initial screening.[751] Before six months of age, those with confirmed hearing "should receive appropriate intervention…from health care and education professionals with expertise in hearing loss and deafness in infants and young children."[752] The group also recommends that well-child visits for all children include "ongoing surveillance of communicative development beginning at 2 months of age during well-child visits."[753]

All states have established Early Hearing Detection and Intervention (EHDI), 43 of which mandate newborn hearing screening programs.[754] These programs are making progress toward the goal of screening all infants, and earlier diagnosis and treatment enrollment for those with hearing loss, as evidenced by a CDC Early Hearing Detection and Intervention survey of 46 U.S. states and territories showing that in 2013, 97 percent of infants were screened for hearing impairments, and 69 percent of infants were diagnosed before three months of age.[755] In fact, the survey shows improvement in several measures for diagnosis and treatment of PHCL.[756,757]

CDC EHDI Survey Data for 2005 and 2013

	2005	2013	Improvement 2005 to 2013
Infants received hearing screening before age 1 month	80.1%	91.7%	14.5%
Infants received recommended diagnostic follow-up before age 3 months	51.5%	69.2%	34.4%
Infants with hearing loss enrolled in early intervention before age 6 months	57.0%	62.1%	8.9%

The USPSTF currently gives a "B" rating to screening for hearing loss in all newborns,[758] although the specific recommendation has been designated "Inactive".[759] Under the ACA, non-grandfathered health insurance plans must fully cover the costs of recommended preventive services graded "A" or "B" without patient cost sharing (no deductibles, coinsurances or copayments).[760,761]

Discussion of the cost of the mandate

The hearing screening for newborns mandate requires coverage for newborn hearing screening tests. The cost of the universal newborn hearing screening is based upon the number of newborns in the state who were tested in 2014. The U.S. Centers for Disease Control and Prevention (CDC) reports that 71,573 newborns were tested under the program in 2013.[762] Applying the statewide 74.7 percent private health insurance rate to the total tested newborns and the 49.1 percent factor representing the proportion of individuals covered by Massachusetts-licensed fully-insured commercial health insurance to that result yields an estimated 26,225 fully-insured and GIC

newborns tested. The average cost of hearing screening tests in the 2014 MA APCD[xxx] was approximately $126.56. This brings the total spent by insurers for the newborn screenings to $3.3 million, or $3.7 million with an 11 percent administrative load. The total expense PMPM for the 2.4 million privately fully-insured and GIC under-65 individuals is then $0.13, or 0.03 percent of the total premium. These results are summarized in Table 34 below.

Table 34
Hearing Screening for Newborns Mandate
Required Direct Cost Estimate

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	N/A		
Sample Units	N/A		
Sample Average Members	N/A		
Paid PMPM	$ 0.12	N/A	N/A
Paid PMPM With Admin	$ 0.13	N/A	N/A
Allowed PMPM	N/A	N/A	N/A

	Required Direct Cost		Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 3,319,019		$ -
Contribution to Total Annual Premium	$ 3,729,235		$ -
Percent of Total Premium	0.03%		0.00%

* This mandate was judged by carriers to contribute $0 marginal cost to premiums.
Required direct cost was estimated using secondary data sources.

Hospice Care

The hospice mandate requires coverage for licensed hospice services for terminally ill patients with a life expectancy of six months or less.[763]

Effect of the mandate on health

Research into the medical effectiveness and efficacy of hospice care is difficult to conduct, given that hospice care is provided to dying patients no longer seeking cures. Hospice care is, instead, "a program of palliative and supportive care services providing physical, psychological, social, and spiritual care for dying persons, their families, and other loved ones."[764] Services are provided in a variety of settings, including the home, nursing home, and hospital, and are tailored to the needs of individual patients and families. Outcomes of such treatment are variable and subjective, given that care is not intended to improve a disease-state, but is instead a multidisciplinary approach to "caring for the whole person including…physical, emotional, social and spiritual needs."[765]

Measures of the quality of the patient's life are a difficult proxy to use, as data are often difficult to obtain from patients in the period immediately preceding death, and many perceive that a patient's

[xxx] HCPCS codes 92586, 92587, and 92588.

quality of life often deteriorates until death.[766] Despite these difficulties, however, some studies have shown hospice care to be associated with a relatively high and stable quality of life,[767] improved pain control, decreased hospitalizations, and decreased tube feedings for terminal nursing home patients,[768] improved quality of death,[769] and a reduction in mortality for the widowed spouse.[770] A Cochrane review found that home-based hospice care increases the number of patients who die at home versus in the hospital, which is more in line with their personal preferences.[771] Two oft-cited studies found that "for certain well-defined terminally ill populations, among the patients who died, patients who choose hospice care live longer on average than similar patients who do not choose hospice care,"[772] although the authors point out that more research is needed before generalizing their findings.[773]

Discussion of the cost of the mandate

In 2009, 22,406 persons received hospice services in Massachusetts through Medicare fee-for-service[774] at a cost of almost $231 million.[775]

Assessing the level of hospice spending in Medicare should take into account managed care plan membership, which is not included in the previously cited fee-for-service figures. In 2009, 23 percent of members were enrolled in Medicare Advantage plans.[776] Assuming that Medicare Advantage members utilize hospice services at the same rate as those in fee-for-service plans, the estimated spending on hospice expense for Medicare would rise to approximately $300 million in total.

According to the Hospice Association of America, Medicare represents about 84.3 percent of spending for hospice services.[777] Based on this proportion, overall spending on hospice expenses would be approximately $356 million in 2009. National Health Expenditures (NHE) data for "other health, residential, and personal care expenditures" reported by for the Centers for Medicare and Medicaid Services (CMS) suggests a 5-year inflation rate of 21 percent for this figure,[778] yielding an estimate of $431 million in total 2014 hospice spending. The portion of this figure paid by private payers is approximately 7.8 percent,[779] or $33.6 million. Applying the 49.1 percent Massachusetts 2014 fully-insured factor provides an estimate of $16.5 million of hospice spending, assuming similar per-case costs across all private payers. With 11 percent administrative loading, the total spending on hospice care for the under-65 fully-insured member population and self-insured GIC enrollees in Massachusetts in 2014 is estimated at approximately $18.5 million, or $0.65 PMPM, representing 0.15 percent of the overall premium. These results are summarized in Table 35 below.

Table 35
Hospice Care Mandate
Required Direct Cost Estimate

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	N/A		
Sample Units	N/A		
Sample Average Members	N/A		
Paid PMPM	$ 0.58	N/A	N/A
Paid PMPM With Admin	$ 0.65	N/A	N/A
Allowed PMPM	N/A	N/A	N/A

	Required Direct Cost		Upper and Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 16,486,810		$ -
Contribution to Total Annual Premium	$ 18,524,505		$ -
Percent of Total Premium	0.15%		0.00%

* This mandate was judged by carriers to contribute $0 marginal cost to premiums.
Required direct cost was estimated using secondary data sources.

Lead Poisoning Screening

The lead screening mandate requires coverage for screening for lead poisoning for all children under age six and for others deemed at risk.[780]

Effect of the mandate on health

Elevated blood lead levels can significantly harm many of the body's systems, including cardiovascular, immune, endocrine, and neurological, with irreversible negative impact on cognitive function, especially attention-related behavior and academic achievement.[781] Numerous studies have shown that even low blood lead levels (BLLs; below 10mg/dL) harm children.[782]

Over time, federal and state legislation has directed the removal of lead from gasoline and residential paints, as well as the reduction of toxic emissions from smelters and other industrial sources.[783] This has resulted in a reduction in the median national BLL for children under age 5 from 15 mcg/dL in 1980 (prior to full implementation and effect of legislation) to 3.6 mcg/dL in 1991, and 1.9 mcg/dL by 1999.[784] According to CDC data, the percentage of children in Massachusetts found to have BLLs greater than 10 mcg/dL has fallen from 3.23 percent in 1997 to 0.32 percent in 2013, a 90 percent reduction over 16 years.[785]

While exposure risk has decreased across the entire population, the prevalence of higher BLLs, as well as risk of exposure, vary significantly within population subgroups and are more frequent among low-income populations more likely to reside in buildings constructed before 1978.[786]

Moreover, research has shifted from focusing on the impact of high BLLs on child health to show the negative impact of lower BLLs (below 10 mcg/dL) on childhood development.[787]

This information has led to a change in public health advocacy from recommending screening of all children for lead exposure, to targeted screening for certain populations and a primary prevention strategy aimed at children and families most likely to live in homes with lead hazards. Many of the recommendations and guidelines issued by public and professional medical organizations have changed over time, as various public health and environmental efforts have been implemented and sometimes phased out, with other approaches evolving and replacing them.[788]

For example, in 2012, the CDC updated its recommendations regarding BLLs in children, and shifted its focus to primary prevention of lead exposure. The new goals are to eradicate BLLs greater than 10 mcg/dL, and eliminate average risk differences that exist "based on race and social class."[789] The threshold BLL used to identify children who need medical intervention is now lower and will be periodically adjusted, rather than remaining fixed at 10 mcg/dL.[790] This public health initiative is part of the National Center for Environmental Health's Division of Emergency and Environmental Health Services, and is in line with the Healthy People 2020 program of the federal government, which revised its targets for reducing BLLs for children in 2014, establishing a 10 percent improvement goal for two areas of measurement.[791]

According to the American Academy of Pediatrics Bright Futures periodicity table of Recommendations for Preventive Pediatric Health Care, a lead exposure risk assessment is recommended at preventive health visits multiple times during infancy through adolescence.[792,793] Finger stick blood sample screenings are to be performed at the 12- and 24-month visits if a patient is identified through screening, lives in a high-prevalence area, or is required by Medicaid rules.[794,795] These rules were updated for children eligible for Medicaid Early and Periodic Screening, Diagnosis and treatment (EPSDT) services in June 2012 by CMS. This policy is now aligned with the CDC recommendations, and supports a targeted screening approach "in States that have sufficient data to support this action."[796]

In Massachusetts, universal screening is required by Department of Public Health regulations, as all children must be screened for lead poisoning at least twice: once between nine and twelve months of age, and again between two and three years of age; children must provide evidence of screening to gain entry to kindergarten.[797] Children living in areas identified as high risk are also required to be screened at age four.[798] Children identified by health care providers as high-risk, including those who live in a pre-1978 home that has not been inspected for lead paint, or who have siblings identified with lead poisoning, should be screened every six months between ages six months and three years, and annually at ages four and five.[799] And children living in a pre-1978 home undergoing renovation and that has not been inspected for lead paint are to be screened within four weeks of the start, monthly during, and once after completion of the renovation.[800]

Only those screenings conducted at age four for children living in areas identified as high risk, or those for children identified by their health care provider as high-risk, are subject to the insurance reimbursement requirements of this mandate.[801]

The USPSTF concludes that evidence is insufficient to recommend routine screening for at-risk children, as there is not enough information to "assess the balance between potential benefits and harms."[802] For children and asymptomatic pregnant women of average risk, the USPSTF has concluded that, "[g]iven the significant potential harms of treatment and residential lead hazard abatement, and no evidence of treatment benefit, ...the harms of [universal] screening…outweigh the benefits."[803]

Discussion of the cost of the mandate

For this analysis, the cost of the lead screening mandate reflected in insurance premiums is estimated as the total cost to fully-insured plans subject to the mandate for lead screening lab tests (HCPCS code 83655) and collection of capillary blood specimens (HCPCS code 36416) within the week prior to the lab test for children aged 5 or younger on the date of service. The estimated RDC PMPM paid claim amount for the calendar 2014 study period was $0.04, with a total PMPM cost, after administrative loading, of $0.05 (or 0.01 percent of the Commonwealth total premium). These results are summarized below in Table 36.

Table 36
Lead Poisoning Screening Mandate
Required Direct Cost Estimate

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	43,023		
Sample Units	49,226		
Sample Average Members	1,871,491		
Paid PMPM	$ 0.04	N/A	N/A
Paid PMPM With Admin	$ 0.05	N/A	N/A
Allowed PMPM	$ 0.04	N/A	N/A

	Direct Cost		Lower Bound
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 1,200,660		$ -
Contribution to Total Annual Premium	$ 1,349,057		$ -
Percent of Total Premium	0.01%		0.00%

* This mandate was judged by carriers to contribute $0 marginal cost to premiums.
Required direct cost was estimated using the Massachusestts APCD.

Mammography

The mammography mandate requires coverage for one "baseline" mammogram between ages 35 and 40, and annual measurements thereafter.[804]

Effect of the mandate on health

According to the CDC, breast cancer is the most common cancer for women in the United States, and is second only to lung cancer in mortality rate.[805] Mammography can detect presymptomatic breast

cancer which can be more effectively treated at this early stage.[806] Screening can also reduce breast cancer mortality, especially for women ages 50 to 74. The U.S. Preventive Services Task Force (USPSTF) states that the "strongest evidence for the greatest benefit is among women aged 60 to 69 years."[807]

However, screening also can result in unnecessary additional tests and treatments, as well as the psychological harm associated with false-positive results.[808] Some cancers found through mammography and treated may not become "clinically apparent during a woman's lifetime", so-called "over-diagnosis", or may become clinically apparent but not result in a shortened life expectancy.[809] False-positive results are more common in women age 40 to 49, while over-diagnosis is "a greater concern" for women who are older.[810]

While experts agree that mammography is effective in identifying breast cancer, the recommended screening schedule is somewhat controversial, particularly regarding the risks and benefits of annual mammography for women of average risk between 40 and 50 years of age. Various organizations have changed their guidelines multiple times within the past 10 to 15 years; the most recent guidelines of seven leading organizations are reflected in the following table.

Screening for Breast Cancer for Women at Average Risk: Comparative Guideline Table

Issuing Organization (Year)	Recommendation for Women			Based on systematic review
	Age 40-49	Age 50-74/75	Age 75+	
American Academy of Family Physicians[811] (2013)	Based on counseling and individual decision	Age 50-74 Screen every 1-2 years	Insufficient evidence for recommendation	Yes (USPSTF cited)
American Cancer Society[812] (2015)	Screen annually beginning at age 45. Opportunity for annual screening for women age 40-44.	Screen biennially. Opportunity for annual screening, until life expectancy is less than 10 years.		Yes[813]
Previous American Cancer Society[814] (2003; revised 2014)	Screen annually	Screen annually indefinitely in healthy patients		No
American Congress of Obstetricians and Gynecologists[815] (2011)	Screen annually		Individualize screening	Yes (based on USPSTF)
American College of Physicians[816,817] (2007) (ACP)	Based on counseling and individual decision	Age 50-74 Screen annually	Based on counseling and individual decision	Yes
American College of Radiology[818] (2013)	Screen annually	Screen annually until life expectancy is less than 5-7 years		No
Institute for Clinical Systems Improvement[819] (2013)	Based on counseling and individual decision	Age 50-75 Screen every 1-2 years; consider screening older women based on shared decision making	Based on counseling and individual decision	No (USPSTF cited)

Issuing Organization (Year)	Recommendation for Women			Based on systematic review
	Age 40-49	Age 50-74/75	Age 75+	
U.S. Preventive Service Task Force (2009)[820]	Based on counseling and individual decision; do not screen routinely	Age 50-74 Screen biennially (Grade B)	Evidence for screening is insufficient	Yes

The Massachusetts mandate is in line with the 2003 American Cancer Society (ACS), American College of Radiology (ACR), and American Congress of Obstetricians and Gynecologists (ACOG) recommendations of annual mammography for women beginning at age 40.[821, 822,823]

In October 2015, the American Cancer Society revised its guidelines, based on its systematic review of evidence on breast cancer screening published to date, as well as judgment on the benefits and harms of screening that incorporated the values and preferences of patients and providers.[824] Screening is now recommended annually for women beginning at age 45.[825]

The final recommendations of the USPSTF, released in 2016, give a "B" rating to the recommendation for women ages 50 to 74 to receive a biennial mammogram.[826] They again state that evidence in support of screening for women ages 75 and over is insufficient, and that for women between the ages of 40 and 49, "[t]he decision to start screening prior to age 50 years should be an individual one. Women who place a higher value on the potential benefit than the potential harms may choose to begin screening between the ages of 40 and 49 years."[827]

Under its current recommendations, the USPSTF gave the recommendations for biennial mammography for women age 50 to 74 a grade of "B".[828] Under the ACA, non-grandfathered health insurance plans must fully cover the costs of recommended preventive services graded "A" or "B" without patient cost sharing (no deductibles, coinsurances or copayments).[829,830]

Discussion of the cost of the mandate

The mammography mandate requires coverage for one "baseline" mammogram between ages 35 and 40, and annual measurements thereafter. For this analysis, the cost of the mammography mandate reflected in insurance premiums is estimated as the total cost to fully-insured plans subject to the mandate for one bilateral (HCPCS code 77056 or 77057) or two unilateral mammograms (HCPCS code 77057), plus the first additional thoracic radiological service[xxxi] incurred subsequent to the mammogram, per woman aged 35 or over receiving at least one mammogram during 2014. The estimated RDC PMPM paid claim amount for the calendar year 2014 study period was $0.62, with a total PMPM cost, after administrative loading, of $0.70 (or 0.16 percent of the Commonwealth total premium). These results are summarized below in Table 37.

[xxxi] HCPCS codes 77051, 77052, 77053, or 77054.

Table 37
Mammography Mandate
Required Direct Cost Estimate

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	251,351		
Sample Units	489,773		
Sample Average Members	1,871,491		
Paid PMPM	$ 0.62	N/A	N/A
Paid PMPM With Admin	$ 0.70	N/A	N/A
Allowed PMPM	$ 0.63	N/A	N/A

	Required Direct Cost		Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$ 17,692,055		$ -
Contribution to Total Annual Premium	$ 19,878,713		$ -
Percent of Total Premium	0.16%		0.00%

* This mandate was judged by carriers to contribute $0 marginal cost to premiums.
Required direct cost was estimated using the Massachusestts APCD.

Maternity Care and Minimum Maternity Stay

The maternity care mandate requires coverage for "prenatal care, childbirth and post partum care to the same extent as provided for medical conditions not related to pregnancy" with a "minimum 48 hours of in-patient care following a vaginal delivery and a minimum of 96 hours of inpatient care following a caesarean section (c-section)."[831]

Effect of the mandate on health

Prenatal care has been practiced widely in the U.S. since the early twentieth century, and has proven effective at minimizing maternal mortality[832] and helping to reduce fetal, newborn, and perinatal (associated with birth) mortality.[833] Further, studies have shown better control of preeclampsia (pregnancy-related high blood pressure),[834] gestational diabetes,[835] and HIV[836] through prenatal care. Some research also points to a reduction in pre-term delivery, full-term low birth weight, and babies small for their gestational age for women with adequate prenatal care.[837]

Length of maternity stay

Studies of maternity stays have found that hospital discharges for newborns at any time less than 48 hours "significantly increases the risk for readmission."[838] The American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG) cite a myriad of problems that may arise if a hospital stay is not sufficiently long to identify problems and ensure the mother "is sufficiently recovered and prepared to care for herself and her newborn at home."[839] Issues include neonatal cardiopulmonary problems, jaundice, ductal-dependent cardiac lesions, and gastrointestinal obstructions for the newborn, as well as endometritis and other significant

maternal complications.[840] Services performed in the post-partum/pre-discharge stay include newborn screenings and risk assessment; administration of immunizations; maternal and family counseling and assessments, and perinatal education on issues such as breast-feeding, newborn sleep position, tobacco smoke exposure, car seat safety, mental health including post-partum depression, and domestic violence; and follow-up care planning for mother and baby.[841]

Post-partum hospital stays for mother and baby have changed significantly over the last four decades, with stays for vaginal delivery dropping from 3.9 to 1.8 days and for caesarian deliveries from 7.8 to 3.5 days between 1970 and 1998.[842] Beginning with a movement to "demedicalize" childbirth, followed by continued pressure to reduce costs,[843] postpartum lengths of stay continued to decrease until the mid-1990s. In 1992, the AAP and ACOG published joint guidelines for postpartum hospital stays, including a 48-hour stay for an uncomplicated vaginal birth, and a 96-hour stay for an uncomplicated c-section, excluding the day of delivery; their 2007 publication restated these guidelines.[844] By 1997, 32 states had adopted laws intended to set minimum required lengths of stay following delivery for both mothers and newborns, with the federal government enacting the federal Newborns' and Mothers' Health Protection Act of 1996, effective in 1998.[845] This federal law provides that "[g]roup health plans that are subject to the Newborns' Act may not restrict benefits for a hospital stay in connection with childbirth to less than 48 hours following a vaginal delivery or 96 hours following a delivery by cesarean section. However, the attending provider may decide, after consulting with the mother, to discharge the mother and/or her newborn child earlier."[846]

In some states, according to the U.S. Department of Labor, "[b]ased on a recent preliminary review of State laws, it appears that State law applies in lieu of the Federal Newborns' Act."[847,848] This is true in Massachusetts, where the state law pertaining to minimum inpatient stays following birth applies. The Massachusetts statute mandates coverage for "expense of prenatal care, childbirth and postpartum care to the same extent as provided for medical conditions not related to pregnancy" with "minimum 48 hours of inpatient care following a vaginal delivery and a minimum of 96 hours of inpatient care following a caesarean section."[849]

The most current APA and ACOG recommendation from 2013 states that "[t]he length of stay of a healthy term newborn should be based on the unique characteristics of each mother-infant dyad, including the health of the mother, the health and stability of the infant, the ability and confidence of the mother to care for her infant, the adequacy of support systems at home, and access to appropriate follow-up care."[850,851] AAP and ACOG further outline the minimal criteria that should be met by mother and newborn when the physician and mother want a shortened hospital stay, stating that "[w]hen no complications are present, the postpartum hospital stay usually ranges from 48 hours for vaginal delivery to 96 hours for cesarean delivery, excluding the day of delivery."[852,853] Other studies echo this conclusion, stating that individualized discharge plans "jointly tailored to a family's needs rather than to a set timescale" are appropriate, as a "lack of readiness" for postpartum discharge was associated with poorer health outcomes and increased health care use by patients (mothers and newborns) in the first 2 to 4 weeks after discharge.[854]

The intended and observed result of legislative mandates targeting postpartum length of stay was to increase average length of stay and to compress variability in length of stay among population

sub-groups.[855,856] Further, evidence has shown that early discharge legislation has decreased risk for infant readmission,[857,858] emergency room visits,[859] morbidity,[860] and mortality.[861] One study found a 36 percent reduction in infant mortality in its study population,[862] while another states that "one infant life could be saved for each 1400 normal newborns moved from early discharge (less than 30 h[ours]) to longer length of stay."[863] Other research suggests that mothers who stayed only one night after vaginal delivery reported more distress, fatigue, and pediatric problems than mothers who stayed two nights, and used more outpatient services following discharge. Likewise, these mothers were less likely to initiate and/or continue breastfeeding.[864] Some research suggests, however, that improved mortality and morbidity rates depend on the content of post-partum services, which should be more uniformly defined and administered.[865,866] On average, the biggest increase in length of stay was for uncomplicated vaginal deliveries, as c-section and more complicated deliveries already resulted in longer stays.[867] However, other research has shown that the impact on both length of stay and marginal charges is much more moderate than was reported in the years immediately following the passage of the legislation.[868]

Home visits

For mothers and newborns discharged early, (after less than 48 hours for vaginal delivery and 96 hours for cesarean delivery), the mandate provides that post-delivery care must include "home visits, parent education, assistance and training in breast or bottle feeding and the performance of any necessary and appropriate clinical tests."[869] The first home visit must be "conducted by a registered nurse, physician, or certified nurse midwife," with subsequent clinically-necessary visits to be conducted by a licensed health care provider.

