STATE MANDATED HEALTH INSURANCE BENEFITS & HEALTH INSURANCE COSTS IN MASSACHUSETTS

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

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

Executive Summary

Massachusetts General Law (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. BerryDunn has been engaged to prepare the 2020 report.

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

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 (DOI). In addition, the Group Insurance Commission (GIC), which provides benefits to public employees in Massachusetts, voluntarily complies with state benefit mandates. Costs associated with mandated benefits are a subset of the total healthcare 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 DOI and not subject to the benefit mandate laws. The cost implication and clinical efficacy of 45 mandates currently in effect are assessed in this report; the cost results are displayed in Table E1.

The first result column in Table E1 shows this study's estimated marginal paid claims cost impact for each mandate and the total (top results row). The second column shows this amount adjusted for carrier retention, or the marginal contribution to Commonwealth of Massachusetts[i] fully insured commercial health insurance premium. Finally, the third result column calculates the retention-adjusted amount from the second result column as a percentage of total Commonwealth premium (calculated as the sum of total estimated fully insured member months and self-insured GIC member months multiplied by this study's estimate for average monthly premium expense for such plans).

The mandates at the bottom of Table E1 labeled "Mandates Estimated to Have Zero Marginal Cost" were deemed so for one or a combination of the following reasons:

- In the survey administered for this study, Massachusetts health insurance carriers indicated they would cover the health benefits regardless of whether they were mandated
- Federal law superseded the state-mandated benefit, thus erasing any incremental effect of the Massachusetts statute

[i] Commonwealth of Massachusetts, Massachusetts, and Commonwealth are used interchangeably throughout this report.

- Measuring their impact is not feasible
- BerryDunn's analysis resulted in an estimate of zero marginal direct cost
- The net estimated material impact of the mandate was zero after subtracting overlaps with other state mandates
- The mandated services had become clinically obsolete

Table E1[ii]

Summary of Estimated Costs for Massachusetts Mandated Benefits as of 2018

Dollars in Millions (000,000s)

Mandate	Marginal Claims Estimate	Marginal Premium Impact	Percent of Premium
Unduplicated Total All Mandates	$ 90.41	$ 103.48	0.72%
Massachusetts State Mandates with Potential Direct Marginal Cost			
Infertility Services	$ 76.38	$ 87.23	0.61%
Chiropractors	$ 4.82	$ 5.64	0.04%
Acute Treatment and Clinical Stabilization Services	$ 3.61	$ 4.16	0.03%
Child Hearing Aids	$ 1.84	$ 2.15	0.02%
Oral Cancer Drugs	$ 1.57	$ 1.80	0.01%
Low Protein Foods	$ 0.60	$ 0.69	0.00%
Chiropractic Services	$ 0.53	$ 0.62	0.00%
Nonprescription Enteral Formulas	$ 0.44	$ 0.50	0.00%
Cleft Palate and Lip	$ 0.44	$ 0.50	0.00%
HIV-Associated Lipodystrophy Treatment	$ 0.18	$ 0.21	0.00%
Mandates Judged to Have Zero or Unmeasurable Marginal Cost			
Abuse-deterrent Opioids	$ -	$ -	0.00%
Autism Services	$ -	$ -	0.00%
Bone Marrow Transplants for Breast Cancer	$ -	$ -	0.00%
Cardiac Rehab	$ -	$ -	0.00%
Certified Nurse Midwives	$ -	$ -	0.00%
Certified Registered Nurse Anesthetists	$ -	$ -	0.00%
Clinical Trials for Cancer	$ -	$ -	0.00%
Contraception	$ -	$ -	0.00%
Cytologic Screening	$ -	$ -	0.00%
Dentists	$ -	$ -	0.00%
Diabetes	$ -	$ -	0.00%
Early Intervention	$ -	$ -	0.00%
Hearing Screening for Newborns	$ -	$ -	0.00%
HLA Testing	$ -	$ -	0.00%
Home Health Care	$ -	$ -	0.00%
Hospice Care	$ -	$ -	0.00%
HRT	$ -	$ -	0.00%
Lead Screening	$ -	$ -	0.00%
Limb Prosthesis	$ -	$ -	0.00%
Long term antibiotic therapy for the treatment of Lyme disease	$ -	$ -	0.00%
Mammography	$ -	$ -	0.00%
Maternity Care	$ -	$ -	0.00%
Mental Health	$ -	$ -	0.00%
Nurse Practitioner	$ -	$ -	0.00%
Off-label Uses of Prescription Drugs - Cancer	$ -	$ -	0.00%
Off-label Uses of Prescription Drugs - HIV/AIDS	$ -	$ -	0.00%
Optometrists	$ -	$ -	0.00%
Physician Assistants	$ -	$ -	0.00%
Podiatrist	$ -	$ -	0.00%
Prescription Eye Drops	$ -	$ -	0.00%
Preventive Care to Age 6	$ -	$ -	0.00%
Scalp Hair Prosthesis	$ -	$ -	0.00%
Speech & Hearing	$ -	$ -	0.00%
Substance Abuse Treatment Prior Authorization.	$ -	$ -	0.00%
Syringe	$ -	$ -	0.00%