According to the AAP, following post-partum discharge, home visits are intended to verify the overall health, hydration, and extent of jaundice of the infant; identify new problems; assess mother's mental health and maternal-infant bond; conduct additional screens and provide immunizations; and reinforce education and health care planning and maintenance.[870] Yet while these visits are not common practice in the United States,[871] they are recommended by many health and public organizations, including the AAP,[872] the US Advisory Board on Child Abuse and Neglect,[873] and the CDC's Task Force on Community Preventive Services.[874,875] These visits have been found to be cost-effective based solely on the observed reduction in costs associated with readmission, and the need for other hospital-based services in the first 10 days of life.[876] However, beyond these savings, a variety of significant health benefits to both child and mother have resulted from these visits, including a decrease in missed well-infant visits;[877] identification of psychosocial issues and post-partum depression and improvement in the maternal-child bond;[878] a reduction of incidence of child abuse or neglect;[879,880] fewer emergency department visits and unintentional injuries, ingestions, and poisonings;[881] and a reduction in sudden infant death syndrome.[882]

Under the ACA, non-grandfathered health insurance plans must fully cover the costs of recommended preventive services without patient cost sharing (no deductibles, coinsurances or copayments).[883,884] These include services graded "A" or "B" by the USPSTF; immunizations recommended by the CDC Advisory Committee on Immunization Practices (ACIP); and screenings and preventive care for infants, children, adolescents and women listed in the comprehensive

guidelines supported by the Health Resources and Services Administration (HRSA).[885] For pregnant women, mandated preventive services include a wide range of screenings and other services.[886] For newborns, mandated preventive services include screenings listed from the previously cited organizations, as well as from the AAP's Bright Futures Recommendations for Preventive Pediatric Health Care.[887,888,889]

Discussion of the cost of the mandate

The Massachusetts statute mandates coverage for "expense of prenatal care, childbirth and post partum care to the same extent as provided for medical conditions not related to pregnancy" with "minimum 48 hours of inpatient care following a vaginal delivery and a minimum of 96 hours of inpatient care following a caesarean section."

A January 2013 study estimated average 2010 Massachusetts private-payer costs for prenatal, delivery, and postpartum care at $16,888 for vaginal births and $20,620 for cesarean births.[890] Trending these costs forward to 2014 using the NHE hospital expenditures data[891] results in 2014 expenses per birth of $21,360 and $26,080 for vaginal and cesarean births, respectively. The Massachusetts Department of Public Health's 2014 births report indicates there were 13,559 privately-insured cesarean births and 28,426 vaginal births in the state in that year,[892] resulting in total privately-insured maternity care costs of $960.8 million. Applying the 49.1 percent fully-insured and GIC factor to this result yields a claims estimate of $471.3 million, or $16.62 PMPM. With administrative loading, the total expense is $529.5 million, or $18.68 PMPM (4.28 percent of total Commonwealth fully-insured premium). These results are summarized in Table 38.

Table 38
Maternity Care Mandate
Required Direct Cost Estimate

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	N/A		
Sample Units	N/A		
Sample Average Members	N/A		
Paid PMPM	$ 16.62	N/A	N/A
Paid PMPM With Admin	$ 18.68	N/A	N/A
Allowed PMPM	N/A	N/A	N/A

	Required Direct Cost		Upper and Lower Bound Impact
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$471,273,073		$ -
Contribution to Total Annual Premium	$529,520,307		$ -
Percent of Total Premium	4.28%		0.00%

* This mandate was judged by carriers to contribute $0 marginal cost to premiums.
Required direct cost was estimated using secondary data sources.

Mental Health Care

The mental health care (or mental health parity) mandate requires coverage for services to treat certain mental illnesses – including schizophrenia, bipolar disorder, obsessive-compulsive disorder, affective disorders, eating disorders, PTSD, and autism, and any biologically-based disorders recognized by the Commissioner of the Department of Mental Health – on a nondiscriminatory basis, meaning the policy does not contain any annual or lifetime dollar or unit of service limitation on coverage for the diagnosis and treatment of such mental disorders which is less than any such limitation imposed on coverage for the diagnosis and treatment of physical conditions. The mandate defines the types of services for which coverage is required, including qualifying facilities, levels of care, and provider types (psychiatrist, psychologist, clinical social worker, alcohol and drug counselor, etc.).[893]

Effect of the mandate on health

Mental illness is the leading cause of disability in America, accounting for 25 percent of all years of life lost to disability and premature mortality.[894] Moreover, suicide, most often attributable to mental illness, is the tenth leading cause of death in America, with over 40,000 cases each year.[895]

According to Healthy People 2020, mental health is "a state of successful performance of mental function, resulting in productive activities, fulfilling relationships with other people, and the ability to adapt to change and to cope with challenges."[896] Mental illness occurs when a person experiences an abnormality in thinking (cognition) or perception, emotion or mood, or behavioral integration, such as planning and social interactions.[897] The American Psychiatric Association (APA)'s Diagnostic and Statistical Manual, 5th edition (DSM-V), defines a mental disorder as:

> [A] syndrome characterized by clinically significant disturbance in an individual's cognition, emotion regulation, or behavior that reflects a dysfunction in the psychological, biological, or developmental processes underlying mental functioning. Mental disorders are usually associated with significant distress or disability in social, occupational, or other important activities.[898]

Major diagnostic categories of mental disorders include:[899]

- Neurodevelopmental disorders
- Schizophrenic spectrum and other psychotic disorders
- Bipolar and related disorders
- Depressive disorders
- Anxiety disorders
- Obsessive-compulsive and related disorders
- Trauma- and stressor-related disorders
- Dissociative disorders
- Somatic symptom and related disorders
- Feeding and eating disorders
- Sleep-wake disorders
- Sexual dysfunctions
- Gender dysphoria
- Disruptive, impulse-control and conduct disorders
- Substance-related and addictive disorders
- Neurocognitive disorders
- Personality disorders
- Paraphilic disorders
- Medication-induced movement disorders and other adverse effects of medication
- Other mental disorders

The National Institutes of Health estimates that 18.5 percent of adults have a mental, behavioral, or emotional disorder (excluding developmental and substance use disorders) diagnosed currently or within the past year of duration sufficient "to meet diagnostic criteria specified within the 4th edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)."[900] In a 2013 survey of the population over age 12, 8.2 percent were classified with a substance abuse or dependence disorder based on the DSM-IV.[901] For adults age 18 and over with any mental illness, 17.5 percent abused or were dependent on alcohol or illicit drugs; this number rose to 23 percent for those with a serious mental illness.[902]

For children ages 13 to 18, the lifetime prevalence of a mental disorder is 43.8 percent, and over 20 percent either currently or at some point in their lives have had a seriously debilitating mental disorder.[903] The most common illness for children was attention deficit-hyperactivity disorder with a prevalence rate of 8.6 percent, followed by 3.7 percent with mood disorders, and 2.7 percent with major depression.[904]

In 2014, 14.8 percent of adults in the United States received treatment (inpatient or outpatient counseling or prescription medication) for a mental health problem,[905] up from 13.4 percent in 2008. Of adults with any mental illness, 44.7 percent received treatment, while 68.5 percent for those with serious mental illness received treatment.[906] For children ages 8-15 with a diagnosed mental disorder, 50.6 percent used mental health services in the last year.[907] Overall, for children ages 12-17, 13.6 percent received specialty mental health services in 2014.[908]

Studies linking physical and mental health issues continue to show successful treatment of mental illness is critical to both mental and physical health. Simply put, those with mental illnesses are less able to exercise health-promoting behaviors, while individuals with chronic illnesses are more likely to suffer from mental health issues that may in turn impede treatment and recovery. Treatments generally fall into the broad categories of psychotherapy and medication, and may incorporate multimodal therapy, or a combination of the two. Psychotherapy is used to help patients understand their illnesses, and provides tools to manage symptoms and improve function. It includes such commonly used methods as cognitive behavioral therapy, dialectical behavioral therapy, interpersonal therapy, and family-focused therapy.[909] Other therapies include psychodynamic, light, expressive or creative arts, animal-assisted, and play.[910] Pharmacological therapy for mental illness generally refers to drugs categorized as antipsychotics, antidepressants, mood stabilizers, antianxiety, and stimulants.[911] New treatments include brain stimulation therapy, the direct activation or touching of the brain with electricity, magnets, or implants.[912]

Treatments vary by individual, illness, and other factors that also influence a patient's outcomes; research on effectiveness reflects these and other variables. The seminal 1999 U.S. Surgeon General's report on mental illness noted that "[t]he efficacy of mental health treatments is well documented, and…a range of treatments exists for most mental disorders."[913] The U.S. Substance Abuse and Mental Health Services Administration lists almost 400 mental health and substance abuse interventions in its National Registry of Evidence-Based Programs and Practices.[914,915]

The National Institute on Drug Abuse (NIDA) published its "Principles of Effective Treatment" for substance abuse disorders, outlining general points that research has shown improve outcomes of

treatment for this chronic disease.[916] In general, NIDA states that while "[e]ach approach to drug treatment is designed to address certain aspects of drug addiction and its consequences for the individual, family, and society," effective treatment is based on the premises that:[917]

- Addiction is a complex but treatable disease that affects brain function and behavior.
- No single treatment is appropriate for everyone.
- Treatment needs to be readily available; remaining in treatment for an adequate period of time is critical.
- Many addicted individuals have other mental disorders; effective treatment attends to all needs of the individual, not just drug abuse.
- Behavioral therapies—including individual, family, or group counseling—are the most common forms of drug abuse treatment.
- Medications are an important element of treatment, especially when combined with counseling and other behavioral therapies.
- Medically-assisted detoxification is only the first stage of addiction treatment and by itself does little to change long-term drug abuse.
- A treatment plan must be assessed continually and modified as necessary.
- Treatment does not need to be voluntary to be effective.
- Drug use during treatment must be monitored continuously.
- Treatment programs should test patients for the presence of HIV/AIDS, tuberculosis, hepatitis, and other infectious diseases and provide risk-reduction counseling, linking patients to needed treatment.

Research continues on the efficacy of specific treatments for specific mental illnesses and co-morbidities, reflected in recommendations such as those from the USPSTF. For example, in a series of 2016 recommendations specific to major depressive disorder (MDD), the USPSTF found that:

> [e]ffective treatment of depression in adults generally includes antidepressants or specific psychotherapy approaches (eg, CBT or brief psychosocial counseling), alone or in combination. Given the potential harms to the fetus and newborn child from certain pharmacologic agents, clinicians are encouraged to consider CBT or other evidence-based counseling interventions when managing depression in pregnant or breastfeeding women.[918]

For adolescents, the USPSTF concluded that:

> [t]reatment options for MDD in children and adolescents include pharmacotherapy, psychotherapy, collaborative care, psychosocial support interventions, and complementary and alternative medicine approaches. Fluoxetine is approved by the FDA for treatment of MDD in children aged 8 years or older, and escitalopram is approved for treatment of MDD in adolescents aged 12 to 17 years. The FDA has issued a boxed warning for antidepressants, recommending that patients of all ages who start antidepressant therapy be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Collaborative care is a multicomponent, health care system–level intervention that uses care managers to link primary care providers, patients, and mental health specialists.[919]

Under the ACA, non-grandfathered health insurance plans must fully cover the costs of recommended preventive services graded "A" or "B" without patient cost sharing (no deductibles, coinsurances or copayments).[920,921] For mental health preventive services, the USPSTF currently gives a grade "B" rating to:

- Screening adults, including pregnant and postpartum women, for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up[922]

- Screening adults 18 years or older for alcohol misuse and providing persons engaged in risky or hazardous drinking with brief behavioral counseling interventions to reduce alcohol misuse[923]
- Screening adolescents (12-18 years of age) for major depressive disorder (MDD) when systems are in place to ensure accurate diagnosis, psychotherapy (cognitive-behavioral or interpersonal), and follow-up[924]

Estimate of the cost of the mandate

The ACA requires coverage for treatment of inpatient and outpatient mental health/substance abuse disorder as an essential health benefit and requires qualified health plans to comply with the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA). The MHPAEA requires parity between coverage for mental health/substance use disorder benefits and medical/surgical benefits.

The state mental health parity mandate explicitly requires coverage for "intermediate services." The MHPAEA categorizes such services as inpatient or outpatient, and this analysis assumes that such an interpretation applies also to the scope of the services required under the ACA, and therefore the ACA requires coverage even for intermediate services, as well as inpatient and outpatient services. Therefore, this analysis assumes the Massachusetts mental health care mandate to be superseded by federal law; the marginal cost of the state mandate is therefore zero.

The estimated RDC PMPM paid claim amount was $16.06, with a total PMPM cost, after administrative loading, of $18.05 (or 4.14 percent of the Commonwealth total premium). Table 39 below displays a summary of these results and related statistics.

Table 39
Mental Health Care Mandate
Required Direct Cost Estimate

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	295,071		
Sample Units	5,752,331		
Sample Average Members	1,871,491		
Paid PMPM	$ 16.06	N/A	N/A
Paid PMPM With Admin	$ 18.05	N/A	N/A
Allowed PMPM	$ 19.09	N/A	N/A

	Required Direct Cost		Upper and Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$455,398,794		$ -
Contribution to Total Annual Premium	$511,684,038		$ -
Percent of Total Premium	4.14%		0.00%

* The requirements of the Massachusetts mandate have been superseded by federal law. Required direct cost was estimated using the Massachusestts APCD.

Off-label Use of Prescription Drugs to Treat Cancer

This mandate requires the Commissioner of Insurance to establish a panel of experts to review off-label uses of prescription drugs for the treatment of cancer for medical appropriateness and to direct insurers to make payments consistent with those recommendations.[925]

Effect of the mandate on health

The off-label use of prescription drugs to treat cancer mandate requires the Commissioner of Insurance to establish a panel of experts to review off-label uses of prescription drugs for the treatment of cancer for medical appropriateness and to direct insurers to make payments consistent with those recommendations.

The Federal Food, Drug and Cosmetics Act of 1938 created the Food & Drug Administration (FDA) in part to control the activities of pharmaceutical and medical device manufacturers in the United States.[926] The act specifically regulates manufacturer's activities, but not physician prescribing practices.[927]

When the FDA approves a drug for market, it also approves its labeling. Labeling is specific to the approved indications for use, dosage, patient population, and method of administration.[928] Physicians, however, are not limited to prescribing the drug according to its label, and may prescribe drugs for "off-label" uses, or those not specifically approved by the FDA. However, manufacturers may not provide information about off-label uses to health care providers or patients, except reprints of peer-reviewed research articles as submitted to the FDA, and only for those products for which the manufacturer is seeking supplemental use approval.[929] Off-label use is not the same as expanded access or special exemption, which are FDA processes allowing patients not eligible for clinical trials access to investigational treatments not yet FDA-approved.[930]

The approval process for drugs can take between eight and twelve years; for every 5,000 to 10,000 compounds that begin the process, only one receives marketing approval.[931] Because of the expense and time needed to obtain FDA-approved use of a drug, off-label prescribing has become "an integral part of contemporary medicine."[932] One study found that 57 percent of new drug uses come from field discovery, and not through clinical trials.[933] Another study, published in 2006, found that 21 percent of prescriptions written in the U.S. were for off-label use.[934] The practice is so widespread that Consumer Reports magazine publishes a guide to off-label prescription drugs,[935] as well as explanations of the risks and benefits of off-label uses.[936] A 2008 survey found that 80 percent of oncologists prescribe off-label treatments, and that 50 percent of chemotherapy treatments are off-label uses.[937]

Off-label use is common in cancer treatment for a variety of reasons. First, certain drugs approved for treatment of specific tumor types are effective against a broader array of tumors. Second, cancer is often treated with drug combinations, including one or more off-label. These combinations change frequently, as evidence gathers about their effectiveness. Third, cancer treatment continues to evolve quickly. Fourth, oncologists often treat terminal patients whose approved treatment options may be exhausted. And finally, oncologists may be more open than are other specialists to experimenting with off-label treatments for their patients.[938]

But this practice is not without significant risks and controversy. Critics stress the risks of drugs where rigorous scientific evidence does not exist for additional applications; such dangers may range from a drug's ineffectiveness to its causing outright harm. Clinical study protocols and the FDA itself were created to protect patients from the harm of unknown outcomes and experimental practices. While the FDA cannot regulate physician prescribing, malpractice suits against practitioners and class action suits against manufacturers have increasingly admitted the court system into this area of medicine, bringing with them the threat of significant financial risk and, more recently, criminal penalties.[939,940] The provider community itself is divided; the same survey of oncologists that revealed widespread off-label prescribing found that "attitudes and practices…vary substantially."[941]

Despite the risks, approved treatment options remain limited for certain patients, leaving doctors to continue to prescribe off-label uses for drugs. However, no widely systematic or transparent method currently exists to collect information on off-label use, and manufacturers are prohibited from distributing any such information they collect. One study found the use of off-label medication to be quite common in outpatient care, with most (73 percent) occurring "without scientific support."[942] Further, "[s]tudies suggest that many physicians rely on experience, anecdotal reports, and opinion leaders to guide their treatment decisions, often failing to demand solid evidence for their prescribing choices."[943] Since the decision to prescribe the off-label drug is a professional judgment, and the mandate is by nature broad, it is inevitable that some uses are efficacious while others are not.

Professional medical societies defend the rights of physicians to prescribe pharmaceuticals for off-label uses, although they differ in the strength of their advocacy. The American Medical Association (AMA) "confirms its strong support for the autonomous clinical decision-making authority of a physician and that a physician may lawfully use an FDA approved drug product or medical device for an unlabeled indication when such use is based upon sound scientific evidence and sound medical opinion," and calls for full reimbursement of such prescriptions as "reasonable and necessary medical care."[944] The American College of Physicians (ACP) states that "physicians should continue to be able to prescribe covered drugs for accepted off-label uses," but "opposes any efforts to weaken FDA authority to demand rigorous evaluations of drugs and medical devices for both safety and effectiveness based on sound scientific and medical evidence and opposes legislative attempts to curtail FDA authority to establish and maintain standards of safety and effectiveness for approval of drugs and medical devices."[945] While these societies leave treatment decisions to physicians, each encourages its members to study available information to determine whether off-label prescribing is in the best interest of the patient.

For anticancer chemotherapeutic regimens, CMS cites three compendia recognized in the Social Security Act as "authoritative sources for use in the determination of a 'medically-accepted indication' of drugs and biologicals used off-label in an anticancer chemotherapeutic regimen."[946] These include the American Medical Association Drug Evaluations (AMA-DE), United States Pharmacopoeia-Drug Information (USP-DI), and the American Hospital Formulary Service-Drug Information (AHFS-DI).[947] Yet a study of these found that while oncologists rely on compendia for off-label indications and reimbursement information, even these "lack transparency, cite little

current evidence, and lack systematic methods to review or update evidence."[948] The ACP states that "[w]hen considering an innovative therapy that has no precedent, the physician should consult with peers, an institutional review board, or other expert group to assess the risks, potential adverse outcomes, potential consequences of foregoing a standard therapy, and whether the innovation is in the patient's best interest."[949]

Reimbursement for off-label prescriptions is inconsistent and complex. Many states, like Massachusetts, mandate coverage for off-label prescriptions for certain types of drugs. Likewise, Medicare Part D only covers payment for drugs with FDA approval, or for uses supported in their approved drug compendia, including DRUGDEX, USP-DI, and AMA-DE.[950] Further, Part B will pay for oral anticancer drugs with the same active ingredients and indications as chemotherapy drugs, even if they have not received FDA approval for that use.[951] However, as the AMA-DE and USP-DI are no longer published, the issue of acceptable compendia has become even more complex.[952]

In response to advocates' calls for expanded access to drugs for additional uses, the FDA has done much in recent years to change its rulings and guidance to enable distribution of therapies which have proven effective, especially in cases in which formal approval has not been applied for or granted. The 2007 FDA Amendments Act made changes that impacted off-label prescribing.[953] First it expands information collected and studied about drugs following approval. The agency now has more authority to monitor safety after approval, and has funding to set up a stronger post-marketing surveillance system as well as an active monitoring system to discover adverse events involving a drug.[954] The agency is empowered to use large clinical databases to determine a drug's safety, including when used off-label, and may now order manufacturers to conduct post-approval studies to identify risks.[955] Second, manufacturers must now register their studies, making the information on off-label use more robust and available to physicians and the public, and further preventing the industry from hiding negative results about their products.[956] And third, the FDA has more power to act when a product appears harmful, including the ability to change labeling to outline harms of certain off-label drug applications.[957] An example is labeling changes to anti-depressants, long prescribed off-label to teenagers and children without FDA approval; studies demonstrated that these drugs may increase suicidal thoughts and tendencies in younger populations, and the FDA recently added this warning to its labels for prescribers and patients. Furthermore, the FDA can limit distribution of certain drugs only to physicians with specialized training.[958] More recently, in 2009, the FDA issued non-binding guidance outlining means by which manufacturers may inform physicians of unapproved uses for approved drugs by distributing articles from independent medical and scientific resources.[959]

Despite these changes, off-label prescribing is still widespread in the practice of medicine. However, most patients are not aware that it happens at all. Physicians are not required to inform a patient that a prescribed treatment is not FDA approved; therefore, patients may not be aware of the treatment's uncertainty and potential risks, nor of the potential additional cost of an off-label treatment that may not be reimbursable. In fact, one poll has shown that half of patients mistakenly think that doctors may only prescribe drugs for FDA approved uses, while another 25 percent are not sure if a drug must be approved to be prescribed, meaning only one-quarter of patients are aware that drugs may be prescribed for unapproved uses. In the same study, almost half state that

doctors should not be able to prescribe off-label uses and 62 percent believe off-label prescribing should be permitted only during an approved clinical trial.[960] However, as the disclosure that a prescribed drug is used off-label is not legally required and is left to the discretion of the treating physician, the American Academy of Pediatrics has concluded, for example, that "discussion about the off-label status of a drug may, as a matter of professional judgment, be part of the information provided to the patient or parents."[961]

Discussion of the cost of the mandate

An estimate of the costs of off-label drug use for cancer treatment would require a large, dedicated research effort, a comprehensive claim database (preferably from Massachusetts), and extensive clinical definition of potential off-label use, associated diagnoses, etc. Even with such an effort, ambiguities would likely remain in the results. Moreover, it was also the opinion of the participating health plans that these costs would be incurred by the plans even without the mandate laws in place (and therefore, the marginal cost of the mandate is zero) because it would be difficult to identify and monitor such prescribing practices. While there was general consensus among the plans about the treatment benefits of using off-label drugs, the cost-effectiveness of such treatments have not been studied comprehensively.

Off-label Use of Prescription Drugs to Treat HIV/AIDS

The general issues arising from the practice of prescribing off-label drugs are outlined in the preceding section on off-label uses of drugs for cancer treatment. This mandate requires coverage for prescription drugs for off-label use in the treatment of HIV/AIDS if the drug is recognized for treatment of such indication in one of the standard reference compendia or in the medical literature.[962]

Effect of the mandate on health

The preceding section on off-label uses of drugs for cancer treatment outlines the general issues arising from prescribing off-label drugs. Off-label prescriptions do not comply with the diagnostic or condition indications, and/or the administration dosage requirements validated as safe and effective by the FDA.[963] Drugs are often used off-label in response to unmet medical needs, the needs of poorly-studied or unstudied populations, or urgent public health needs, when it is reasonable to assume that the drug could effectively treat a given condition.[964] Yet off-label use is complicated by a lack of information regarding safety and effectiveness, appropriate route, use and dosage, as well as complex reimbursement issues, especially in relation to insurance coverage for non-approved pharmaceuticals. This mandate requires coverage for prescription drugs for off-label use in treating HIV/AIDS if the drug is recognized for treatment of such in one of the standard reference compendia or in the medical literature.

Off-label prescribing became standard practice early in the history of the U.S. AIDS crisis. This was especially true in medicine's attempt to stop or limit the spread of opportunistic infections, as approved-use treatments were not available,[965] and a large body of scientific evidence had not yet been developed to specifically treat the disease. Doctors learned in the field, finding new uses for

old drugs with similar application or approved for a different population. These treatment attempts were sometimes the only hope of survival for a dying patient.

The HIV/AIDS crisis, and the lack of effective treatments for the condition and its complications, led directly to significant changes by the FDA to: 1) make experimental drugs more widely available to severely ill patients with life threatening diseases; and 2) speed the review and approval process for these treatments.[966] In 1987, the FDA created expanded access mechanisms that allow patients to use certain investigational drugs outside of a clinical trial because they have no other therapeutic options, as other available treatments have proven ineffective or are not tolerated. These regulations were revised and expanded in 2009.[967] Moreover, the FDA created parallel track mechanisms in 1992 specifically for those with HIV/AIDS who could not participate in controlled clinical trials; only one drug was submitted to the FDA for consideration.[968]

While investigational therapies have thus become more widely available before formal approval, the FDA has, over time, also created procedures and review designations to reduce approval time for therapies, including the:

- AA priority category (1987) giving all applications for potential AIDS therapies the highest priority in the review process
- So-called Subpart E regulations (1988)
- Accelerated approval regulations (1992)
- Priority review policies (1997)
- Fast-track drug development programs (1997)
- Breakthrough therapy programs (2013)[969]

These systems are intended to prioritize and speed review for new drugs and biologics to encourage their development, and to provide incentives to the developers to pursue formal approval.

Thirty-two therapies are now approved to treat complications related to HIV/AIDS since the first was approved in 1981.[970] Antiretroviral drugs used to treat the HIV infection, which may prevent or stall progression to AIDS and minimize its complications, were first approved in 1987; 37 anti-retrovirals have received FDA-approval,[971] including 35 for pediatric use[972] and 33 in generic form.[973]

Given these developments, the availability of more approved treatments, and research regarding their safety and efficacy, it is not known how widely off-label treatments are used for HIV/AIDS, or their effectiveness. Research on off-label use continues to be scarce, as gathering data regarding these applications is challenging,[974] and access to these treatments is often limited through actual supply or because of complex reimbursement issues. One recent long-term study of the use of off-label anti-retroviral drugs for children with HIV/AIDS concluded that off-label use was common, as were "adverse events" related to over- or under-dosing; the study authors highlighted the need for more studies to prevent such mis-dosing which may lead to treatment failure.[975]

Discussion of the cost of the mandate

For reasons similar to those presented above for off-label drug use in cancer treatment it is not feasible to measure costs of off-label prescription drug use for the treatment of HIV/AIDS in Massachusetts. It was the opinion of the participating health plans that these costs would be incurred by the plans even without the mandate laws in place because it would be difficult for the health plans to identify and monitor such prescribing practices, and therefore, the marginal cost of the mandate is estimated to be zero.

Preventive Care for Children to Age Six

The preventive care mandate requires coverage for preventive and primary care services for children up to age six, including physical exams, sensory screening, neuropsychiatric evaluation and developmental screening, hereditary and metabolic screening at birth, appropriate immunizations, blood tests, and urinalysis.[976]

Effect of the mandate on health

Child health has been defined as "the extent to which individual children or groups of children are able or enabled to (1) develop and realize their potential; (2) satisfy their needs; and (3) develop the capacities to allow them to interact successfully with their biological, physical, and social environments."[977] Given this broad definition, pediatric care in America has evolved over time, changing its focus from the prevention and treatment of illness and infection to a focus on prevention and the promotion of healthy physical, cognitive, social, and emotional development,[978] as well as the family's capacity and functioning.[979]

As care changed, criticism arose as to the inconsistency of the content and quality of well-child care, as well as a lack of research proving the effectiveness of each of its elements.[980,981] Minority children,[982] children receiving Medicaid,[983] and children without special health care needs[984] were shown to receive less adequate care than comparison groups. In response to such observations, researchers began to review the content and quality of well-child care as well as the methods by which it is studied; at present, much of pediatric medicine is considered to be "evidence-informed, rather than fully evidence-driven."[985]

Disease detection, disease prevention, health promotion, and anticipatory guidance are now advocated as part of the American Academy of Pediatrics (AAP)/Bright Futures model. The Bright Futures program began in 1990 to "to improve the quality of health services for children through health promotion and disease prevention;"[986] and has developed a robust set of recommendations for providing well-child care, including a newly-revised periodicity schedule that provides evidence of the effectiveness of each recommendation and intervention.[987] This model, and its periodicity schedule of preventive services, was formally incorporated into the federal ACA in 2010. The law requires that all children enrolled in all individual and group non-grandfathered health care plans are covered without cost-sharing for all routine immunizations recommended by the CDC Advisory Committee on Immunization Practices (ACIP),[988] and all evidence-informed preventive care screening and services recommended in the comprehensive guidelines supported by the Health

Resources and Services Administration (HRSA).[989,990] This latter category includes a schedule of services outlined in the Bright Futures Guidelines for Health Supervision of Infants, Children, and Adolescents,[991,992] and the Recommendations of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, including its Uniform Screening Panel.[993] The rationale and evidence for the various elements of the American Academy of Pediatrics Bright Futures Guidelines and the Uniform Screening Panel is summarized in Chapter 13 of the Bright Futures publication.[994]

Discussion of the cost of the mandate

The preventive care mandate requires coverage for preventive and primary care services for children up to age six, including physical exams, sensory screening, neuropsychiatric evaluation and developmental screening, hereditary and metabolic screening at birth, appropriate immunizations, blood tests, and urinalysis.

Under Section 2713 of the ACA, commercial insurance plans must provide coverage for a range of preventive services without imposing cost-sharing requirements (such as copayments, deductibles, or co-insurance). For infants, children, and adolescents, these services include evidenced-informed preventive care and screenings recommended by the Health Resources and Services Administration and outlined in the Bright Futures Guidelines. These preventive health services apply to all commercial plans (individual, small group, large group, and self-insured plans), unlike other essential health benefits (EHBs) that apply only to individual and small group plans.[995]

To calculate the effect of the preventive care mandate on commercial insurance costs in Massachusetts, Compass reviewed a 2005 study that examined components of preventive care for both "not-at-risk" and "at-risk" children. Multiplying each average preventive service cost by an estimated 42,000 children and summing the product results in an estimate of $106 million, or $2.95 PMPM. These costs do not include neuropsychiatric evaluations, as they were not included in the cited cost study. However, the costs do include newborn hearing screening, costs for which were estimated in the "Newborn Hearing Screening" section above. Lacking more specific data, Compass assumes that the costs for hearing screening and neuropsychiatric evaluations are approximately equal, and that any difference is within the range of estimation error for the preventive care mandate as a whole.

Based on this assumption, Compass trended the 2005 estimate forward to 2014 using NHE physician and clinical expense private insurer expense data[996] to obtain a 2014 estimated PMPM paid claim amount for preventive care for children under age 6 of $4.31 PMPM ($122.1 million), or a $4.84 total cost PMPM amount ($137.2 million) and a 1.11 percent of total Commonwealth premium calculation with 11 percent administrative loading. These results are summarized in Table 40 below.

Table 40
Preventive Care for Children to Age Six Mandate
Required Direct Cost Estimate

Measures	Sample FI Amount	Sample SI Amount	FI-SI Allowed & Lower Bound PMPMs
Sample Users	N/A		
Sample Units	N/A		
Sample Average Members	N/A		
Paid PMPM	$ 4.31	N/A	N/A
Paid PMPM With Admin	$ 4.84	N/A	N/A
Allowed PMPM	N/A	N/A	N/A

	Required Direct Cost		Upper and Lower Bound Impact*
Insured Population	2,362,745		2,362,745
Contribution to Total Annual Claims	$122,141,048		$ -
Contribution to Total Annual Premium	$137,237,132		$ -
Percent of Total Premium	1.11%		0.00%

* This mandate was judged by carriers to contribute $0 marginal cost to premiums.
Required direct cost was estimated using secondary data sources.

Summary of Mandate Cost Estimates

Table 41 below displays a summary of the cost estimates for all 39 mandates, including those estimated using secondary data sources. The first column displays total required direct costs, or RDCs,[xxxii] which measure the claim costs for services described in the mandate laws, and so include both costs for services that would be provided voluntarily in the absence of the mandates and incremental costs resulting from the mandates, and are estimated to be $1.9 billion after elimination of overlaps in cost between mandates, and $2.1 billion with administrative costs. This estimate is not a measure of the impact of the mandates, as it includes the portion of the costs that would be provided voluntarily in the absence of the mandate laws.

The lower bound marginal claims estimate of $46.9 million in the second column represents the marginal impact of the mandates on claims spending calculated from per person mandated benefit allowed expense[xxxiii] differences between the fully-insured population subject to the mandates, and the self-insured population not subject to the mandates.[xxxiv] This difference represents $1.66 PMPM, or 0.43 percent of premium, meaning that the additional medical claim spending on mandated services in plans subject to the mandates compared to those plans not subject to the mandates represents approximately one half of one percent of premium.

[xxxii] Required Direct Costs, defined in the report introduction and Appendix B.
[xxxiii] Allowed Amount = Insurer Paid Amount + Member Cost Sharing Amounts
[xxxiv] Note that the zero marginal cost mandates have been treated as having zero marginal cost, and that a number of the mandates with potential marginal cost were measured to have zero marginal cost relative to self-insured plan spending.

To measure the mandates' full impact, insurer administrative costs need to be added. In the next two columns of Table 41 the lower bound estimate of $46.9 million becomes $52.7 million with administration, and the upper bound estimate becomes $796.8 million after removing zero marginal cost mandates and adding administrative expense.

The range of the marginal direct cost impact of all 39 mandate laws studied, including administrative costs, is therefore between $52.7 million and $796.8 million. The true value is not likely to be near either end of this range. The upper end of the range includes all RDCs except those for mandates judged by the carriers likely to have zero marginal costs, and includes an additional provision for carrier administrative costs. This upper bound estimate assumes that 100 percent of the RDC for mandates with potential marginal direct cost is marginal, and that carriers would pay zero dollars in claims for the services described by the mandates in the absence of the mandate laws.

The lower end of the range subtracts from the RDCs the dollars implied by the per person spending rate in the self-insured market, which is not subject to the mandate laws. This estimate assumes that 100 percent of the spending for the mandates with potential marginal direct cost in the self-insured market would occur in the absence of the mandate laws, and that none of the spending is influenced by the mandated spending levels in the fully-insured market.

The range of estimates is associated with between 0.43 percent of premium for the low-end estimate and 6.45 percent for the high-end estimate. The estimated range does not consider indirect costs, which, as noted above, previous research finds will increase costs for some mandates and offset costs for others.

The two most expensive mandates in the potential marginal direct cost group are home health care services ($0 to $289 million gross of mandate overlaps) and diabetes-related services and supplies ($0 to $197.5 million gross of mandate overlaps). Both are provided in the self-insured market at the same or higher levels than they are provided in the fully-insured market, suggesting that these benefits are cost-effective, popular with employees, or both. Combined, and with overlaps removed, these two mandates have a low-end estimate of 0 percent of premium and a high-end estimate of 3.8 percent of premium.

Table 41
Summary of Estimated Costs for Massachusetts Mandated Benefits as of 2014
Dollars in Millions (000,000s)

	Required Direct Cost Claims Estimate	Lower Bound Marginal Claims Estimate	Lower Bound Estimate with Admin Exp	Upper Bound Estimate with Admin Exp	Lower Bound Percent of Premium	Upper Bound Percent of Premium
Unduplicated Total All Mandates	$ 1,912.96	$ 46.94	$ 52.74	$ 796.81	0.43%	6.45%
Mandates with Potential Marginal Direct Cost						
Service Mandates						
Autism Spectrum Disorders Services	$ 39.54	$ 15.25	$ 17.13	$ 44.42	0.14%	0.36%
Chiropractic Services	$ 2.68	$ 0.94	$ 1.06	$ 3.01	0.01%	0.02%
Child Hearing Aids	$ 6.89	$ -	$ -	$ 7.74	0.00%	0.06%
Cleft Palate and Lip	$ 3.30	$ 0.10	$ 0.12	$ 3.70	0.00%	0.03%
Diabetes-related Services and Supplies	$ 175.79	$ -	$ -	$ 197.52	0.00%	1.60%
Early Intervention Services	$ 25.72	$ 2.78	$ 3.12	$ 28.90	0.03%	0.23%
Home Health Care	$ 257.25	$ -	$ -	$ 289.04	0.00%	2.34%
Hormone Replacement Therapy (HRT)	$ 11.56	$ 0.74	$ 0.83	$ 12.99	0.01%	0.11%
Human Leukocyte Antigen Testing	$ 0.02	$ -	$ -	$ 0.02	0.00%	0.00%
Hypodermic Syringes or Needles	$ 1.08	$ -	$ -	$ 1.22	0.00%	0.01%
Infertility Treatment	$ 104.73	$ 12.67	$ 14.24	$ 117.67	0.12%	0.95%
Low Protein Food Products for Inherited Amino Acid and Organic Acid Diseases (PKU)	$ 1.53	$ 0.08	$ 0.09	$ 1.71	0.00%	0.01%
Nonprescription Enteral Formulas	$ 0.92	$ -	$ -	$ 1.04	0.00%	0.01%
Oral Cancer Drugs	$ 1.38	$ 0.49	$ 0.55	$ 1.55	0.00%	0.01%
Prosthetic Limbs and Associated Services	$ 3.87	$ -	$ -	$ 4.35	0.00%	0.04%
Scalp Hair Prostheses for Cancer Patients	$ 0.41	$ -	$ -	$ 0.46	0.00%	0.00%
Speech, Hearing and Language Disorders	$ 7.12	$ -	$ -	$ 8.00	0.00%	0.06%
Provider Mandates						
Certified Nurse Midwives	$ 1.62	$ -	$ -	$ 1.83	0.00%	0.01%
Certified Registered Nurse Anesthetists	$ 22.09	$ -	$ -	$ 24.83	0.00%	0.20%
Chiropractors	$ 7.97	$ 0.81	$ 0.91	$ 8.96	0.01%	0.07%
Dentists	$ 1.39	$ -	$ -	$ 1.56	0.00%	0.01%
Nurse Practitioners	$ 44.63	$ 9.31	$ 10.46	$ 50.15	0.08%	0.41%
Optometrists	$ 6.23	$ -	$ -	$ 7.00	0.00%	0.06%
Physician Assistants	$ 41.01	$ 2.01	$ 2.26	$ 46.07	0.02%	0.37%
Podiatrists	$ 16.38	$ 0.81	$ 0.91	$ 18.41	0.01%	0.15%
Mandates Judged to Have Zero Marginal Cost						
Bone Marrow Transplants for Treatment of Breast Cancer	$ -	$ -	$ -	$ -	0.00%	0.00%
Cardiac Rehabilitation	$ 2.28	$ -	$ -	$ -	0.00%	0.00%
Clinical Trials (to treat cancer)	$ 2.28	$ -	$ -	$ -	0.00%	0.00%
Contraceptive Services	$ 94.20	$ -	$ -	$ -	0.00%	0.00%
Cytologic Screening	$ 17.54	$ -	$ -	$ -	0.00%	0.00%
Hearing Screening for Newborns	$ 3.32	$ -	$ -	$ -	0.00%	0.00%
Hospice Care	$ 16.49	$ -	$ -	$ -	0.00%	0.00%
Lead Poisoning Screening	$ 1.20	$ -	$ -	$ -	0.00%	0.00%
Mammography	$ 17.69	$ -	$ -	$ -	0.00%	0.00%
Maternity Health Care (including minimum maternity stay)	$ 471.27	$ -	$ -	$ -	0.00%	0.00%
Mental Health Care	$ 455.40	$ -	$ -	$ -	0.00%	0.00%
Preventive Care for Children Up to Age Six	$ 122.14	$ -	$ -	$ -	0.00%	0.00%
Off-Label Uses of Prescription Drugs to Treat Cancer	$ -	$ -	$ -	$ -	0.00%	0.00%
Off-Label Uses of Prescription Drugs to Treat HIV/AIDS	$ -	$ -	$ -	$ -	0.00%	0.00%

We note that, owing in part to general cost inflation but in large part to an expansion of the service codes that carriers have provided as services covered under the mandates, the RDCs in the current study at $1.9 billion are far higher than the $1.2 billion in the 2012 study. However, relative to the 2012 results these additional RDCs had a minimal effect on the upper bound estimate because the mental health and contraceptive services coverage are now required by federal law. They also had a minimal impact on the lower bound estimate since self-insured plans also tend to cover both contraceptive services and mental health at or near the levels provided by fully-insured plans, and also cover many of the additional service codes in the carriers' expanded lists.