This study estimates a total Commonwealth 2018 paid claim marginal cost impact of health mandate benefits of $90 million. Adjusting this amount for carrier administrative costs (including profits) results in an estimated $103 million

[ii] The estimates used in this analysis are not to be used to determine the defrayal amounts required under the federal Patient Protection and Affordable Care Act for mandates enacted after 12/31/2011 which are to be based solely on the cost of the mandate to Qualified Health Plans. The defrayal analysis is being done separately through the Division of Insurance and the Commonwealth Health Insurance Connector Authority.

marginal impact on Commonwealth fully insured (and self-insured GIC) health insurance premium, or 0.7% of total Commonwealth premium.

BerryDunn developed the mandated cost ranges by considering costs reported by carrier and by market segment, as well as academic literature, market and legal conditions, and carrier-provided information regarding coverage in the absence of the mandate or coverage in other states without a similar mandate in effect. The approach to each mandate calculation is described in the individual mandate results sections below. Marginal cost estimates are bounded at zero. That is, this analysis does not consider the possibility that some mandates (e.g., home health services preventing hospitalizations) are actually cost-saving on net. Overlaps between mandates (e.g., low-protein foods and nonprescription enteral formulas) are netted out in the individual mandate calculations, as described in the individual mandate results sections below. Individual mandate results are summed to calculate the overall mandate marginal cost estimate.

In addition to the direct cost impacts, there are indirect cost effects, such as avoided hospitalizations as a result of the home health mandate, which we are not able to address in this study. There are individual and socially beneficial impacts aside from health care spending that these mandates may, and in many cases certainly do, provide.[1]

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

Introduction and Background

Statutory Basis and Scope

Massachusetts General Law (M.G.L.) Chapter 3 Section 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. BerryDunn was engaged to prepare this analysis. This is the fourth comprehensive review of health benefit mandates, and the third under the M.G.L. Chapter 3 Section 38C. The first comprehensive review was published in 2008 as required under Chapter 58 of the Laws of 2006.

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 three mandate review reports, and adds to that set new mandates passed since the analysis period for the 2016 report. This report addresses mandates in force throughout 2018. It does not address Chapter 120 of the Acts of 2017, "An Act Relative to Advancing Contraceptive Coverage and Economic Security in our State," the relevant portions of which were not effective until July 2018, 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 members with specific conditions. 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 nonmedical 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, with the exception of the cleft lip and palate mandate, 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 BerryDunn performed this analysis were from calendar year 2018 (as paid through June 30, 2019), which sets the time frame basis for the study.

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.[iii] This approach is consistent with the treatment of indirect costs in the economic analysis, and consistent with the treatment of indirect costs in the previous reviews.