Discussion and Conclusions

The explicit empirical results of the study produce a wide range of potential impacts of mandated benefits on health insurance direct costs in the fully-insured market. At one extreme, summing the costs of all the benefits described in the 39 mandates in total represented in 2014 approximately $2.1 billion in required direct costs, including administrative costs, or 17.4 percent of the average fully-insured commercial premium in the Commonwealth. Removing the cost of those benefits that carriers say they would provide even without the mandate laws, the total is $796.8 million or 6.45 percent of premium. At the other extreme, the difference in allowed expense per-person between fully-insured and self-insured employers implies a direct cost impact of only $52.7 million, or 0.43 percent of premium. Table 42 displays this impact range in percent of premium, PMPM, and total implied spending in the fully-insured market. Examining the assumptions required to use either of these numbers as an impact estimate makes it clear that the direct cost impact is neither as low as $52.7 million nor as high as $796.8 million.

Table 42
Cost Implications of Impact Assumptions

Percent of Premium	PMPM	Dollars (millions)
0.5%	$ 2.18	$ 61.81
1.0%	$ 4.36	$ 123.62
2.0%	$ 8.72	$ 247.24
3.0%	$ 13.08	$ 370.85
4.0%	$ 17.44	$ 494.47
5.0%	$ 21.80	$ 618.09
6.0%	$ 26.16	$ 741.71
6.5%	$ 28.34	$ 803.52

The $796.8 million estimate is far too high as a measure of direct costs. This estimate requires us to assume that all mandated benefits would be dropped completely by all insurers in Massachusetts if the laws were repealed. No fully-insured policies would include any of the mandated benefits, including home health care, diabetes services and supplies, nurse practitioner services, or any of the other mandates. If instead, after mandates were hypothetically repealed, some of these benefits were offered and purchased, then the impact estimate of $796.8 million is too large by the amount of voluntarily offered benefits, since not all of that spending would have been compelled by the state mandate laws. Many of the larger-dollar benefits are offered, perhaps at lower levels, in states without mandate laws, either voluntarily or as a result of federal mandates. Home health, a benefit not likely to be eliminated, accounts for $289 million of the total, and many other benefits such as nurse practitioners, CRNAs, and diabetes-related services would be unlikely to disappear from benefit packages. Without being able to analytically arrive at an alternative, it would seem that $796.8 million is hundreds of millions of dollars too high as an impact estimate.

The $52.7 million estimate implied by the allowed expense difference between fully-insured and self-insured plans requires us to assume that the presence of the mandate laws places no upward

pressure on the benefits offered by self-insured firms. However, the need for self-insured firms to not disadvantage themselves in the labor market in the presence of the fully-insured firms with mandated benefit coverage seems certain to influence benefit levels. The magnitude of any such effect would increase the impact estimate above $52.7 million, and would vary by mandate. Certain highly-visible and expensive benefits such as infertility treatment ($117.7 million) would seem most subject to upward pressure of the labor market. On the other hand, for many of the mandates in Table 41, the per-person allowed costs are actually higher in the self-insured market than in the fully-insured market (those with a zero lower-bound), suggesting no upward pressure induced by the fully-insured market.

Applying both these lines of reasoning to narrow the range displayed in Table 42, it seems likely that the direct cost impact of the mandates is somewhere between one percent and four percent of total premium.

In addition to the direct cost impacts, there are indirect cost effects on other service categories not directly affected by the mandate that Compass is not able to address in this study. Some of these indirect costs may increase overall costs, such as additional births resulting from fertility treatment, while others would reduce costs, such as hospitalizations avoided as result of diabetes coverage. To the extent that mandates induce utilization increases within the services addressed by a mandate, such costs are covered in both the RDC upper bound estimates and the lower bound estimates. About 75 percent of the total estimated direct cost stems from three of the mandates: home health, diabetes services and supplies, and infertility; nearly an additional 20 percent is comprised by the provider mandates. Consideration of these eleven mandates and their likely indirect cost effects would provide most of the required information on how the direct costs might be increased or reduced by indirect cost effects. It is possible that after consideration of indirect cost effects, the net impact of these eleven mandates is cost reducing, though we cannot estimate that impact in this study. Finally, there are individual and socially beneficial impacts aside from health care spending that these mandates may, and in many cases certainly do, provide. Benefit mandates are often enacted when such beneficial effects are widely perceived but something short of government provision of the benefit is the balance point of the political process.[997]

Appendices

Appendix A: Summary of Health Insurance Benefit Mandates

Appendix B: Methodology of Cost Estimation

Appendix C: Estimation of Population Subsets

Appendix D: Cost by Type of Service for Mandates with Potential Marginal Direct Cost

Appendix E: List of Study Acronyms

Appendix A: Summary of Health Insurance Benefit Mandates

Service mandates

Mandate	Statute	Summary	In 2012 Report
Autism	c.175 §47AA; c.176A §8DD; c.176B §4DD; c.176G §4V; c.32A §25	Mandates coverage for treatment for autism spectrum disorder, on a "non-discriminatory basis," meaning on the same terms as coverage for physical conditions. The mandate includes in the treatment of ASDs: habilitative or rehabilitative care, pharmacy care, psychiatric care, psychological care, therapeutic care, some of which are covered by the mental health services mandate. The primary net effect is to mandate coverage for medically necessary habilitative care, i.e., "professional, counseling, and guidance services and treatment programs, including applied behavior analysis supervised by a Board Certified Behavior Analyst."	Yes
Bone marrow transplants for treatment of breast cancer	c.175 §47R; c.176A §8O; c.176B §4O; c.176G §4F; c.32A §17D	Provides coverage for bone marrow transplants for breast cancer patients who've progressed to metastatic disease if they meet criteria provided by DPH.	Yes
Cardiac rehabilitation	c.175 §47D; c.176A §8G; c.176B §4F; c.176G §4	Covers the expense of cardiac rehabilitation, i.e., multidisciplinary, medically necessary treatment of persons with documented cardiovascular disease.	Yes
Chiropractic services	c.176B §4L	Covers expenses of chiropractic services. Applies to medical service corporations only.	Yes
Cleft palate and cleft lip	c.175 §47BB; c.176A §8EE; c.176G §4W; c.32 §17J	Requires coverage for the cost of treating cleft lip and cleft palate for the child, including medical, dental, oral and facial surgery, surgical management and follow-up care by oral and plastic surgeons, orthodontic treatment and management, preventive and restorative dentistry to ensure good health and adequate dental structures for orthodontic treatment or prosthetic management therapy, speech therapy, audiology, and nutrition services.	No (enacted 2013)
Clinical trials (to treat cancer)	c.175 §110L; c.176A §8X; c.176B §4X; c.176G §4P	Mandates coverage for patient care services for patients enrolled in a qualified clinical trial to the same extent as the services would be covered if the patient was not receiving care in a qualified clinical trial. A qualified clinical trial must be cancer-related and must meet other criteria set forth in the law.	Yes
Contraceptive services	c.175 §47W; c.176A §8W; c.176B §4W; c.176G §4O	Requires coverage for outpatient contraceptive services and prescription contraceptive drugs and devices. Provides exclusions for church-affiliated employers.	Yes

Mandate	Statute	Summary	In 2012 Report
Cytological screening	c.175 §§47G and 110(L); c.176A §8J; c.176G §4	Mandates coverage for cytological screening (Pap smear) annually for women 18 years and older.	Yes
Diabetes-related services and supplies	c.175 §47N; c.176A §8P; c.176B §4S; c.176G §4H; c.32A §17G	Mandates coverage for items medically necessary for diabetics that fall within a category of benefits and services for which coverage is otherwise afforded and that have been prescribed by a healthcare professional: includes blood glucose monitors, monitoring strips, lancets, insulin, syringes, lab tests, urine & lipid profiles, special shoes, etc.	Yes
Early Intervention services	c.175 §47C; c.176A §8B; c.176B §4C; c.176G §4	Mandates coverage for early intervention services from birth to age 3 for children with or at risk for specific developmental delays including chromosomal abnormality, neurological condition, metabolic disorder, visual impairments, permanent hearing loss, and delayed cognitive, physical, communicative, social, or emotional development.	Yes
Hearing aids for children	c.175 §47X; c.176A §8Y; c.176B §4EE; c.176G §4N; c.32 §23	Mandates coverage for any child, 21 years of age or younger for the cost of 1 hearing aid per hearing-impaired ear up to $2,000 for each hearing aid every 36 months. Coverage includes all related services prescribed by a licensed audiologist or hearing instrument specialist, including the initial evaluation, fitting and adjustments, and supplies, including ear molds.	No (enacted 2013)
Hearing screening for newborns	c.175 §47C (c.111 §67F); c.176A §8B; c.176B §4C (c.111 §67F); c.176G §§4, 4K (c.111 §67F); c.32A §17F	Mandates coverage for newborn hearing screening tests.	Yes
Home health care	c.175 §110(K); c.176A §8I; c.176G §4C	Mandates coverage for home care services: services provided by a home health agency in a patient's residence.	Yes
Hormone replacement therapy	c.175 §47W; c.176A §8W; c.176B §4W; c.176G §4O	Requires policies providing outpatient services to provide hormone replacement therapy for peri- and post-menopausal women.	Yes
Hospice care	c.175 §47S; c.176A §8R; c.176B §4Q; c.176G §4L; c.32A §17B	Mandates coverage for licensed hospice services to terminally ill patients with a life expectancy of six months or less.	Yes
Human leukocyte antigen testing	c.175 §47V; c.176A §8V; c.176B §4V; c.176G §4Q; c.32A §17H	Mandates coverage for the cost of human leukocyte antigen testing or histocompatibility locus antigen testing necessary to establish bone marrow transplant donor suitability.	Yes

Mandate	Statute	Summary	In 2012 Report
Hypodermic syringes or needles	c.175 §47Y; c.176A §8CC; c.176B §4CC; c.176G §4U	Mandates coverage for medically necessary hypodermic syringes or needles.	Yes
Infertility treatment	c.175 §47H; c.176A §8K; c.176B §4J; c.176G §4	Requires policies including pregnancy-related benefits to provide, to the same extent benefits are provided for other pregnancy-related procedures, coverage for medically necessary expenses of diagnosis and treatment of infertility.	Yes
Lead poisoning screening	c.175 §47C; c.176A §8B; c.176B §4C; c.176G §4	Mandates coverage for screening for lead poisoning for all children under age six and others deemed at risk.	Yes
Low protein food products	According to DOI c.175 §47I; c.176A §8L; c.176B §4K; c.176G §4D But possibly c.175 §47C; c.176A §8B; c.176B §4C; c.176G §4	Mandates coverage for low protein food products required to treat infants and children with specified metabolic disorders (for inherited amino acid and organic acid diseases) as well as fetuses of pregnant women with PKU.	Yes
Mammography	c.175 §§47G and 110(L); c.176A §8J; c.176G §4	Mandates coverage for one "baseline" mammogram between ages 35 and 40, and annual measurements thereafter.	Yes
Maternity health care (including minimum maternity stay)	c.175 §47F; c.176A §8H; c.176B §4H; c.176G §§4, 4I; c.32A §17C	Benefits providing for "expense of prenatal care, childbirth and post partum care to the same extent as provided for medical conditions not related to pregnancy" with "minimum 48 hours of in-patient care following a vaginal delivery and a minimum of 96 hours of inpatient care following a caesarean section."	Yes
Mental health care	c.175 §47B; c.176A §8A; c.176B §4A; c.176G §4M; c.32A §22	Requires coverage for the diagnosis and treatment of specified biologically-based mental disorders including schizophrenia, bipolar disorder, obsessive-compulsive disorder, affective disorders, eating disorders, PTSD, and autism, and any biologically-based disorders recognized by the Commissioner of the Department of Mental Health.	Yes
Nonprescription enteral formulas	c.175 §47I; c.176A §8L; c.176B §4K; c.176G §4D; c.32A §17A	Mandates coverage for nonprescription enteral formulas for home use when medically necessary to treat malabsorption caused by Crohn's disease, ulcerative colitis, gastroesophageal reflux, gastrointestinal motility, chronic intestinal pseudo-obstruction, and inherited diseases of amino acids and organic acids, in an amount not to exceed $2,500 annually.	Yes
Off-label uses of prescription drugs to treat cancer	c.175 §§47K, 47L; c.176A §8N; c.176B §4N; c.176G §4E	Requires the Commissioner of Insurance to establish a panel of experts to review off-label uses of prescription drugs for the treatment of cancer for medical appropriateness and to direct insurers to make payments consistent with those recommendations.	Yes

Mandate	Statute	Summary	In 2012 Report
Off-label uses of prescription drugs to treat HIV/AIDS	c.175 §§47O, 47P; c.176A §8Q; c.176B §4P; c.176G §4G	Mandates coverage for prescription drugs for off-label use in the treatment of HIV/AIDS if the drug is recognized for treatment of such indication in one of the standard reference compendia or in the medical literature.	Yes
Oral chemotherapy	c.175 §47DD; c.176A §8FF; c.176B §4FF; c.176G §4X; c.32 §17K	Mandates medical expense coverage for cancer chemotherapy treatment for prescribed, orally-administered anticancer medications used to kill or slow the growth of cancerous cells on a basis not less favorable than intravenously administered or injected cancer medications that are covered as medical benefits.	No (enacted 2013)
Preventive care for children to age six	c.175 §47C; c.176A §8B; c.176B §4C; c.176G §4	Mandates coverage for preventive and primary care services for children up to age six, including physical exams, sensory screening, neuropsychiatric evaluation and developmental screening, hereditary and metabolic screening at birth, appropriate immunizations, blood tests, and urinalysis.	Yes
Prosthetic Devices	c.175 §47Z; c.176A §8AA; c.176B §4AA; c.176G §4S; c.32A §17I	Requires coverage for prosthetic devices and repairs under the same terms and conditions that apply to other durable medical equipment covered under the policy; however the mandate places restrictions on the use of annual or lifetime limits for prosthetic devices.	Yes
Scalp hair prostheses for cancer patients	c.175 §47T; c.176A §8T; c.176B §4R; c.176G §4J; c.32A §17E	Requires policies providing coverage for any other prosthesis to provide coverage for scalp hair prostheses worn for hair loss suffered as a result of the treatment of cancer or leukemia, in an amount not to exceed $350 per year.	Yes
Speech and audiology services	c.175 §47X; c.176A §8Y; c.176B §4Y; c.176G §4N; c.32A §23	Mandates coverage for expenses incurred in the medically necessary diagnosis and treatment of speech, hearing and language disorders by individuals licensed as speech-language pathologists or audiologists.	Yes

Provider-centered mandates

Mandate	Statute*	Summary	In 2012 Report
Certified Nurse Midwives	c.175 §47E; c.176B §4G; also c.176B §7	Mandates benefits for services of midwives when services are reimbursed when performed by any other practitioner and are within the lawful scope of practice of midwives. (Not in HMO or HSC statutes.) Also, c. 176B § 7 provides no MSC shall "discriminate in any way against participating nurse midwives in the furnishing of midwifery service." This is redundant to § 4G.	Yes
Certified Registered Nurse Anesthetists	c.175 §47Q; c.176A §8S; c.176B §4T; c.176G §4	Mandates benefits for services of nurse anesthetists when services are reimbursed when performed by any other practitioner and are within the lawful scope of practice of nurse anesthetists.	Yes
Nurse Practitioners	c.175 §47Q; c.176A §8S; c.176B §4T; c.176G §4; also c.176R	Statute sections affecting various forms of insurance, plus c. 176R, require all forms of insurance (and GIC under c. 176R) to cover services of nurse practitioners (NPs) when services are reimbursed when performed by any other practitioner and are within the lawful scope of practice of NPs. c. 176R allows NPs to serve as PCPs and prohibits NPs from being subject to smaller coverage limits.	Yes
Chiropractors	c.175 §108D; c.176B §7 see also “chiropractic services” (c.176B §4L)	c. 175 § 108D requires a payer to pay for chiropractic services whether they are performed by a physician or chiropractor, and c. 176B § 7 statute prohibits an MSC from "discriminating" against chiropractors in providing chiropractic services. (Not in HSC or HMO statutes.) This mandate is technically different from the chiropractic services mandate, but analysis of this mandate will probably overlap with it.	Yes
Dentists	c.175 §108B	The insurance statute requires a dentist to be considered a physician for purposes of paying for any oral surgical care, services, or benefits covered by the policy/contract which dentists are licensed to perform. (The insurance statute might reach MSCs. Not in HSC or HMO statutes.)	Yes
Optometrists	c.175 §108(8)(D); c.175 §110(F)	Requires coverage for services of optometrists when services are reimbursed when performed by physicians or optometrists and are within the lawful scope of practice of optometrists. (Not in HSC, MSC, or HMO statutes.)	Yes
Podiatrists	c.175 §110(I); c.176G §1 (See “nondiscriminatory”)	Requires coverage for services of podiatrists when services are reimbursed when performed by physicians or podiatrists and are within the lawful scope of practice of podiatrists. (Not in HSC or MSC statute.)	Yes

* Note that many provider-centered mandates, unlike the typical service-centered mandate, are not uniform across the standard forms of health care insurance license (general insurance company, medical and hospital service corporation, HMO).

Appendix B: Methodology of Cost Estimation

Definition of population and costs measured

This study estimates the calendar year 2014 costs to the Massachusetts health care system of state mandates in force during that year. This study estimates health care costs only for that portion of the Massachusetts population with health insurance subject to health benefit mandate laws, which is composed of two segments. First, all of the mandates in the study apply to those with coverage in fully-insured commercial products regulated by the Massachusetts Division of Insurance. Second, a subset of the mandates in this study also applies to coverage for public employees provided under the Group Insurance Commission (GIC). The great majority of the GIC coverage is provided on a self-insured basis, with the remainder included among the fully insured plans subject to all the mandates. However, self-insured GIC plans voluntarily follow all benefit mandates. The fully-insured and GIC segment of the commercial insurance market comprised approximately 49.1 percent of the 4.8 million member under-65 commercial market in 2014, with the other 50.9 percent provided by self-insured employers not subject to state benefit mandates (other than the approximately 261,400 under-65 members of self-insured GIC plans). A more detailed discussion of the study population is contained below.

Costs associated with mandated benefits are a relatively small subset of the total health care costs for the affected population; to begin to address by how much mandate laws impact total costs it will be helpful to define terminology for the purpose of this report. The general cost concepts defined below will aid in interpreting the results of the study. In practice these cost sub-categories are difficult to measure, and no precise measurement of these cost breakouts can be achieved within the scope of this project, although conceptual definition will aid in interpreting the results of the analysis. There are two general types of costs that may be associated with any mandate:

- **Required direct costs**. These are the costs of services that are explicitly described in a mandate law, used by covered members and paid for by the regulated insurance plans, whether or not some or all of the costs would have been incurred in the absence of the mandate through voluntary provision of the benefits. These costs are the primary focus of this study, and are the most easily measurable. Required direct costs (RDCs) are the sum of *base direct costs* and *marginal direct costs.*
    - *Base direct costs* (BDCs) are those costs that would be present even if the mandate law were not in force. Mandate laws may require benefits that would be provided, wholly or in part, voluntarily (by some or all of the market) or that are required by another mandate law (state or federal).
    - *Marginal direct costs* (MDCs) are those additional costs beyond the base direct costs that the imposition of the mandate impels.
- **Indirect costs.** Indirect costs are those costs that may be added as a result of the related delivered services associated with the mandate (e.g., costs of additional complicated births associated with infertility treatment) or those service costs avoided (these would be "negative costs" or cost offsets) as a result of the mandate (e.g., fewer

emergency department visits for diabetics due to coverage for diabetes services and supplies).

While we can measure RDCs reasonably, measuring their breakdown into base and marginal direct costs is far more difficult, and measuring indirect costs even more difficult. As a hypothetical example of the distinction between base and marginal direct costs, if a mandate law requiring coverage of an annual EKG were passed, additional (marginal) direct costs for this service would likely result, but significant dollars are already being covered under existing policies (base direct costs) for this service. Measurement of the RDC for this mandate after passage of the law could be calculated as the number of persons receiving the test once or more per year, times the average cost per test. The resulting RDC would contain a mix of base and marginal RDC, since a large portion of the cost was already being incurred voluntarily (i.e., a large number of covered EKG tests would have been paid for by carriers anyway). Any indirect effects, such as increased interventional cardiology costs or avoided heart attack admissions, would be difficult to quantify directly.