Approach to Analyzing Mandate Costs

For calendar year 2018, 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

[iii] 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.

the study apply to fully insured commercial plans regulated by the DOI. 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, it is BerryDunn'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 Employee Retirement Income Security Act of 1974 (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 Employees Health Benefit Plan (FEHB) Program

This analysis excludes members of fully insured plans over 64 years of age, and it 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 2018 MA APCD formed the base for this study's insured member population projections. The MA APCD provided fully insured membership by insurance carrier. The MA APCD was also used to estimate the number of nonresidents covered by a Commonwealth policy. These are typically cases in which a nonresident works for a Commonwealth employer that offers employer-sponsored coverage. BerryDunn made adjustments to the data for membership not in the MA APCD, based on published membership reports available from CHIA and the DOI. The projections lead to an estimate of 3.7 million Massachusetts residents under age 65 covered by employer-sponsored plans in 2018, approximately 1.4 million of whom are fully insured. BerryDunn used MA APCD residential status data to develop an estimate of approximately 293,600 additional individuals under age 65 residing in other states who are covered by Massachusetts-issued fully insured employer-sponsored insurance subject to the mandates. Finally, the CHIA enrollment trends report through March 2020[2] yielded an estimate of approximately 306,000 persons under age 65 who purchased insurance in the non-group market in 2018. The sum of the employer-sponsored state residents, nonresidents, and individually insured produces a total estimate of two million fully insured members. Because self-insured GIC plans follow the mandates voluntarily, an additional 320,000 members are added to the covered population (based on membership figures provided directly to BerryDunn by the GIC) for a total of 2.3 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, health maintenance organization (HMO)); some, however, apply only to subsets of licenses. Others effectively apply only to the large

group market because the mandates were in place for the 2014 plan year, and therefore, they were included in that year's Massachusetts Affordable Care Act (ACA) benchmark plan.

To calculate the percentage of premium, the analysis uses as a member-months denominator the sum of member-months for all license types to estimate the per-person costs of the benefits with respect to the overall average fully insured health insurance premium in the Commonwealth. However, for the mandates that apply to less than the entire fully insured population, estimated claims were included in the numerator only for the subgroups 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 subgroup(s) to which the mandate applies.

Table 1
2018 Estimates of Populations to Which Mandates Apply

Mandate	Applicable Population	EHB in Benchmark Plan? (i.e., Lg group only)	Estimated Statute Membership	Estimated Effective Membership (incl. SI GIC)
Certified Nurse Midwives Chiropractors Dentists Optometrists	Indemnity and Blue Cross/Blue Shield fully insured members	NO	511,274	831,041
Chiropractic Services	Blue Cross/Blue Shield fully insured members, *excluding* HMO Blue	NO	172,158	172,158
Infertility Services	All fully insured Massachusetts-resident members	YES	1,059,974	1,379,741
Certified Registered Nurse Anesthetists	All fully insured members	YES	1,281,109	1,600,876
Early Intervention		YES		
Home Health Care		YES		
HRT		YES		
Low-Protein Foods		YES		
Nurse Practitioner		YES		
Podiatrist		YES		
Syringe		YES		
Cardiac Rehab		YES		
Clinical Trials for Cancer		YES		
Contraception		YES		
Cytologic Screening		YES		
Lead Screening		YES		
Mammography		YES		
Off-Label Uses of Prescription Drugs - Cancer		YES		
Off-Label Uses of Prescription Drugs - HIV/AIDS		YES		
Preventive Care to Age 6		YES		
Acute Treatment and Clinical Stabilization Services	All fully insured members and all GIC members (fully and self-insured)	NO	2,326,947	2,326,947
Substance Abuse Treatment Prior Authorization		NO		
Abuse-Deterrent Opioids		NO		
HIV Associated Lipodystrophy Treatment		NO		
Long term antibiotic therapy for the treatment of Lyme disease		NO		
Prescription Eye Drops		NO		
Autism Services		YES	1,600,876	1,600,876
Child Hearing Aids		YES		
Cleft Palate and Lip		YES		
Diabetes		YES		
HLA Testing		YES		
Limb Prosthesis		YES		
Mental Health		YES		
Nonprescription Enteral Formulas		YES		
Oral Cancer Drugs		YES		
Physician Assistants		YES		
Scalp Hair Prosthesis		YES		
Speech & Hearing		YES		
Bone Marrow Transplants for Breast Cancer		YES		
Hearing Screening for Newborns		YES		
Hospice Care		YES		
Maternity Care		YES		