To measure the true cost impact of a mandate law on the regulated insurance product premiums, one would need to include only marginal costs, which would consist of marginal direct costs and marginal indirect costs (those indirect costs associated with the marginal utilization produced by the mandate law). Since marginal indirect costs may be either positive or negative, the net impact of any one mandated benefit on total costs may be either increasing or decreasing, depending on:

- How much of the direct cost associated with the mandate is marginal (i.e., attributable to the imposition of the mandate)
- Whether indirect costs are positive or negative on net
- The size of those indirect costs relative to the direct costs

While not within the scope of this study, a well-conducted multi-variate statistical analysis using multi-state data would be better able to estimate marginal costs that include both direct and indirect components. Some multivariate econometric studies comparing benefit mandates and cost levels across states have shown that some specific mandated benefits decrease costs on net, while others increase costs on net.[998]

This study provides some information that may be useful in understanding the proportion of the required direct costs that are likely to be marginal for the mandates. The scope of this study does not attempt to measure precisely the amount of RDC that is marginal (which would require multi-state data), and the report does not include evaluation of indirect costs. As a result, it is not possible to ascertain from the information in this study the net impact on health care costs in the Commonwealth associated with the mandate laws, but previous research suggests that total RDCs will greatly overstate the net effect of the mandates, that offsetting indirect cost savings can be larger than direct cost effects (making the net effect of a mandate cost decreasing), and that the impact of mandate laws on insurance premium levels will not be directly inferable from the RDC estimates contained herein.[999]

This report does, however, present a comparison of the fully-insured and self-insured GIC population RDCs to the RDCs observed in the Massachusetts' non-GIC self-insured sector not subject to the mandate laws, the difference between which provides one estimate of the direct marginal differences (that is, net direct cost impact) introduced by the mandate legislation. Previous research has found that benefit levels, including mandated benefits, are similar, if not richer, in the self-insured market.[1000] Mandate laws may have small effects if firms offer the benefits voluntarily. However, in that employers in Massachusetts that self-insure must compete in the labor market with fully-insured firms that must offer the mandated benefit package and public-sector employers offering GIC plans that voluntarily include all mandated health insurance benefits (even when the text of the mandate laws does not reach the self-insured GIC), the benefits in the non-GIC self-insured firms are likely to be at least somewhat richer than they would be in the absence of the mandate laws. This competitive labor market effect would shrink the cost difference between fully-insured and self-insured GIC plans and non-GIC self-insured plans and understate (or provide a lower bound for) the implied impact of benefit laws on health care costs provided by the difference between fully-insured and self-insured GIC costs and non-GIC self-insured costs.

The measurement of costs in this study was carried out in one of two ways for each of the mandated benefit laws currently in effect in Massachusetts, summarized above in Appendix A.[i] The exhibit displays 39 mandated benefit laws, and describes in summary fashion the requirements of the mandate. The next section describes in detail the two approaches used for measurement.

Methodology and data sources

Project organization and study design

In initial project discussions with CHIA, it was decided that major health insurance carriers in Massachusetts would be approached to provide input about the specifications for measuring the cost of each mandate. The following nine carriers provided input on the mandates:

- Blue Cross Blue Shield of Massachusetts
- Fallon Community Health Plan
- Harvard Pilgrim Health Care
- Health New England
- Minuteman Health, Inc.
- Neighborhood Health Plan
- Tufts Health Plan
- UniCare
- UnitedHealthcare Insurance Company

Government relations staff at each carrier served as contact points, and in turn consulted their colleagues, including medical directors, other clinical experts, actuarial staff, and data management

[i] As discussed above, this list includes mandated benefits and provider mandates. This study does not address population coverage mandates.

and analysis staff. In addition, the Massachusetts Association of Health Plans (MAHP) provided assistance with coordination and communication with its participating member plans.

An initial discussion with participating health plans and MAHP reviewed the process that had been used for the 2012 study and described the new mandates to be added to the current study. In the original 2008 study, a collaborative process with the carriers was used to develop the data to measure the costs of the mandates. At that time, CHIA did not have data available for the analysis, so it was agreed that extraction of claim data from the carriers would be the best approach; it was also clear that this would require significant effort on the part of the carriers if all 26 mandates included in the 2008 analysis were to be studied this way. To reduce the burden on the carriers to a reasonable level, a prioritization process was conducted, during which mandates were categorized into one of two groups. The first group consisted of mandates that were considered by the carriers to be most relevant for the study due to meeting the following criteria:

- The mandate required benefits that were judged likely to be reduced or eliminated if the mandate were to be repealed.
- The mandate covered benefits which were judged to be currently clinically relevant and being drawn on and paid for by the carriers.
- The services related to the mandate could be readily identified and extracted from claim history files.

The mandates meeting these criteria were included in the potential marginal direct cost portion of the study; cost estimates for these mandates relied on primary claim data analysis using claims extracted by the carriers. The mandates failing to meet one or more of the criteria listed above were included in the zero marginal direct cost portion of the study. Cost estimates for these mandates were produced using secondary data sources (e.g., literature review) where possible. These mandates:

- Were judged to require benefits that the carriers would substantially provide regardless of the mandate law, or
- Had become clinically obsolete, or
- Could not be feasibly measured as part of the study, nor monitored by the carriers, regardless of the presence of a mandate.

For both the 2012 study and the present study, the original potential marginal direct cost and zero marginal direct cost mandate designations were reviewed and confirmed by the carriers. In addition, in light of federal benefit requirements in the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) and the Patient Protection and Affordable Care Act of 2010 (ACA), Compass re-classified the mental health and contraceptive services mandates as zero marginal direct cost mandates in the present study.[ii] RDC estimates for these two mandates were prepared with MA APCD data. In the present study, the MA APCD also allowed estimation of the RDCs for four of the original zero marginal direct cost mandates (cardiac rehabilitation, cytological screening, lead

[ii] The contraceptive services and mental health mandates were treated as "mandates with potential marginal direct cost" in the 2008 and 2012 studies.

poisoning screening, and mammography) with claim data. RDCs for the remaining zero marginal direct cost mandates identified by the carriers, where measurable, were calculated using secondary data sources.

Each carrier participating in the current study was asked to review the data specifications used for the 2012 study to update them for any changes in clinical practice, coding, or other relevant factors. Five mandates were added to the mandate list for the present study: autism services,[iii] cleft palate and cleft lip services, hearing aids for children, oral cancer drugs, and physician assistants. The autism services specification developed for the 2012 study by a volunteer carrier was included in the above specification review process, as well as Compass-developed initial specifications for the hearing aids for children, oral cancer drugs, and physician assistant mandates. Two carriers developed specifications for the cleft palate and cleft lip mandate at CHIA's request.

Data sources

Since the initial study was published, CHIA developed health care claim database resources. The allowed amount and paid claims PMPM estimates developed from claim data for the present study drew upon calendar year 2014 data from CHIA's Massachusetts All Payer Claim Database (MA APCD),[1001] Release 4.0.[iv] CHIA collects and manages data from commercial carriers, third party administrators, and public programs.[1002] CHIA works with each carrier to conduct a quality control process on the MA APCD data, and "clears" data through this process on a carrier-by-carrier basis as this process is complete. This quality-controlled sample of carriers comprises approximately 87 percent of total commercial fully-insured and GIC primary medical membership under age 65 in the Commonwealth.[v] Compass relied upon this quality-controlled data sample after verifying basic reasonableness checks on membership and expenses. The analogous figure for pharmacy membership is somewhat lower, at 60 percent; the quality control process is ongoing, and focused on the medical claims initially. Therefore, fewer carriers' pharmacy claims have been cleared through CHIA's quality control process. Cost estimates contained in this report assume that the PMPM costs obtained from the MA APCD sample data are representative of the overall fully-insured commercial under-65 population.

Compass used the MA APCD claims, eligibility, product, and provider data to extract claims and estimate per member costs for services required by the 25 potential marginal direct cost mandates. The MA APCD contains both fully-insured and self-insured claims,[vi] allowing Compass to compare

[iii] The autism services mandate, effective for policy renewals on or after January 1, 2011, was discussed in the 2012 report, but no cost estimates were presented, given that the report study period was 2009.
[iv] Service year 2014 (paid through June 30, 2015) is the most recent full year available in Release 4.0.
[v] Total average fully-insured commercial primary medical insurance membership under age 65 reported in the MA APCD for all carriers is approximately 2 million, or 94 percent of Compass's 2014 fully-insured commercial membership estimate of 2.1 million. Total average under-65 fully-insured and self-insured GIC primary medical insurance membership from the MA APCD is 2.1 million, or 90 percent of Compass's 2.4 million population estimate (not all carriers' GIC accounts can be identified in the MA APCD; these accounts are excluded from the 2.1 million estimate).
[vi] On 1 March, 2016, the U.S. Supreme Court decided, in *Gobeille v. Liberty Mut. Ins. Co.,* that self-insured plans regulated under ERISA can not be compelled to submit data to state APCDs. This decision will imply a

the per-person spending level in the fully-insured and self-insured GIC business (subject to the mandates) to the per-person costs in the non-GIC self-insured business (not subject to the mandates) to generate estimates of the mandates' impact.

The potential direct marginal cost mandates are shown in Table B-1 below.

Table B-1
Mandates with Potential Marginal Direct Cost

Service Mandates
Autism Spectrum Disorders
Child Hearing Aids
Chiropractic Services
Cleft Palate and Lip
Diabetes-related Services and Supplies
Early Intervention Services
Home Health Care
Hormone Replacement Therapy (HRT)
Human Leukocyte Antigen Testing
Hypodermic Syringes or Needles
Infertility Treatment
Limb Prostheses
Low Protein Food Products for Inherited Amino Acid and Organic Acid Diseases (PKU)
Nonprescription Enteral Formulas
Oral Cancer Drugs
Scalp Hair Prostheses for Cancer Patients
Speech, Hearing and Language Disorders
Provider Mandates
Certified Nurse Midwives
Certified Registered Nurse Anesthetists
Chiropractors
Dentists
Nurse Practitioners
Optometrists
Physician Assistants
Podiatrists

In the terminology defined above, for these mandates it was assumed possible that both RDC and MDC were greater than zero, and thus they were the focus of more precise measurement using claim data.

The mandates judged likely to have little or no marginal direct costs are shown in Table B-2 below. Treatment of breast cancer using bone marrow transplant was demonstrated to be clinically obsolete in the 2008 study by analysis of Commonwealth employee claims, and thus was assumed to no longer have marginal cost to the system. As discussed in more detail above, in this study it is included within the clinical trials mandate analysis. Two mandates were judged to be not

significant methodological change in future reports in the likely event that self-insured groups cease MA APCD submissions in light of this decision.

measurable within the scope of the original study: Off-label uses of prescription drugs to treat HIV/AIDS and off-label uses of prescription drugs to treat cancer. Because the off-label uses of prescription drugs are not considered monitorable or manageable, elimination of these mandates would be likely to have little effect on utilization.

The remaining mandates in Table B-2 were judged to be benefits the carriers would likely pay for even if the state mandate law was repealed, due to proven cost-effectiveness, demand from members, or redundancy with federal mandates. In all cases the marginal cost (i.e., cost caused by the presence of the mandate law) associated with the mandates in Table B-2 was assumed to be at or near zero.

In previous studies, RDCs for all measurable zero marginal direct cost mandates were estimated using secondary data sources. In the present study, availability of the MA APCD allowed estimation of the RDCs for six of the zero marginal direct cost mandates (cardiac rehabilitation, contraceptive services, mental health services, cytological screening, lead poisoning screening, and mammography) with claim data. RDCs for the remaining measurable zero marginal direct cost mandates were calculated using secondary data sources. Compass reviewed and updated these models, using Massachusetts (rather than national or regional) data wherever possible for the utilization rates, prevalence figures, and other components underlying the calculations.

With marginal costs assumed to be zero, the estimated total RDCs for these 14 mandates were added to the RDC costs, but no additional costs were included in the marginal cost estimates for these mandates (more precisely, zero was added to the marginal cost estimates).

The methodologies used in the analysis of both the potential marginal direct cost and zero marginal direct cost mandates are discussed in detail further below.

Table B-2
Mandates Judged to Have Zero Marginal Cost

Bone Marrow Transplants for Treatment of Breast Cancer
Cardiac Rehabilitation
Clinical Trials (to treat cancer)
Contraceptive Services
Cytologic Screening
Hearing Screening for Newborns
Hospice Care
Lead Poisoning Screening
Mammography
Maternity Health Care (including minimum maternity stay)
Mental Health Care
Preventive Care for Children Up to Age Six
Off-Label Uses of Prescription Drugs to Treat Cancer
Off-Label Uses of Prescription Drugs to Treat HIV/AIDS

Applicable population

Laws mandating insurance benefits in the Commonwealth of Massachusetts vary in the populations to which they apply. This study estimates the effect of mandates on health care costs only for people in Massachusetts with health insurance plans subject to health benefit mandate laws; those plans fall into two main groups. First, all mandates in the study apply to fully-insured commercial plans regulated by the Massachusetts Division of Insurance. Second, a subset of the mandates in this study also applies to coverage for public employees provided under the GIC. The great majority of the GIC coverage is provided on a self-insured basis, with the remainder included among the fully-insured plans subject to all the mandates. However, self-insured GIC plans voluntarily follow all benefit mandates. Therefore, in this analysis Compass has treated both fully-insured and self-insured GIC plans as part of the mandate-affected population for all mandates.

State health insurance benefit mandates do not apply to individuals covered under:

- Self-insured policies (except the GIC population, as discussed throughout this appendix), as these policies are governed by federal ERISA statutes and not subject to state mandate laws
- Medicare and Medicare Advantage plans, the benefits of which are qualified by Medicare
- Federally-funded plans including the Veterans Administration, TRICARE (covering military personnel and dependents), and the Federal Employee's Health Benefit Plan

This analysis excludes members of fully-insured plans over 64 years of age, and does not address potential effects on Medicare supplement plans (which generally cover patient cost sharing within the Medicare benefit structure) even to the extent they are regulated by state law. Finally, some Massachusetts mandate laws affect MassHealth, which administers the Massachusetts Medicaid program; however, this analysis does not address the potential effect of those mandates on MassHealth expenditures.

U.S. Census Bureau data on the Massachusetts population and percent covered by employer-sponsored plans and MA APCD eligibility data[1003] lead to an estimate of 3.8 million Massachusetts residents under age 65 covered by employer-sponsored plans in 2014, approximately 1.8 million of whom are fully-insured. Compass used Massachusetts Department of Insurance (DOI),[1004,1005] MA APCD eligibility,[1006] and CHIA enrollment trends[1007] data to develop an estimate of approximately 139,000 additional individuals under age 65 residing in other states are covered by Massachusetts-issued fully-insured employer-sponsored insurance subject to the mandates. Finally, MA APCD eligibility data[1008] yielded an estimate of approximately 170,000 persons under age 65 purchased insurance in the non-group market in 2014, for a total estimate of 2.1 million fully-insured members.

Because self-insured GIC plans follow the mandates voluntarily, an additional 261,000 members are added to the covered population (based on GIC annual reports)[1009] for a total of 2.4 million individuals. Appendix C contains more details about these population calculations.

The statutory language varies across the mandates as to which of the geographic categories and license types contained in the insurance statutes the mandate is applicable. Generally, the

mandates apply to residents of Massachusetts and to those with a principal place of employment in Massachusetts, and so effectively apply to all members covered by fully-insured policies issued in Massachusetts. There are a few exceptions to this general case apparent in the statutory language. First, the infertility mandate applies only to Massachusetts residents. The infertility sample cost estimates therefore include only those claims and members indicating a member state of residence of Massachusetts, and the population paid expenses PMPM are calculated over the member-resident insured population only. Second, four provider mandates (certified nurse midwives, chiropractors, dentists, and optometrists) do not have language in Chapter 176G (the HMO license). As a result, in our calculations we have not applied the cost estimates to this population for these four mandates. Third, the chiropractic services mandate applies only to medical service corporations (Chapter 176B), and as a result the cost estimates are applied only to the BCBSMA membership.

Table B-3
Populations to Which Mandates Apply

Mandate	Applicable Population	Estimated Statute Membership	Est. Effective Membership (incl. SI GIC)
Certified Nurse Midwives Chiropractors Dentists Optometrists	Indemnity and Blue Cross Blue Shield fully-insured members	479,865	730,715
Chiropractic Services	Blue Cross Blue Shield fully-insured members, *excluding* HMO Blue	165,174	165,174
Infertility Services	All fully-insured Massachusetts-resident members	1,962,021	2,206,099
Certified Registered Nurse Anesthetists Early Intervention Home Health Care HRT Infertility Low Protein Foods Nurse Practitioner Podiatrist Syringe Cardiac Rehab Clinical Trials for Cancer Contraception Cytologic Screening Lead Screening Mammography Off-label Uses of Prescription Drugs - Cancer Off-label Uses of Prescription Drugs - HIV/AIDS Preventive Care to Age 6	All fully-insured members	2,101,336	2,362,745
Autism Services Child Hearing Aids Cleft Palate and Lip Diabetes HLA Testing Limb Prosthesis Mental Health Nonprescription. Enteral Formulas Oral Cancer Drugs Physician Assistants Scalp Hair Prosthesis Speech & Hearing Bone Marrow Transplants for Breast Cancer Hearing Screening for Newborns Hospice Care Maternity Care	All fully-insured members and all GIC members (fully and self-insured)	2,362,745	2,362,745

Table B-3 summarizes the license types and populations to which the mandates apply per the statutory language, and the applicable population used in the Compass analysis (which always includes the self-insured GIC). The PMPM cost estimate from our sample data for each mandate was multiplied by the indicated estimated member population number to arrive at the total dollar cost estimate for each mandate.[vii]

For calculating the percent of premium, the analysis uses as a member-months denominator the sum of member-months for all license types (for Massachusetts residents and non-residents with a principal place of employment in Massachusetts), since it estimates the per-person costs of the

[vii] As discussed below, for aggregated cost estimates, overlap between mandates is removed when summing total dollars.

benefits with respect to the overall average fully-insured health insurance premium. However, for the five mandates that apply to less than the entire fully-insured population, estimated claims were included in the numerator only for the sub-groups indicated in Table B-3, as these are the only claims related to benefits required by those mandates. The self-insured GIC was included in both the numerator claims and denominator membership for all mandates. The resulting estimates represent the impact on the average fully-insured premium, not on the premium for the sub-group(s) to which the mandate applies.

Sample population

To develop the dollar estimates in the study, PMPM claim expense estimates were developed from the data sources described above. Paid claim expenses PMPM from representative samples were developed, and then multiplied by the applicable populations discussed in the preceding section. In general, the PMPM claim expense estimates developed from claim data drew upon CHIA's MA APCD Release 4.0. The MA APCD quality-controlled medical claim data sample described above in the data sources section includes 27 carriers (including MassHealth). This quality-controlled sample comprises approximately 2 million members, or 87 percent of Compass's estimate of 2.4 million total commercial fully-insured and GIC primary medical membership under age 65 in the Commonwealth.[viii]

Compass joined claims for the 27 quality-controlled medical carriers to de-duplicated eligibility data to review match rates and average PMPM allowed amount expenses by carrier. The 11 medical carriers with at least 95 percent of claims matching to a primary medical insurance eligibility span and a reasonable resulting "matched" 2014 average PMPM allowed expenditure comprised the analytical sample. Combined fully-insured, self-insured, and GIC matched 2014 average PMPM allowed expenditures by payer in the medical sample ranged from $214 for one small individual-market carrier to $402 for a carrier whose sample data are likely comprised almost exclusively of GIC accounts, as described below.

The average fully-insured and self-insured GIC medical membership subject to the mandates represented in the 11-carrier sample passing this additional quality-control step for 2014 is 1.9 million, or 79 percent of the estimated 2.4 million total average membership for the fully-insured, self-insured GIC, non-Medigap population under age 65 in Massachusetts.

The MA APCD quality-controlled pharmacy claim data sample includes four carriers (including MassHealth). The average membership under age 65 represented in this sample for commercial fully-insured non-Medigap and self-insured GIC products for calendar year 2014 was 1.4 million. This represents 60 percent of the 2.4 million total average fully-insured and self-insured GIC population. Combined fully-insured, self-insured, and GIC matched 2014 average PMPM allowed expenditures by payer in the pharmacy sample ranged from $81 to $88, and the claims to eligibility

[viii] Total average fully-insured commercial primary medical insurance membership under age 65 reported in the MA APCD is approximately 2 million, or 94 percent of Compass's 2014 fully-insured commercial membership estimate of 2.1 million. Total average under-65 fully-insured and self-insured GIC primary medical insurance membership from the MA APCD is 2.1 million, or 90 percent of Compass's 2.4 million population estimate (not all carriers' GIC accounts can be identified in the MA APCD; these accounts are excluded from the 2.1 million estimate).

match rate for the three quality-controlled pharmacy carriers ranged from 94 to 99 percent. Data for all three commercial carriers in CHIA's quality-controlled sample were therefore used in the analysis. Cost estimates contained in this report assume that the PMPM costs obtained from the MA APCD sample data are representative of the overall fully-insured commercial under-65 population.

In general, the entire database sample population was used for calculations. Exclusions from the sample data were made where the analysis of applicable populations above indicated this would be appropriate:

- For one carrier, the sample includes only the 38 percent of claims and 24 percent of reported membership identifiable as indemnity products. The remaining 62 percent of claims volume for this payer matched to products with a medical services corporation/hospital services plan carrier license type, or matched to products for which carrier license type could not be determined. Given that the carrier is not licensed as a medical service corporation or hospital service plan in Massachusetts, the medical service corporation/hospital service plan and license type unknown volume were excluded from this analysis under the assumption the situs of the plans was not Massachusetts (no situs indicator was available on Release 4.0 of the MA APCD). Upon further review of the indemnity portion of the data, Compass noted that although the products were not identified as GIC products in the MA APCD, the associated membership was a near-match to the GIC's reported membership for the same carrier for fiscal year 2014. Given this fact, and the high matched 2014 average allowed expenses PMPM for these products ($402), suggesting rich benefits on average, Compass treated these indemnity claims and eligibility as GIC products.
- The chiropractic services mandate applies only to Blue Cross and Blue Shield of Massachusetts (BCBSMA), the data for which are represented in the MA APCD sample. Therefore, only BCBSMA data were used to calculate the PMPM for this mandate.[ix]
- For the six mandates including pharmaceuticals among their mandated services, all of which also include medical components, only the three commercial carriers in the MA APCD pharmacy sample were used to calculate both the medical and pharmacy PMPMs.
- Identifying claims by provider type required knowledge and coding of carrier-specific provider type identifiers. Therefore, for the eight provider-centered mandates, only data for the three largest carriers (all of whom provided guidance in their specification review responses on identifying the provider types in their data) were used to calculate the PMPMs for these mandates. Review of preliminary results indicated that the provider type and specialty information provided by one carrier did not reliably identify claims performed by the specific provider types in question. Therefore, this carrier's data were dropped from the sample, leaving two of the three largest carriers in the initial provider mandate sample.

[ix] In this case, since the applicable population membership and the sample population membership are the same, the dollars measured in the MA APCD data were used directly as the aggregate dollar impact of the mandate. In most cases, however, the sample is smaller than the population, and the resulting sample PMPM was multiplied times the larger population membership estimate to arrive at a population estimate for aggregate dollars.

- Furthermore, four of the eight provider-centered mandates do not apply to HMO licenses. Review of the preliminary results for these four mandates showed that effectively all fully-insured volume for the smaller of the two carriers in the initial provider mandate sample was identified as HMO-licensed. Therefore, this carrier was dropped from the sample for these four mandates (chiropractors, certified nurse midwives, dentists, and optometrists). Both carriers' data were used for the four provider mandates including all license types (certified registered nurse anesthetists, podiatrists, nurse practitioners, and physician assistants).

In addition, not all carriers' GIC accounts can be identified in the MA APCD; these accounts are excluded from the 1.9 million fully-insured and self-insured GIC sample population estimate. In the analysis, these products, where applicable, are included in the 1.5 million member non-GIC self-insured comparison population.

With respect to data extraction from the MA APCD, there was one additional relevant issue related to the study population. Identifying average costs for the six mandates including pharmaceuticals must take into account that the carriers have some accounts that use a third-party pharmacy benefit manager (PBM), and that for some of these accounts (particularly those that are self-insured) pharmacy claims were not included in the three-carrier MA APCD sample. As a result, the sample pharmacy membership and their associated claims are smaller than the medical membership and associated claims. To address this issue, medical PMPMs were calculated for the medical data using the medical membership, and the pharmacy data PMPMs were calculated using the pharmacy membership. The PMPMs were then added together, and were multiplied by the population membership to calculate the estimated total dollar impact. The total dollar estimates were then divided by medical membership to derive combined pharmacy and medical PMPMs. This prevented a downward bias to the PMPM estimates that would otherwise have been caused by missing pharmacy claims. For estimates of the total dollar impact in the Commonwealth, the full population membership (all fully-insured and self-insured GIC members in the Commonwealth) is multiplied by the estimated PMPMs calculated without carved out pharmacy benefit accounts.[x]

Cost estimation methodology for mandates with potential marginal direct cost

The mandates with potential marginal direct cost were analyzed using detailed clinical data specifications applied to detailed claim data. CHIA provided an extract from the Massachusetts MA APCD Release 4.0 as the data source for required direct cost estimates of the mandated benefits shown in Table B-2. Compass studied calendar year 2014 (paid through June 30, 2015, the most recent full year of data available in this extract) claims and membership from the extract for this review.

The availability of the MA APCD data (and the Health Care Quality and Cost Containment 2009 data extract made available to Compass by CHIA for the 2012 study) allowed Compass to address two

[x] Note that this assumes that the overall PMPM cost profiles (including pharmaceuticals) for the plans with and without carved-out pharmacy benefits are similar.

significant shortcomings in other state-level impact analyses that were reviewed prior to commencing this study.[1010] First, the data used in the study are specifically from Massachusetts, rather than national data or data from other states. The MA APCD medical data sample used in the analysis represents approximately 79 percent of the fully-insured and self-insured GIC population under age 65 in Massachusetts. Second, the data largely allow measurement specifically of the fully-insured population subject to the mandate laws and the self-insured GIC population voluntarily provided the mandated benefits even when not required by law, and allow for a comparison to the non-GIC self-insured population (unregulated and not subject to mandate laws), rather than inappropriately mixing these populations together.

The approach taken to RDC measurement involved rigorous definition of costs associated with the mandate laws' required benefits, and careful measurement based on the definitions.

There were four general steps in the cost measurement:

- Review and updating of specifications developed for the previous comprehensive mandate review study, and development of new specifications for more recently enacted mandates.
- Quality control assessment of specifications and follow-up by Compass.
- Extracting and quality checking the data using programming language to implement the specifications.
- Summarization of totals and adjustments to arrive at meaningful aggregate values.

The specification of the data requirements included the following steps:

- *Initial Completion or Revision of Data Specification Templates.* Each carrier participating in the current study was asked to review the data specifications used or developed for the 2012 study and Compass-developed initial specifications for the hearing aids for children, oral cancer drugs, and physician assistant mandates to edit them for any changes in clinical practice, coding, or other relevant factors. Two carriers developed specifications for the cleft palate and cleft lip mandate at CHIA's request.
- *Review and refinement of the specifications.* Compass reviewed the feedback for each specification and translated each of the specifications into programming code to extract and summarize the data. In general, carrier-recommended additions of services, products, or diagnoses were incorporated into the specifications. Compass did not remove services, products, or diagnoses from the specifications at a carrier's recommendation unless independent research of the codes marked for removal validated the recommendation.
- *Quality checking the data.* The data extracted for each mandate included in the 2012 study were summarized and compared to the 2012 results. Results for newly-enacted mandates were compared to CHIA's prospective mandated benefit review studies, the results for similar, previously-studied mandates, and/or independent publically-available data sources. Where mandate results diverged significantly from the previous

study or other benchmarks, Compass reviewed the specifications and programming code for errors and corrected results as necessary. Where these results continued to diverge from expected results, Compass drilled into the results (by carrier, code, etc.) and performed further research to validate or further refine the results.

Comparing the present study to the 2012 reports shows that RDC results for some mandates have changed dramatically; most notably, the RDC estimates for diabetes services and supplies and mental health care show nearly three-fold and two-fold increases, respectively. The main drivers of these and other significant differences, illustrated by selected examples, follow.

- *Carrier Input*
  - For the mental health mandate, the carriers provided an extensive list of procedure and diagnosis codes to be added to the cost model specifications they had provided in the two previous iterations of this study (2008 and 2012).
  - This was also true for the speech, hearing, and language and the non-prescription enteral formulas mandates, which had many-fold cost increases (but very small absolute RDCs even after the large increases shown in this study).
  - Significant additions were also made to the diabetes services and supplies specification to include new products, such as the new insulin pumps discussed below.
- *Price and service mix changes*
  - A recent study found that the average price of insulin has tripled in the past decade.[1011]
  - New and expensive insulin pumps have also become popular with clinicians and diabetes patients in recent years.[1012]
- *Clinical practice and guideline changes*
  - Decreased frequency guidelines for mammographic and cytological screening (Pap smear) have been released by U.S. government agencies and medical societies since the previous study period.[1013,1014]

After completion of the quality control process, a number of calculations were carried out to produce the results of the study. Prior to executing those calculations, a claim analysis was performed to eliminate overlap between mandates. Claims for which coverage is mandated by multiple mandates in the study ("mandate overlap") must be identified and quantified to avoid double-counting in aggregate analyses. To quantify overlaps, all claims in the MA APCD sample were flagged for inclusion in each mandate. Areas of overlap were identified where the same claim was flagged for inclusion in multiple mandates. Total sample claims expense (in millions of dollars) for the observed areas of overlap are summarized in Table B-4.

Table B-4
Summary of Mandate Overlaps (in millions of dollars)

	Mandate	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
A	Autism Services Mandate							$ 0.1	$23.8								
B	Children's Hearing Aids Mandate															$ 1.0	
C	Chiropractor Provider Mandate				$ 0.6												
D	Chiropractic Services Mandate																
E	Cleft Palate and Lip Mandate								$ 0.1								
F	Diabetes Services Mandate								$12.1				$ 0.2	$ 0.1			$ 0.5
G	Early Intervention Services Mandate								$14.9				$ 0.3				
H	Home Health Services Mandate									$ 2.7	$ 1.2	$ 0.7	$ 0.3	$ 0.1	$ 0.3	$ 0.2	
I	Limb Prosthesis Mandate																
J	Low Protein Foods Mandate											$ 0.4					
K	Nonprescription Enteral Formulas Mandate																
L	Nurse Practitioner Provider Mandate																
M	Podiatrist Provider Mandate																
N	Scalp Hair Prosthesis Mandate																
O	Speech, Hearing, and Language Services Mandate																
P	Syringe and Needle Mandate																

Overlap amounts must be subtracted from the totals for the mandates when calculating: (i) costs across mandates, or (ii) the incremental cost attributable to the given mandate, i.e. the amount that mandated coverage costs to the Massachusetts healthcare system would be reduced if a given mandate, and only that mandate, were repealed. The mandate-level results *include* the overlap amounts; the overall aggregated result for all mandates with potential marginal direct cost removed the overlapping (double-counted) amounts, that is, each claim identified as a mandated service for any primary data analysis mandate is only summed once in these aggregated results.[xi]

Paid claim expenses PMPM were calculated for each mandate, and administrative loading (the additional costs over and above health care claim costs required to administer the health plan) was added. According to CHIA's September 2016 report on the performance of the Massachusetts health care system,[1015] average administrative loading (including profit) in the fully-insured commercial market was estimated to be 11 percent in 2014. Therefore, to arrive at estimates of total healthcare premium costs, claim costs were divided by one minus the 11 percent administrative load (1 – 0.11), or 0.89.[xii] Individual mandates may add more or less administrative cost than the average; determining the level of additional administrative cost required for any individual mandate would require more effort than is required to estimate the medical expense portion of the estimate, but only represents about 11 percent of total costs. Variations in the relatively small administrative cost levels around the average would be covered by the ranges provided for the cost impacts contained in this study.

[xi] Amounts larger than those shown in Table B-4 were removed from the aggregated study totals, as the sample amounts shown in the table were adjusted to the total population level at the same time that the sample PMPMs were adjusted to the population-level RDCs.

[xii] This assumes that the carriers apply the same percentage gross up for these incremental claim expenses as for their baseline claim expenses. If a carrier elects to only apply incremental variable expenses, then the incremental premium may be 2-3 percent lower, based on an assumption that 2-3 percent of a carrier's administrative cost structure represents fixed overhead that is independent of claim volume. The actual percentages would vary by carrier.

Total cost in the healthcare system associated with each mandated benefit was computed by multiplying the paid claim plus administration PMPM estimate by the estimated number of persons subject to Commonwealth mandates from Table B-3.

These estimated premium amounts were calculated as an approximate percentage of healthcare premiums in Massachusetts by using the estimated average commercial fully-insured 2014 premium of $436.00 from CHIA's September 2016 report.[1016]

As discussed in the introduction, we are unable within the scope of this study to produce precise estimates of the marginal cost of the mandates to the system, the focus of this study being primarily on required direct cost, that is, the total cost to the system of benefits described in the statutory language of the various mandates. The only information available for the study that can shed some light on the question of marginal costs is the MA APCD non-GIC self-insured data. Since these self-insured plans are subject to Federal ERISA law and are not regulated by The Division of Insurance, they are not required to comply with the mandates, and are free (subject to competitive labor market constraints) to reduce or remove these benefits from their health benefit packages. Because labor market pressures may compel the non-GIC self-insured employers to offer richer benefits than they would if other employers (fully-insured employers or those offering GIC plans voluntarily including the mandated benefits) were not required to offer the mandated benefits, any differences identified between the non-GIC self-insured and fully-insured and self-insured GIC benefit costs are likely to be underestimates of the true impact of the mandate. However, they may provide useful lower bound estimates of the marginal direct cost, or actual direct mandate cost impact to the system.

In the cost estimates displayed in the Results section, these lower-bound estimates are derived from the difference between insurer spending in the fully-insured and self-insured GIC population for the mandated benefit and the insurer spending in the non-GIC self-insured population for the same benefit. To reduce the impact that differences in average patient cost sharing between these populations may have on the result, the calculation is performed by computing the percentage by which the fully-insured and self-insured GIC allowed (before cost sharing) expense PMPM exceeds the non-GIC self-insured allowed expense PMPM, and applying that percentage to the fully-insured and self-insured GIC paid claim expense PMPM. The result is a lower-bound estimate of the impact of the mandate on fully-insured and self-insured GIC health insurance expenditures. Where the non-GIC self-insured allowed expense PMPM is higher than the fully-insured and self-insured GIC allowed expense PMPM, we treat the impact as zero, rather than negative; we assume that if non-GIC self-insured firms on average have a higher spending level than fully-insured and self-insured GIC products subject to the mandates, it is not caused by the existence of the mandate. That is:

Lower Bound Marginal Cost = [(FI[xiii] Allowed – SI Allowed)/FI Allowed]*FI paid RDC, *if FI Allowed – SI Allowed > 0*

Lower Bound Marginal Cost = 0, *otherwise*

[xiii] In this and other equations and exhibits in this report, the abbreviation "FI" refers to the fully-insured and self-insured GIC population subject to the mandates, and "SI" refers to the non-GIC self-insured comparison population.

An upper-bound claim cost estimate is also provided for each mandate, which includes the entire RDC, except for those mandates judged by the carriers likely to have zero marginal costs. This upper-bound estimate assumes that 100 percent of the RDC for mandates with potential marginal direct cost is marginal, and that carriers would pay zero dollars in claims for the services described by the mandates in the absence of the mandate laws. For most mandates there is good reason to believe the actual marginal cost is far lower, though we do not have a direct method of estimating by how much. For example, home health care services are widely considered to be cost-effective in many contexts. In all likelihood carriers would cover this benefit, if at a somewhat lower level, in the absence of the mandate.

Cost estimation methodology for mandates judged likely to have zero marginal cost

As described above, 14 mandates were judged likely to have zero marginal cost. Also as discussed above, it was not feasible to calculate RDCs for three of the mandates (bone marrow transplants for treatment of breast cancer and off-label uses of prescription drugs to treat cancer and HIV/AIDS). For another six of the 14 mandates (cardiac rehabilitation services, contraception services, cytological screening, child lead screening, mammography, and mental health) RDCs were calculated from the MA APCD following the upper-bound methodology described above for the potential marginal direct cost mandates.

The estimation process for the remaining five mandates (clinical trials for the treatment of cancer, hospice care, maternity care, newborn hearing screening, and preventive care up to age six) judged likely to have zero marginal cost drew upon secondary data sources rather than primary claim and membership data from the MA APCD. The modeling for these five mandates had the following methodological features in common:

- Estimates were produced for the same under-65, commercial, fully-insured and self-insured GIC Massachusetts population analyzed for the 25 potential marginal direct cost mandates.
- Literature and internet data sources, along with some calculations using MA APCD data, were drawn upon for the individual facts that were combined into calculations for the estimated cost of each mandate.
- For each mandate, adjustments were made to make the estimate applicable to the relevant population. For example, if a national commercial population estimate was available and deemed to be reasonably applicable to Massachusetts, the national per person rate was applied to the number of persons in the under-65 commercial fully-insured and self-insured GIC population in Massachusetts.
- Total cost, PMPM cost, and percent of premium estimates were calculated using the population numbers from Table B-3 and the same $436.00 average premium and 11 percent administrative load figures cited above.
- The enabling statutory language for each mandate was adhered to as closely as possible given the limitations of the approach described.

The form of each calculation was dependent to a significant extent on the data available. For example, in some cases cost per person per year data were available, but in others data on

incidence of an illness and cost per episode of that illness were multiplied together to produce the estimate. In all cases, the costs estimated were total required direct costs. As discussed above, marginal direct cost for each mandate in the secondary cost group is assumed to be zero.

Most of the estimates relying on secondary data drew on sources that were not specific to the fully-insured population in Massachusetts. As a result, data from broader populations (e.g., Massachusetts statewide) had to be adjusted to the sub-population using population estimates drawn from a number of sources, including Census Bureau data and a model of the Massachusetts insured population developed by Compass for its work for CHIA. These estimates and their sources are summarized in Appendix C.

Appendix C: Estimation of Population Subsets

Membership potentially affected by a proposed mandate may include Massachusetts residents with fully-insured employer-sponsored health insurance issued by a Massachusetts licensed company (including through the GIC), non-residents with fully-insured employer-sponsored insurance issued in Massachusetts, Massachusetts residents with individual (direct) health insurance coverage, and lives covered by GIC self-insured coverage (which complies with the mandates voluntarily). Membership projections for 2017 to 2021 are derived from the following sources.

The 2014 Massachusetts All Payer Claim Database (MA APCD) formed the base for the projections. The APCD provided fully-insured and self-insured membership by insurance carrier. The APCD was also used to estimate the number of non-residents covered by a Massachusetts policy. These are typically cases in which a non-resident works for a Massachusetts employer offering employer-sponsored coverage.

The Massachusetts Center for Health Information and Analysis (CHIA) uses supplemental information beyond the data in the MA APCD to develop their enrollment trends reports and provided us with information on where they sourced the data in their report (MA APCD and supplemental carrier information). We adjusted our membership estimates for the data not in the MA APCD where appropriate.

The 2014 combined membership projection by carrier was compared to Massachusetts Department of Insurance (DOI) reports estimating fully-insured covered members by insurance carrier. The membership projections were increased to include insurance carriers that were reported by the DOI but not in the MA APCD or CHIA supplementary report. These were typically insurance carriers with small membership in the state.

The distribution of members by age and gender was estimated using MA APCD population distribution ratios and was checked for reasonableness and validated against the U.S. Census[1017]. Membership was projected forward from the 2014 base year through 2021 using Census Bureau population growth rate estimates by age and gender[1018].

Projections for the GIC self-insured lives were developed using GIC base data for 2013,[1019] 2014,[1020] and 2015,[1021] and the same projected growth rates from the Census Bureau that were used for the Massachusetts population. Breakdowns of the GIC self-insured lives by gender and age were based on the Census Bureau distributions.

Appendix D: Cost by Type of Service for Mandates with Potential Marginal Direct Cost

This appendix presents required direct claims cost (RDC) broken down by service category for the twenty-five mandates judged to have potential marginal direct cost that were analyzed using the MA APCD.