Estimates of the insured population by carrier license type and market segment were derived from CHIA's December 2019 report on the performance of the health care market in Massachusetts in 2018.[3]

Sample Population

To develop a cost estimate for each mandate with potential marginal cost, 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. The estimated PMPM cost developed from claim data drew upon calendar year 2018 data from

CHIA's MA APCD, Release 8.0. CHIA collects and manages data from commercial carriers, third-party administrators, and public programs.[4] 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 completed. This quality-controlled sample comprises approximately 90% of total commercial fully insured and self-insured GIC primary medical membership under age 65 in the Commonwealth. BerryDunn relied upon this quality-controlled data sample after verifying basic reasonableness checks on membership and expenses. BerryDunn 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 2018 was 1.7 million, or 74% of the estimated 2.3 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.

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 Mandate Costs

Before addressing the total costs of mandate laws, it is first important to define terminology for the purpose of this report. 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 (RDCs).** 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. RDCs are the sum of *base direct costs* and *marginal direct costs.*
    - ***Base direct costs*** 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*** are those additional costs beyond the base direct costs that the imposition of the mandate impels. This study estimates these costs.
- **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).

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 (e.g., those indirect costs associated with the marginal utilization produced by the mandate law). Because 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

This study estimates marginal direct costs of the mandates only. BerryDunn developed marginal direct cost estimates by considering costs reported by carrier and by market segment, as well as academic literature, market and legal conditions, and carrier-provided information regarding coverage in the absence of the mandate.

Measuring indirect costs is far more difficult and not within the scope of this study. A well-conducted multivariate statistical analysis using multistate data would be better able to estimate marginal costs that include both direct and indirect components, as well as isolate their individual effects. 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.[5]

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 plan) must be added to the claims expense measures described above. BerryDunn estimated administrative loading for the populations to which the mandates apply based CHIA's December 2019 report on the performance of the Massachusetts health care system[6] and data provided to BerryDunn by the GIC. These administrative loading factors are shown in Table 2 below. To arrive at estimates of fully loaded healthcare premium costs, claims costs were divided by one minus the applicable administrative load. For example, this study estimates 2018 fully insured administrative loading across all market segments. Premium impacts applicable to this population are therefore calculated as paid claim expenses divided by (1 – 0.145), or 0.855.

Table 2
2018 Administrative Loading Factor Estimates

Funding Type/Market Segment	2018 Admin Factor
All Fully Insured (FI)	14.5%
Large Group FI	14.5%
All FI + self-insured (SI) GIC	13.1%
Large Group FI + SI GIC	12.4%

The mandates in the study were reviewed by the major carriers in Massachusetts to ascertain whether, in their opinion, the benefits would be offered if the mandate were repealed. Those for which the law was judged not to affect benefit offerings were deemed "zero marginal direct cost" mandates. In addition, this analysis deemed a number of additional mandates to have zero marginal direct cost, for one or a combination of the following reasons:

- Federal law superseded the state-mandated benefit, thus erasing any incremental effect of the Massachusetts statute
- Measuring their impact is not feasible
- BerryDunn's analysis resulted in an estimate of zero marginal direct cost
- The net estimated material impact of the mandate was zero after subtracting overlaps with other state mandates
- The mandated services had become clinically obsolete

The reasoning for the zero-cost determination is described for each mandate in the mandate-specific results sections following. Costs of the remaining "mandates with potential marginal direct cost" were estimated using the MA APCD, except as noted.

Effect of the Affordable Care Act (ACA) on the Incremental Cost of the Mandates

The ACA creates statutory 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. For the 2018 study year, the plan as offered in 2014 served as the benchmark.[7] 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.[iv] The benefits of the benchmark plan are required by the ACA in all health insurance plans sold on the state's ACA exchange. Effectively, this means any mandate in force throughout 2018 is a required benefit in the Massachusetts individual and small-group health insurance market. Therefore, the effects of these state mandates on the individual and small-group markets are considered superseded by federal law for purposes of this study, and their marginal impact only affects large-group fully insured and self-insured GIC plans. Table 1 above indicates which mandates were included as EHBs in the benchmark plan.

Finally, Section 1311 of the ACA[8] 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. [i] The estimates used in this analysis are not to be used in determining defrayal amounts required under the ACA for mandates enacted after 12/31/2011 which are to be based solely on the cost of the mandate to Qualified Health Plans. The defrayal analysis is performed separately through the Division of Insurance and the Commonwealth Health Insurance Connector Authority.

[iv] 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.

Results

This section presents results of both the efficacy and cost reviews for mandates with positive estimated marginal direct cost and mandates with zero marginal direct cost. The mandates with positive estimated marginal direct cost are presented in descending order of total dollar impact on Commonwealth fully insured and self-insured GIC commercial health insurance expense.

1.0 Mandates with Positive Estimated Marginal Direct Cost

Infertility Treatment

For members covered under plans that include pregnancy-related benefits, the infertility mandate requires coverage for the diagnosis and treatment of infertility to the same extent benefits are provided for other pregnancy-related procedures.[9]

Effect of the Mandate on Health

Infertility is a term describing the inability of a couple to get pregnant or the inability of a woman to carry a pregnancy to term.[10] Infertility is clinically defined as the inability to achieve pregnancy after one year of having regular, unprotected intercourse, or after six months for a woman over age 35.[11] An estimated 13.1% of women age 15 to 44 have an impaired fecundity (the ability to get pregnant and carry a baby to term).[12] Between 2006 and 2010, 12% of women age 15 to 44 as well as their husbands or partners had ever used infertility services; among women age 25 to 44, 17% had used any infertility service, a significant decrease from 20% in 1995.[13] From 2015–2017, 12.7% of women age 15 to 49 had ever used infertility services, representing a continued decrease in utilization of infertility services.[14]

Research shows that infertility affects about 12% of all people of reproductive age, women and men, and is caused by a range of factors from: environmental factors, such as exposure to chemicals or smoking; to physical factors, such as blocked fallopian tubes or obesity; to conditions that prevent production of sperm or mature eggs.[15] Infertility is attributable to the woman about a third of the time, to the man about a third of the time, and to undetermined causes for the remainder of cases.[16] For women, the most common cause of infertility results from problems with ovulation, but it can also result from age, physical and hormonal problems, or environmental or lifestyle factors.[17] For men, the most common causes of infertility are problems with the way in which the testicles, which make and store sperm, function; hormonal imbalances; blockages in the male reproductive organs; or genetic disorders.[18,19] As with female infertility, the causes of male infertility might be a result of environmental and lifestyle factors or certain medical conditions or treatments such as chemotherapy or surgery resulting in the removal of one or both testicles.[20]

Infertility can be treated with medicine, surgery, intrauterine insemination, or assisted reproductive technology (ART).[21] Doctors recommend specific treatments based on the age of the female, the factors contributing to and duration of infertility, and the couple's treatment preferences after counseling about success rates, risk, and benefits of each treatment option.[22] In addition to medications and surgery, infertility treatments might also include lifestyle

changes with some treatments being combined.[23] In some cases, infertility can be successfully treated even if no cause is found.[24]