Table D-1: Autism Spectrum Disorders

Autism Spectrum Disorders Mandate

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Behavioral Health and/or Substance Abuse Treatment Services	$31,316,705	$39,537,136	$ 1.39
All Services	**$31,316,705**	**$39,537,136**	**$ 1.39**

Table D-2: Chiropractic Medicine

Chiropractic Medicine Mandate

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Chiropractic Manipulative Treatment	$2,304,438	$2,677,008	$ 1.35
All Services	**$2,304,438**	**$2,677,008**	**$ 1.35**

Table D-3: Cleft lip and Cleft palate

Cleft lip and Cleft palate Mandate

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Inpatient Services	$690,412	$871,641	$0.031
Surgery, Digestive System	$525,878	$663,917	$0.023
Anesthesia	$275,765	$348,151	$0.012
Surgery, Respiratory System	$160,822	$203,037	$0.007
Office/Other Outpatient Services	$156,818	$197,982	$0.007
Hospital Observation Services	$107,889	$136,210	$0.005
Surgery, Musculoskeletal System	$102,106	$128,908	$0.005
Surgery, Integumentary System	$98,350	$124,166	$0.004
Special Otorhinolaryngologic Services	$81,405	$102,773	$0.004
Inpatient Neonatal Intensive, and Pediatric/Neonatal Critical Ca	$71,858	$90,720	$0.003
Behavioral Health and/or Substance Abuse Treatment Services	$41,161	$51,966	$0.002
Pathology & Laboratory	$35,582	$44,922	$0.002
Dental Procedures	$32,477	$41,003	$0.001
Temporary National Codes Est. by Private Payers	$32,189	$40,638	$0.001
Enteral and Parenteral Therapy	$30,534	$38,549	$0.001
Surgery, Auditory System	$23,907	$30,182	$0.001
Hospital Inpatient Services	$16,754	$21,152	$0.001
Radiology	$14,483	$18,285	$0.001
Durable Medical Equipment	$13,180	$16,640	$0.001
Drugs Other Than Chemotherapy	$12,101	$15,277	$0.001
Transport Services Including Ambulance	$11,322	$14,294	$0.001
Preventive Medicine Services	$10,523	$13,286	$0.000
Consultations	$10,301	$13,005	$0.000
CMS Hospital Outpatient Payment System	$9,322	$11,769	$0.000
Immune Globulins, Serum, or Recombinant Prods	$8,679	$10,957	$0.000
Temporary National Codes Est. by Medicaid	$8,438	$10,653	$0.000
Unclassified Services	$4,205	$5,309	$0.000
Immunization Administration for Vaccines/Toxoids	$4,153	$5,243	$0.000
Surgery, Male Genital System	$3,217	$4,062	$0.000
Emergency Department Services	$2,567	$3,240	$0.000
Ophthalmology	$2,226	$2,811	$0.000
Central Nervous System Assessments/Tests (Neuro-Cognitive, M	$1,904	$2,403	$0.000
Medical & Surgical Supplies	$1,745	$2,203	$0.000
Cardiovascular	$1,657	$2,092	$0.000
Psychiatry	$1,184	$1,494	$0.000
Health & Behavior Assessment/Intervention	$1,177	$1,486	$0.000
Temporary Procedures & Professional Services	$979	$1,236	$0.000
Vaccines, Toxoids	$811	$1,024	$0.000
Critical Care Services	$794	$1,003	$0.000
Special Services, Procedures, and Reports	$535	$675	$0.000
Newborn Care Services	$362	$457	$0.000
Pulmonary	$102	$129	$0.000
Qualifying Circumstances for Anesthesia	$66	$84	$0.000
Hydration, Therapeutic, Prophylactic, Diagnostic Injections & Ir	$41	$51	$0.000
Temporary Codes for Durable Medical Equipment Regional Carr	$28	$35	$0.000
Other Services & Procedures	$23	$28	$0.000
Surgery, Cardiovascular System	$19	$23	$0.000
All Services	**$2,610,049**	**$3,295,170**	**$ 0.12**

Table D-4: Diabetes-related Services and Supplies

Diabetes-related Services and Supplies Mandate

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Pharmacy Claims	$87,417,466	$143,654,795	$5.067
Administrative, Miscellaneous & Investigational	$4,891,877	$8,038,916	$0.284
Pathology & Laboratory	$4,101,261	$6,739,681	$0.238
Medical & Surgical Supplies	$3,853,956	$6,333,280	$0.223
Durable Medical Equipment	$3,391,982	$5,574,109	$0.197
Temporary Procedures & Professional Services	$1,496,366	$2,459,007	$0.087
Medical Nutrition Therapy	$1,117,904	$1,837,073	$0.065
Ophthalmology	$387,196	$636,286	$0.022
Surgery, Integumentary System	$187,048	$307,380	$0.011
Endocrinology	$54,092	$88,890	$0.003
Preventive Medicine Services	$44,919	$73,816	$0.003
Drugs Other Than Chemotherapy	$13,032	$21,416	$0.001
Temporary National Codes Est. by Private Payers	$10,795	$17,740	$0.001
Orthotics	$5,758	$9,462	$0.000
All Services	**$106,973,652**	**$175,791,850**	**$ 6.20**

Table D-5: Early Intervention Services

Early Intervention Services Mandate

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Behavioral Health and/or Substance Abuse Treatment Services	$14,216,047	$17,947,666	$0.633
Temporary National Codes Est. by Medicaid	$4,683,775	$5,913,236	$0.209
Health & Behavior Assessment/Intervention	$1,469,498	$1,855,232	$0.065
Consultations	$225	$284	$0.000
Office/Other Outpatient Services	$171	$216	$0.000
Preventive Medicine Services	$57	$72	$0.000
All Services	**$20,369,774**	**$25,716,707**	**$ 0.91**

Table D-6: Hearing Aids for Children

Hearing Aids for Children Mandate

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Special Otorhinolaryngologic Services	$4,701,980	$5,936,219	$0.209
Hearing Services	$753,459	$951,237	$0.034
Surgery, Auditory System	$4,344	$5,485	$0.000
All Services	**$5,459,783**	**$6,892,940**	**$ 0.24**

Table D-7: Home Health Care

Home Health Care Mandate

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Drugs Other Than Chemotherapy	$54,578,177	$68,904,593	$2.430
Behavioral Health and/or Substance Abuse Treatment Services	$40,163,888	$50,706,647	$1.788
Durable Medical Equipment	$26,135,778	$32,996,250	$1.164
Medical & Surgical Supplies	$18,237,749	$23,025,039	$0.812
Temporary National Codes Est. by Private Payers	$13,660,316	$17,246,060	$0.608
Unclassified Services	$9,529,481	$12,030,907	$0.424
Orthotics	$7,042,962	$8,891,693	$0.314
Administrative, Miscellaneous & Investigational	$6,760,780	$8,535,441	$0.301
Temporary Procedures & Professional Services	$5,592,887	$7,060,983	$0.249
Enteral and Parenteral Therapy	$5,068,539	$6,398,998	$0.226
Inpatient Services	$4,804,697	$6,065,899	$0.214
Prosthetics	$3,171,974	$4,004,596	$0.141
Temporary Codes for Durable Medical Equipment Regional Carriers	$2,506,788	$3,164,803	$0.112
Home Health Procedures/Services	$2,058,987	$2,599,457	$0.092
Temporary National Codes Est. by Medicaid	$1,332,662	$1,682,477	$0.059
Psychiatry	$537,907	$679,104	$0.024
Pulmonary	$524,226	$661,831	$0.023
Physical Medicine & Rehabilitation	$291,259	$367,713	$0.013
Special Otorhinolaryngologic Services	$260,045	$328,305	$0.012
Home Services	$252,856	$319,229	$0.011
Vision Services	$219,560	$277,194	$0.010
Pathology & Laboratory	$173,408	$218,926	$0.008
Temporary Codes Assigned by CMS	$155,657	$196,516	$0.007
Chemotherapy Drugs	$103,538	$130,716	$0.005
Surgery, Musculoskeletal System	$94,206	$118,935	$0.004
Immune Globulins, Serum, or Recombinant Prods	$70,925	$89,542	$0.003
Neurology & Neuromuscular Procedures	$67,448	$85,153	$0.003
Hearing Services	$62,335	$78,697	$0.003
Health & Behavior Assessment/Intervention	$54,879	$69,285	$0.002
Dialysis	$45,710	$57,708	$0.002
Surgery, Maternity Care & Delivery	$28,763	$36,314	$0.001
Vaccines, Toxoids	$20,090	$25,363	$0.001
Transport Services Including Ambulance	$18,439	$23,279	$0.001
Surgery, Nervous System	$17,000	$21,462	$0.001
Hydration, Therapeutic, Prophylactic, Diagnostic Injections & Infusions, and Chemotherapy & Other Highly Complex Drug or Highly Complex Biologic Agent Administration	$13,844	$17,478	$0.001
Cardiovascular	$13,547	$17,103	$0.001
Preventive Medicine Services	$10,153	$12,819	$0.000
Domiciliary, Rest Home (boarding home) or Custodial Care Services	$10,110	$12,764	$0.000
Hospital Inpatient Services	$8,770	$11,073	$0.000
Office/Other Outpatient Services	$8,118	$10,249	$0.000
Central Nervous System Assessments/Tests (Neuro-Cognitive, Mental Status, Speech Testing)	$6,869	$8,673	$0.000
Domiciliary, Rest Home (assisted living facility) or Home Plan Oversight Services	$6,684	$8,439	$0.000
Laboratory Services	$6,122	$7,729	$0.000

Home Health Care Mandate

Summary of Services Used by Category (cont'd)

		Adjusted to Fully Insured Population	PMPM
Anesthesia	$5,608	$7,080	$0.000
Education & Training for Patient Self-Management	$4,270	$5,390	$0.000
Special Dermatological Procedures	$2,943	$3,715	$0.000
Surgery, Integumentary System	$2,602	$3,285	$0.000
Radiology	$1,869	$2,360	$0.000
Immunization Administration for Vaccines/Toxoids	$1,640	$2,070	$0.000
Ophthalmology	$1,636	$2,065	$0.000
Special Services, Procedures, and Reports	$1,525	$1,925	$0.000
Diagnostic Radiology Services	$1,331	$1,680	$0.000
Surgery, Eye & Ocular Adnexa	$1,250	$1,578	$0.000
Care Plan Oversight Services	$1,228	$1,550	$0.000
Surgery, Male Genital System	$1,126	$1,422	$0.000
Other Services & Procedures	$966	$1,220	$0.000
Surgery, Cardiovascular System	$774	$977	$0.000
Surgery, Digestive System	$706	$891	$0.000
Newborn Care Services	$655	$827	$0.000
Consultations	$591	$746	$0.000
Chiropractic Manipulative Treatment	$534	$674	$0.000
Case Management Services	$380	$480	$0.000
Nursing Facility Services	$261	$330	$0.000
Surgery, Auditory System	$138	$175	$0.000
Other Evaluation and Management Services	$115	$145	$0.000
Noninvasive Vascular Diagnostic Studies	$107	$135	$0.000
Surgery, Female Genital System	$81	$102	$0.000
Medical Nutrition Therapy	$79	$100	$0.000
Surgery, Respiratory System	$77	$98	$0.000
Moderate (conscious) Sedation	$74	$93	$0.000
Surgery, Urinary System	$73	$92	$0.000
Allergy & Clinical Immunology	$2	$3	$0.000
Prolonged Services	$0	$0	$ -
All Services	**$203,760,773**	**$257,246,649**	**$ 9.07**

Table D-8: Hormone Replacement Therapy

Hormone Replacement Therapy Mandate

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Pharmacy Claims	$5,873,488	$9,652,016	$0.340
Office/Other Outpatient Services	$711,427	$1,169,101	$0.041
Preventive Medicine Services	$398,042	$654,110	$0.023
Pathology & Laboratory	$23,108	$37,974	$0.001
Consultations	$15,544	$25,544	$0.001
Surgery, Integumentary System	$11,183	$18,377	$0.001
Drugs Other Than Chemotherapy	$4,154	$6,827	$0.000
All Services	**$7,036,946**	**$11,563,949**	**$ 0.41**

Table D-9: Human Leukocyte Antigen Testing

Human Leukocyte Antigen Testing Mandate

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Pathology & Laboratory	$14,526	$18,339	$0.001
All Services	**$14,526**	**$18,339**	**$0.001**

Table D-10: Hypodermic Syringes or Needles

Hypodermic Syringes or Needles Mandate

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Pharmacy	$496,900	$816,566	$0.029
Medical & Surgical Supplies	$162,308	$266,724	$0.009
All Services	**$659,209**	**$1,083,290**	**$ 0.04**

Table D-11: Infertility Treatment

Infertility Treatment Mandate

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Pharmacy Claims	$28,614,597	$54,302,681	$2.051
Temporary National Codes Est. by Private Payers	$17,916,345	$34,000,324	$1.284
Surgery, Female Genital System	$3,677,979	$6,979,798	$0.264
Pathology & Laboratory	$2,224,355	$4,221,218	$0.159
Office/Other Outpatient Services	$1,641,581	$3,115,273	$0.118
Radiology	$431,432	$818,741	$0.031
Preventive Medicine Services	$239,984	$455,424	$0.017
Surgery, Auditory System	$224,577	$426,186	$0.016
Consultations	$150,025	$284,707	$0.011
Special Otorhinolaryngologic Services	$35,647	$67,649	$0.003
Surgery, Digestive System	$20,129	$38,200	$0.001
Surgery, Maternity Care & Delivery	$8,990	$17,060	$0.001
All Services	**$55,185,642**	**$104,727,260**	**$ 3.96**

Table D-12: Low Protein Foods (LPF)

Low Protein Foods (LPF) Mandate

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Enteral and Parenteral Therapy	$1,144,495	$1,444,918	$0.051
Temporary National Codes Est. by Private Payers	$64,152	$80,992	$0.003
All Services	**$1,208,647**	**$1,525,909**	**$ 0.05**

Table D-13: Nonprescription Enteral Formulas

Nonprescription Enteral Formulas Mandate

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Enteral and Parenteral Therapy	$732,663	$924,982	$0.033
All Services	**$732,663**	**$924,982**	**$ 0.03**

Table D-14: Oral Chemotherapy Treatment of Cancer

As discussed above in the report body, the oral chemotherapy mandate is a cost-sharing mandate only. The claims summarized below include all 2014 sample and estimated population carrier payments for oral cancer drugs claims used to derive the mandate cost estimate, and will therefore not match the oral chemotherapy mandate results presented above.

Oral Chemotherapy Treatment of Cancer Mandate

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Pharmacy	$44,508,253	$73,141,263	$2.580
Drugs Other Than Chemotherapy	$12,323	$20,251	$0.001
All Services	**$44,520,576**	**$73,161,515**	**$ 2.58**

Table D-15: Prosthetic Devices

Prosthetic Devices Mandate

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Prosthetics	$3,063,784	$3,868,008	$0.136
All Services	**$3,063,784**	**$3,868,008**	**$ 0.14**

Table D-16: Scalp Hair Prostheses

Scalp Hair Prostheses

Summary of Services Used by Category

Procedure Code	Description	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
A9282	Wig, any type, each	$325,539	$410,990	$0.014
All Services		**$325,539**	**$410,990**	**$ 0.01**

Table D-17: Speech and Audiology Services

Speech and Audiology Services

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Special Otorhinolaryngologic Services	$3,210,954	$4,053,808	$0.143
Hearing Services	$735,387	$928,422	$0.033
Surgery, Auditory System	$711,401	$898,140	$0.032
Prosthetics	$600,349	$757,937	$0.027
Inpatient Services	$280,689	$354,368	$0.012
Central Nervous System Assessments/Tests (Neuro-Cognitive, Mental Status, Speech Testing)	$37,459	$47,292	$0.002
Temporary Procedures & Professional Services	$24,772	$31,275	$0.001
Surgery, Digestive System	$7,928	$10,009	$0.000
Hospital Observation Services	$7,618	$9,617	$0.000
Surgery, Integumentary System	$3,258	$4,113	$0.000
Radiology	$3,073	$3,880	$0.000
Surgery, Musculoskeletal System	$2,927	$3,695	$0.000
Pathology & Laboratory	$2,879	$3,635	$0.000
Drugs Other Than Chemotherapy	$2,612	$3,297	$0.000
Cardiovascular	$1,833	$2,314	$0.000
Anesthesia	$1,669	$2,108	$0.000
Medical & Surgical Supplies	$618	$780	$0.000
Neurology & Neuromuscular Procedures	$517	$653	$0.000
Temporary National Codes Est. by Private Payers	$305	$385	$0.000
CMS Hospital Outpatient Payment System	$177	$223	$0.000
Pulmonary	$97	$122	$0.000
Temporary Codes Assigned by CMS	$71	$89	$0.000
Surgery, Cardiovascular System	$9	$12	$0.000
Ophthalmology	$2	$2	$0.000
Surgery, Respiratory System	$0	$0	$0.000
Administrative, Miscellaneous & Investigational	$0	$0	$ -
All Services	**$5,636,603**	**$7,116,174**	**$ 0.25**

Table D-18: Certified Nurse Midwives

Certified Nurse Midwife Services

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Surgery, Maternity Care & Delivery	$187,264	$962,380	$ 0.110
Preventive Medicine Services	$29,820	$153,249	$ 0.017
Pathology & Laboratory	$26,547	$136,430	$ 0.016
Unclassified Services	$23,392	$120,216	$ 0.014
Office/Other Outpatient Services	$20,466	$105,178	$ 0.012
Drugs Other Than Chemotherapy	$15,298	$78,618	$ 0.009
Vaccines, Toxoids	$3,830	$19,685	$ 0.002
Immunization Administration for Vaccines/Toxoids	$3,332	$17,123	$ 0.002
Surgery, Female Genital System	$2,533	$13,018	$ 0.001
Temporary Codes Assigned by CMS	$822	$4,222	$ 0.000
Surgery, Integumentary System	$591	$3,037	$ 0.000
Hydration, Therapeutic, Prophylactic, Diagnostic Injections & Infusions, and Che	$571	$2,932	$ 0.000
Hospital Observation Services	$556	$2,858	$ 0.000
Immune Globulins, Serum, or Recombinant Prods	$467	$2,399	$ 0.000
Home Services	$156	$802	$ 0.000
Emergency Department Services	$149	$764	$ 0.000
Surgery, Male Genital System	$99	$511	$ 0.000
Temporary National Codes Est. by Private Payers	$90	$463	$ 0.000
Surgery, Cardiovascular System	$79	$406	$ 0.000
Hospital Inpatient Services	$0	$0	$ -
All Services	**$316,062**	**$1,624,290**	**$ 0.19**

Table D-19: Certified Registered Nurse Anesthetists

Certified Registered Nurse Anesthetist Services

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Anesthesia	$9,772,491	$22,003,254	$ 0.776
Surgery, Nervous System	$11,644	$26,218	$ 0.001
Preventive Medicine Services	$4,596	$10,347	$ 0.000
Surgery, Digestive System	$3,653	$8,224	$ 0.000
Surgery, Eye & Ocular Adnexa	$3,494	$7,866	$ 0.000
Office/Other Outpatient Services	$3,067	$6,905	$ 0.000
Surgery, Cardiovascular System	$2,859	$6,437	$ 0.000
Radiology	$2,074	$4,669	$ 0.000
Surgery, Female Genital System	$2,068	$4,656	$ 0.000
Drugs Other Than Chemotherapy	$1,725	$3,884	$ 0.000
Surgery, Musculoskeletal System	$1,300	$2,927	$ 0.000
Hospital Inpatient Services	$1,293	$2,911	$ 0.000
Moderate (conscious) Sedation	$1,068	$2,405	$ 0.000
Inpatient Neonatal Intensive, and Pediatric/Neonatal Critical Care Services	$825	$1,858	$ 0.000
Cardiovascular	$750	$1,689	$ 0.000
Qualifying Circumstances for Anesthesia	$666	$1,499	$ 0.000
Consultations	$425	$957	$ 0.000
Surgery, Urinary System	$382	$861	$ 0.000
Surgery, Respiratory System	$256	$576	$ 0.000
Hydration, Therapeutic, Prophylactic, Diagnostic Injections & Infusions, and Chemotherapy & Other Highly Complex Drug or Highly Complex Biologic Agent Administration	$218	$492	$ 0.000
Emergency Department Services	$210	$473	$ 0.000
Pulmonary	$196	$441	$ 0.000
Immunization Administration for Vaccines/Toxoids	$131	$295	$ 0.000
Vaccines, Toxoids	$107	$241	$ 0.000
Surgery, Maternity Care & Delivery	$82	$186	$ 0.000
Pathology & Laboratory	$46	$104	$ 0.000
Ophthalmology	$6	$14	$ 0.000
Unclassified Services	-$2,707	-$6,095	$(0.000)
All Services	**$9,812,925**	**$22,094,293**	**$ 0.78**

Table D-20: Nurse Practitioners

Nurse Practitioner Services

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Office/Other Outpatient Services	$11,107,518	$25,009,134	$ 0.882
Preventive Medicine Services	$3,039,299	$6,843,134	$ 0.241
Psychiatry	$934,552	$2,104,191	$ 0.074
Immunization Administration for Vaccines/Toxoids	$672,655	$1,514,516	$ 0.053
Chemotherapy Drugs	$513,553	$1,156,290	$ 0.041
Vaccines, Toxoids	$475,106	$1,069,724	$ 0.038
Surgery, Integumentary System	$435,571	$980,709	$ 0.035
Drugs Other Than Chemotherapy	$263,777	$593,908	$ 0.021
Allergy & Clinical Immunology	$262,762	$591,621	$ 0.021
Behavioral Health and/or Substance Abuse Treatment Services	$241,484	$543,712	$ 0.019
Temporary Procedures & Professional Services	$230,139	$518,170	$ 0.018
Hospital Inpatient Services	$223,490	$503,199	$ 0.018
Emergency Department Services	$210,139	$473,139	$ 0.017
Hydration, Therapeutic, Prophylactic, Diagnostic Injections & Infusions, and Chemotherapy & Other Highly Complex Drug or Highly Complex Biologic Agent Administration	$202,404	$455,722	$ 0.016
Consultations	$115,437	$259,912	$ 0.009
Temporary National Codes Est. by Medicaid	$100,044	$225,254	$ 0.008
Pathology & Laboratory	$88,411	$199,062	$ 0.007
Surgery, Cardiovascular System	$78,101	$175,849	$ 0.006
Surgery, Musculoskeletal System	$64,701	$145,678	$ 0.005
Inpatient Neonatal Intensive, and Pediatric/Neonatal Critical Care Services	$50,337	$113,337	$ 0.004
Surgery, Respiratory System	$49,570	$111,609	$ 0.004
Temporary Codes Assigned by CMS	$33,266	$74,901	$ 0.003
Central Nervous System Assessments/Tests (Neuro-Cognitive, Mental Status, Speech Testing)	$33,186	$74,721	$ 0.003
Surgery, Female Genital System	$30,924	$69,626	$ 0.002
Special Otorhinolaryngologic Services	$27,710	$62,391	$ 0.002
Surgery, Urinary System	$27,235	$61,321	$ 0.002
Home Health Procedures/Services	$25,078	$56,463	$ 0.002
Temporary National Codes Est. by Private Payers	$25,070	$56,447	$ 0.002
Cardiovascular	$24,816	$55,874	$ 0.002
Nursing Facility Services	$20,998	$47,278	$ 0.002
Pulmonary	$20,552	$46,273	$ 0.002
Surgery, Digestive System	$17,243	$38,824	$ 0.001
Hospital Observation Services	$17,091	$38,481	$ 0.001
Surgery, Nervous System	$15,720	$35,393	$ 0.001
Surgery, Maternity Care & Delivery	$14,362	$32,336	$ 0.001
Critical Care Services	$14,178	$31,923	$ 0.001
Surgery, Auditory System	$14,034	$31,599	$ 0.001
Newborn Care Services	$14,031	$31,591	$ 0.001
Photodynamic Therapy	$13,964	$31,441	$ 0.001
Anesthesia	$13,051	$29,386	$ 0.001
Radiology	$10,609	$23,887	$ 0.001
Neurology & Neuromuscular Procedures	$9,732	$21,913	$ 0.001

Nurse Practitioner Services

Summary of Services Used by Category (cont'd)

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Gastroenterology	$6,780	$15,266	$ 0.001
Physical Medicine & Rehabilitation	$6,733	$15,160	$ 0.001
Special Services, Procedures, and Reports	$4,732	$10,654	$ 0.000
Medical Nutrition Therapy	$4,199	$9,454	$ 0.000
Orthotics	$3,713	$8,360	$ 0.000
Home Services	$2,929	$6,595	$ 0.000
Endocrinology	$2,377	$5,353	$ 0.000
Surgery, Male Genital System	$2,111	$4,754	$ 0.000
Surgery, Eye & Ocular Adnexa	$1,600	$3,603	$ 0.000
Prolonged Services	$1,462	$3,292	$ 0.000
Special Dermatological Procedures	$1,066	$2,399	$ 0.000
Other Services & Procedures	$1,063	$2,394	$ 0.000
Surgery, Hemic and Lymphatic Systems	$945	$2,128	$ 0.000
Noninvasive Vascular Diagnostic Studies	$742	$1,670	$ 0.000
Immune Globulins, Serum, or Recombinant Prods	$638	$1,437	$ 0.000
Surgery, General	$573	$1,290	$ 0.000
Medical & Surgical Supplies	$448	$1,009	$ 0.000
Durable Medical Equipment	$410	$922	$ 0.000
Health & Behavior Assessment/Intervention	$358	$806	$ 0.000
Surgery, Endocrine System	$289	$651	$ 0.000
Ophthalmology	$289	$651	$ 0.000
Moderate (conscious) Sedation	$152	$343	$ 0.000
Domiciliary, Rest Home (boarding home) or Custodial Care Services	$142	$320	$ 0.000
Administrative, Miscellaneous & Investigational	$108	$244	$ 0.000
Chiropractic Manipulative Treatment	$14	$32	$ 0.000
Hearing Services	$13	$28	$ 0.000
Unclassified Services	-$1,993	-$4,487	$ (0.000)
All Services	**$19,823,794**	**$44,634,265**	**$ 1.57**

Table D-21: Physician Assistants

Physician Assistant Services

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Office/Other Outpatient Services	$8,227,023	$18,523,554	$0.653
Preventive Medicine Services	$3,225,276	$7,261,871	$0.256
Surgery, Musculoskeletal System	$1,124,869	$2,532,698	$0.089
Pathology & Laboratory	$793,004	$1,785,488	$0.063
Drugs Other Than Chemotherapy	$656,447	$1,478,023	$0.052
Surgery, Integumentary System	$536,993	$1,209,066	$0.043
Vaccines, Toxoids	$505,590	$1,138,361	$0.040
Psychiatry	$369,187	$831,243	$0.029
Hospital Inpatient Services	$367,589	$827,645	$0.029
Surgery, Digestive System	$345,418	$777,726	$0.027
Immunization Administration for Vaccines/Toxoids	$286,280	$644,574	$0.023
Allergy & Clinical Immunology	$222,408	$500,762	$0.018
Emergency Department Services	$172,171	$387,652	$0.014
Surgery, Nervous System	$157,655	$354,968	$0.013
Surgery, Female Genital System	$154,704	$348,324	$0.012
Temporary Procedures & Professional Services	$123,065	$277,086	$0.010
Nursing Facility Services	$122,731	$276,336	$0.010
Surgery, Maternity Care & Delivery	$110,779	$249,425	$0.009
Hospital Observation Services	$80,820	$181,970	$0.006
Critical Care Services	$74,723	$168,242	$0.006
Temporary National Codes Est. by Private Payers	$74,545	$167,842	$0.006
Surgery, Cardiovascular System	$69,213	$155,836	$0.005
Hydration, Therapeutic, Prophylactic, Diagnostic Injections & Infusions, and Chemotherapy & Other Highly Complex Drug or Highly Complex Biologic Agent Administration	$65,363	$147,169	$0.005
Anesthesia	$45,544	$102,545	$0.004
Pulmonary	$32,183	$72,461	$0.003
Health & Behavior Assessment/Intervention	$31,346	$70,578	$0.002
Temporary Codes Assigned by CMS	$31,045	$69,899	$0.002
Central Nervous System Assessments/Tests (Neuro-Cognitive, Mental Status, Speech Testing)	$28,644	$64,494	$0.002
Surgery, Urinary System	$16,307	$36,716	$0.001
Cardiovascular	$16,243	$36,573	$0.001
Surgery, Respiratory System	$15,327	$34,510	$0.001
Surgery, Auditory System	$14,065	$31,667	$0.001
Special Otorhinolaryngologic Services	$11,884	$26,758	$0.001
Inpatient Neonatal Intensive, and Pediatric/Neonatal Critical Care Services	$9,678	$21,790	$0.001
Surgery, Male Genital System	$9,316	$20,976	$0.001
Physical Medicine & Rehabilitation	$9,171	$20,650	$0.001
Orthotics	$8,038	$18,098	$0.001
Unclassified Services	$7,614	$17,144	$0.001
Special Dermatological Procedures	$6,486	$14,603	$0.001
Domiciliary, Rest Home (boarding home) or Custodial Care Services	$5,400	$12,159	$0.000
Radiology	$4,566	$10,281	$0.000

Physician Assistant Services

Summary of Services Used by Category (cont'd)

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Surgery, Endocrine System	$4,460	$10,042	$0.000
Special Services, Procedures, and Reports	$4,411	$9,933	$0.000
Consultations	$3,889	$8,757	$0.000
Medical Nutrition Therapy	$3,883	$8,744	$0.000
Behavioral Health and/or Substance Abuse Treatment Services	$3,720	$8,376	$0.000
Surgery, Operating Microscope	$3,286	$7,398	$0.000
Newborn Care Services	$2,862	$6,445	$0.000
Immune Globulins, Serum, or Recombinant Prods	$2,619	$5,897	$0.000
Chemotherapy Drugs	$2,377	$5,351	$0.000
Surgery, Eye & Ocular Adnexa	$1,891	$4,259	$0.000
Home Services	$1,854	$4,175	$0.000
Surgery, Hemic and Lymphatic Systems	$1,787	$4,024	$0.000
Neurology & Neuromuscular Procedures	$1,516	$3,413	$0.000
Medical & Surgical Supplies	$1,012	$2,278	$0.000
Other Services & Procedures	$964	$2,171	$0.000
Surgery, Mediastinum & Diaphragm	$845	$1,902	$0.000
Prolonged Services	$693	$1,559	$0.000
Durable Medical Equipment	$648	$1,460	$0.000
Photodynamic Therapy	$468	$1,053	$0.000
Gastroenterology	$352	$793	$0.000
Surgery, General	$292	$658	$0.000
Chiropractic Manipulative Treatment	$35	$78	$0.000
Temporary National Codes Est. by Medicaid	$15	$34	$0.000
Laboratory Services	$10	$23	$0.000
Administrative, Miscellaneous & Investigational	$0	$0	$ -
All Services	**$18,212,602**	**$41,006,587**	**$ 1.45**

Table D-22: Chiropractors

Chiropractor Provider Mandate Services

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Physical Medicine & Rehabilitation	$795,453	$4,087,950	$0.466
Chiropractic Manipulative Treatment	$603,976	$3,103,920	$0.354
Office/Other Outpatient Services	$139,158	$715,154	$0.082
Radiology	$11,883	$61,068	$0.007
Psychiatry	$464	$2,385	$0.000
Temporary Procedures & Professional Services	$320	$1,645	$0.000
Medical Nutrition Therapy	$130	$668	$0.000
Osteopathic Manipulative Treatment	$66	$341	$0.000
Surgery, Cardiovascular System	$22	$113	$0.000
Ophthalmology	$0	$0	$ -
Special Services, Procedures, and Reports	$0	$0	$ -
All Services	**$1,551,472**	**$7,973,244**	**$ 0.91**

Table D-23: Dentists

Dentist Services

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Durable Medical Equipment	$55,029	$282,803	$0.032
Office/Other Outpatient Services	$53,189	$273,346	$0.031
Dental Procedures	$50,663	$260,365	$0.030
Surgery, Musculoskeletal System	$32,024	$164,578	$0.019
Temporary National Codes Est. by Private Payers	$24,826	$127,584	$0.015
Surgery, Digestive System	$23,568	$121,119	$0.014
Surgery, Respiratory System	$10,174	$52,285	$0.006
Physical Medicine & Rehabilitation	$7,472	$38,400	$0.004
Radiology	$4,656	$23,927	$0.003
Pathology & Laboratory	$3,996	$20,538	$0.002
Hospital Inpatient Services	$1,326	$6,812	$0.001
Surgery, Integumentary System	$1,146	$5,890	$0.001
Surgery, Female Genital System	$1,000	$5,139	$0.001
Surgery, Nervous System	$472	$2,424	$0.000
Moderate (conscious) Sedation	$396	$2,037	$0.000
Surgery, Auditory System	$227	$1,169	$0.000
Medical & Surgical Supplies	$80	$411	$0.000
Hydration, Therapeutic, Prophylactic, Diagnostic Injections & I	$32	$167	$0.000
Drugs Other Than Chemotherapy	$0	$0	$ -
Temporary National Codes Est. by Medicaid	$0	$0	$ -
All Services	**$270,277**	**$1,388,993**	**$ 0.16**

Table D-24: Optometrists

Optometrist Services

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Ophthalmology	$1,070,692	$5,502,446	$0.628
Office/Other Outpatient Services	$81,961	$421,210	$0.048
Vision Services	$34,101	$175,250	$0.020
Temporary National Codes Est. by Private Payers	$14,213	$73,043	$0.008
Surgery, Eye & Ocular Adnexa	$4,832	$24,831	$0.003
Surgery, Musculoskeletal System	$3,659	$18,806	$0.002
Psychiatry	$610	$3,134	$0.000
Radiology	$570	$2,928	$0.000
Orthotics	$497	$2,557	$0.000
Neurology & Neuromuscular Procedures	$355	$1,826	$0.000
Surgery, Integumentary System	$329	$1,688	$0.000
Physical Medicine & Rehabilitation	$213	$1,093	$0.000
All Services	**$1,212,032**	**$6,228,813**	**$ 0.71**

Table D-25: Podiatrists

Podiatrist Services

Summary of Services Used by Category

Category	Raw Sample Claims	Adjusted to Fully Insured Population	PMPM
Office/Other Outpatient Services	$3,567,939	$8,033,394	$ 0.283
Surgery, Integumentary System	$1,680,783	$3,784,368	$ 0.133
Surgery, Musculoskeletal System	$1,221,009	$2,749,163	$ 0.097
Orthotics	$298,594	$672,300	$ 0.024
Radiology	$213,312	$480,282	$ 0.017
Surgery, Nervous System	$82,818	$186,469	$ 0.007
Physical Medicine & Rehabilitation	$76,949	$173,254	$ 0.006
Consultations	$33,225	$74,807	$ 0.003
Medical & Surgical Supplies	$24,132	$54,335	$ 0.002
Drugs Other Than Chemotherapy	$23,549	$53,022	$ 0.002
Hospital Inpatient Services	$11,746	$26,448	$ 0.001
Pathology & Laboratory	$10,640	$23,956	$ 0.001
Other Services & Procedures	$8,977	$20,213	$ 0.001
Temporary Codes Assigned by CMS	$5,553	$12,503	$ 0.000
Temporary Procedures & Professional Services	$5,103	$11,490	$ 0.000
Temporary National Codes Est. by Private Payers	$4,808	$10,826	$ 0.000
Hydration, Therapeutic, Prophylactic, Diagnostic Injections & Infusions, and Chemotherapy & Other Highly Complex Drug or Highly Complex Biologic Agent Administration	$1,811	$4,078	$ 0.000
Durable Medical Equipment	$1,499	$3,376	$ 0.000
Nursing Facility Services	$1,474	$3,318	$ 0.000
Prosthetics	$1,223	$2,754	$ 0.000
Home Services	$1,131	$2,548	$ 0.000
Surgery, Digestive System	$882	$1,986	$ 0.000
Noninvasive Vascular Diagnostic Studies	$521	$1,174	$ 0.000
Critical Care Services	$334	$753	$ 0.000
Domiciliary, Rest Home (boarding home) or Custodial Care Services	$326	$735	$ 0.000
Preventive Medicine Services	$307	$691	$ 0.000
Transport Services Including Ambulance	$263	$592	$ 0.000
Prolonged Services	$225	$507	$ 0.000
Vaccines, Toxoids	$208	$468	$ 0.000
Surgery, Cardiovascular System	$96	$216	$ 0.000
Immunization Administration for Vaccines/Toxoids	$83	$187	$ 0.000
Chemotherapy Drugs	$82	$186	$ 0.000
Emergency Department Services	$75	$169	$ 0.000
Special Services, Procedures, and Reports	$56	$126	$ 0.000
Neurology & Neuromuscular Procedures	$39	$89	$ 0.000
Administrative, Miscellaneous & Investigational	$33	$73	$ 0.000
Special Otorhinolaryngologic Services	$12	$26	$ 0.000
Unclassified Services	-$3,473	-$7,820	$(0.000)
All Services	**$7,276,347**	**$16,383,060**	**$ 0.58**

Appendix E: List of Study Acronyms

AAFP	American Academy of Family Physicians
AAP	American Academy of Pediatrics
ABA	Applied Behavior Analysis
ACA	Patient Protection and Affordable Care Act
ACIP	Advisory Committee on Immunization Practices
ACOG	American College of Obstetrics and Gynecology
ACOG	American Congress of Obstetricians and Gynecologists
ACP	American College of Physicians
ACR	American College of Radiology
ACS	American Cancer Society
ADDM	Autism and Developmental Disabilities Monitoring
AHFS-DI	American Hospital Formulary Service-Drug Information
AHRQ	The National Guideline Clearing House under the federal Agency for Healthcare Research and Quality
AMA	American Medical Association
AMA-DE	American Medical Association Drug Evaluations
APA	American Psychiatric Association
APN	Advanced Practice Nurse
APRN	Advanced Practice Registered Nurse
ART	Assisted Reproduction Techniques
ASD	Autism Spectrum Disorder
ASCP	American Society for Clinical Pathology
ASCCP	American Society for Colposcopy and Cervical Pathology
BDC	Base Direct Cost
BLL	Blood Lead Level
BMT	Bone Marrow Transplant
C-Section	Caesarean Section
CAM	Complementary and Alternative Medicine
CDC	Centers for Disease Control and Prevention
CHIA	Center for Health Information and Analysis
CHT	Combined Hormone Therapy

CIA	Chemotherapy-Induced Alopecia
CMS	Centers for Medicare and Medicaid Services
CNM	Certified Nurse-Midwife
COH	Controlled Ovarian Hyperstimulation
CR	Collaborative Reanalysis
CR	Cardiac Rehabilitation
CRNA	Certified Registered Nurse Anesthetist
CVD	Cardiovascular Disease
DIR	Developmental, Individual Differences, Relationship-Based Approach
DMEPOS	Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
DPA	Diagnostic Pharmaceutical Agents
DPM	Doctor of Podiatric Medicine
DSM	Diagnostic and Statistical Manual of Mental Disorders
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, 4th Edition
DSM-V	Diagnostic and Statistical Manual of Mental Disorders, 5th edition
DTT	Discrete Trial Training
DVT	Deep Vein Thrombosis
EHB	Essential Health Benefit
EHDI	Early Hearing Detection and Intervention
EIBI	Early Intensive Behavioral Intervention
EN	Enteral Nutrition
EPC	Evidence-based Practice Center
EPSDT	Early and Periodic Screening, Diagnosis and Treatment
ET	Estrogen Therapy
FDA	Food & Drug Administration
FEDVIP	Federal Vision Insurance Program
HDC-ABMT	High-dose Chemotherapy plus Autologous Bone Marrow Transplant
HEN	Home Enteral Nutrition
HHA	Home Health Agency
HLA	Human Leukocyte Antigen
HMO	Health Maintenance Organization
HPV	Human Papillomavirus

HRSA	Health Resources and Services Administration
HRT	Hormone Replacement Therapy
HSC	Health Service Corporation
HSCT	Hematopoietic (blood) Stem Cell Transplants
ICSI	Intracytoplasmic Sperm Injection
IDEA	Public Law 108-77: Individuals with Disabilities Education Improvement Act (2004)
IVF	In-Vitro Fertilization
JCIH	Joint Committee on Infant Hearing
Kuvan	Sapropterin Dihydrochloride
LPF	Low Protein Food
MD	Medical Doctor
MDC	Marginal Direct Cost
MDD	Major Depressive Disorder
MEPS	Medical Expenditure Panel Survey
MSC	Medical Service Corporation
MWS	Million Women Study
NBEO	National Board of Examiners in Optometry
NCSBN	National Council of State Boards of Nursing
NIDA	National Institute for Drug Abuse
NMDP	The National Marrow Donor Program
NP	Nurse Practitioner
NPA	Non-Physician Anesthetists
NPDC-ASD	The National Professional Development Center on Autism Spectrum Disorder
PA	Physician Assistants
PAM	Patient Assessment and Management
PCHL	Permanent Congenital Hearing Loss
PECS	Picture Exchange Communication System
Phe	Phenylalanine
PKU	Phenylketonuria
PRT	Pivotal Response Training
RDC	Required Direct Cost
RN	Registered Nurse

SNF	Skilled Nursing Facility
SNRI	Selective Serotonin/Norepinephrine Reuptake Inhibitors
SSRI	Selective Serotonin Reuptake Inhibitors
TEACCH	Treatment and Education of Autistic and Related Communication Handicapped Children
TMOD	Treatment and Management of Ocular Disease
TPA	Therapeutic Pharmaceutical Agents
USP-DI	United States Pharmacopoeia-Drug Information
USPSTF	U.S. Preventive Services Task Force
VBI	Verbal Behavior Intervention
WHI	Women's Health Initiative

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> Section 112 of Chapter 224 of the Acts of 2012 amends M.G. L. Chapter 94 C, Section 7 (g) and M.G.L. Chapter 112, Section 9E to remove the requirement that any prescription of medication made by a physician assistant must include the name of the supervising physician.
>
> 263 CMR 5.07: PAs must have written prescription guidelines that are mutually developed and agreed to by the supervising physician and PA. Guidelines must to be reviewed annually and signed by both the PA and the supervising physician. See Prescription Practice" under "Scope of Practice". See 263 CMR 5.07.

[532] *Op. cit.* MA-EOHHS: Physician Assistants, Scope of Practice, Frequently Asked Questions.

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Joint committee member organizations that have adopted this statement include (in alphabetical order): the Alexander Graham Bell Association for the Deaf and Hard of Hearing, the American Academy of Audiology, the American Academy of Otolaryngology-Head and Neck Surgery, the American Academy of Pediatrics, the American Speech-Language-Hearing Association, the Council on Education of the Deaf, and the Directors of Speech and Hearing Programs in State Health and Welfare Agencies. The member organizations of the Council of Education of the Deaf include Council of Education of the Deaf include the Alexander Graham Bell Association for the Deaf and Hard of Hearing, American Society for Deaf Children, Conference of Educational Administrators of Schools and Programs for the Deaf, Convention of American Instructors of the Deaf, National Association of the Deaf, and Association of College Educators of the Deaf and Hard of Hearing.

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The U.S. Preventive Services Task Force (USPSTF) has decided not to review the evidence and update its recommendations for this topic. The previous evidence review and recommendation may contain information that is outdated.

The USPSTF bases its recommendations on current evidence about preventive services. The USPSTF decides not to update some topics (or "inactivate" them) for a number of reasons. Topics may be inactivated because they are no longer relevant to clinical practice. This may be the result of changes in technology, a new understanding of the etiology or natural history of the disease, or the evolving natural history of the disease. Topics may also be inactivated because they involve services that cannot be implemented in a primary care setting or are not referable by a primary care clinician. In addition, topics that have a low public health burden or that otherwise fall outside the scope of the USPSTF may be inactivated.

The USPSTF encourages primary care clinicians to consult other sources for current evidence regarding this topic. If new evidence becomes available, the USPSTF may elect to update this topic.

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1) Reduce blood lead level in children aged 1–5 years: Baseline 5.8 mcg/dL: Concentration level of lead in blood samples at which 97.5 percent of the population aged 1-5 years is below the measured level in 2005–08. Target 5.2 mcg/dL.

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PHS Act section 2713 and the interim final regulations require non-grandfathered group health plans and health insurance coverage offered in the individual or group market to provide benefits for and prohibit the imposition of cost-sharing requirements with respect to, the following:

- Evidenced-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force (USPSTF) with respect to the individual involved;
- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) of CHIAs for Disease Control and Prevention (CDC) with respect to the individual involved;
- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA); and
- With respect to women, evidence-informed preventive care and screening provided for in comprehensive guidelines supported by HRSA, to the extent not already included in certain recommendations of the USPSTF.

If a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of that service, the plan or issuer can use reasonable medical management techniques to determine any coverage limitations.

These requirements do not apply to grandfathered health plans.

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For pregnant women, these include:

- Anemia screening on a routine basis
- Breastfeeding comprehensive support and counseling from trained providers, and access to breastfeeding supplies, for pregnant and nursing women
- Folic acid supplements for women who may become pregnant
- Gestational diabetes screening for women 24 to 28 weeks pregnant and those at high risk of developing gestational diabetes
- Gonorrhea screening for all women at higher risk
- Hepatitis B screening for pregnant women at their first prenatal visit
- Rh Incompatibility screening for all pregnant women and follow-up testing for women at higher risk
- Syphilis screening

- Expanded tobacco intervention and counseling for pregnant tobacco users
- Urinary tract or other infection screening

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