Medications are most often used to induce ovulation through various techniques such as ovulation induction or controlled ovarian hyperstimulation (COH).[25] In ovulation induction, the goal is to stimulate growth, maturation, and ovulation of a single follicle with medication, whereas, multiple follicles are stimulated to grow and mature with medications with COH.[26] After ovulation induction, the single follicle is then fertilized secondary to timed intercourse or artificial insemination, where semen is injected directly into the uterus; artificial insemination or intrauterine insemination can also be used with either natural or drug-induced ovulation.[27] COH is necessary for ARTs that are more complex and invasive techniques in which eggs are manipulated and fertilized outside the body with the resulting embryos either returned to the uterus for implantation or cryopreserved.[28] The main type of ART is in vitro fertilization (IVF).[29] Surgeries that may be used to treat infertility in women repair blocked or damaged fallopian tubes, treat endometriosis, and remove polyps or fibroids in the uterus; in men, surgery is most commonly used to treat swollen veins in the scrotum.[30] Most infertility cases, 85% to 90%, are treated with conventional medical therapies such as medication or surgery; IVF and other similar forms of ART account for less than 3% of infertility services.[31]

The effectiveness of infertility treatment is difficult to summarize, as the factors leading to the treatment's use vary for each patient. One study summarized that personalization of therapy might help to optimize efficacy and safety outcomes for individual patients; however, additional well-designed, good-quality studies are required to drive improvements in the diagnosis and management of ART processes in future years.[32] Testing and treatment practices of infertility specialists continue to vary widely and evolve, with practice patterns being influenced by both ART and the increasing age of couples seeking help for infertility.[33]

One large study reviewed the evidence regarding the outcomes of interventions used in ovulation induction, COH, and IVF for the treatment of infertility, 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 infants.[34] The authors found that despite the large emotional and economic burden resulting from infertility, there is relatively little high-quality evidence to support the choice of specific interventions.[35] Other studies have found that ART, with nearly continuous improvement in the years since its inception, results in reasonably high pregnancy rates, prompting couples to move to ART more quickly in the management of their infertility.[36,37]

Older studies found an increased risk for adverse pregnancy outcomes associated with ART, with more than 30% of ART pregnancies resulting in twins or higher-order multiple gestations (triplets or greater),[38] and more than half of all ART neonates are the products of multifetal gestations, with an attendant increase in prematurity complications.[39] Although much of the morbidity in children born after ART is the result of multiples, even singletons are at a higher risk for perinatal morbidity, including preterm delivery and small for gestational age infants.[40] Children born via such treatments are at risk for complications associated with abnormal placentation or implantation; the degree to which this is due to underlying infertility, treatment, or both is unclear.[41] However, a more recent study noted that this major risk of multiple births and the associated excess of perinatal morbidity has been reduced over time, with fewer and better-quality embryos being transferred.[42]

Maternal complications, such as preeclampsia, gestational diabetes, placenta previa, placental abruption, and cesarean delivery, have also been associated with ART, although it is not possible to separate ART-related risks from those secondary to the underlying reproductive pathology.[43] Beyond these complications, the major short-term complication of ART for women is ovarian hyperstimulation syndrome, but new treatments are being developed that might limit its frequency.[44]

Information from the National Institutes of Health found that, for women treated with the medication Clomiphene to stimulate hormones to help eggs mature in the ovaries, 80% ovulate, and about half of those who ovulate are able to achieve a pregnancy or live birth.[45] The drugs Bromocriptine or Cabergoline are taken to reduce abnormally high levels of prolactin, which has been shown to interfere in ovulation, resulting in 90% of women having normal prolactin levels, with 85% of these women then being able to ovulate.[46] The success of surgical treatment for infertility caused by diseases of the fallopian types is low and can increase the risk of ectopic pregnancy; however, surgeries to remove endometrial patches can double the chances for pregnancy.[47] Pregnancy rates from ART depend, among other factors, on the age of the mother. The following table summarizes national ART success rates:[48]

Table 3

2017 National ART Summary Success Rates

(Based on cycles that started in calendar year 2016 and were followed for 12 months)

	Age of Women				
	<35	35-37	38-40	41-42	> 42
Percentage of retrievals[v] resulting in live births – using their own eggs					
Singleton	44.9	34.4	23.2	12.5	4.0
All	54.5	41.1	26.7	13.8	4.2
Percentage of egg or embryo transfers[vi] resulting in live births – using their own eggs					
Singleton	40.0	36.0	31.1	22.5	10.3
All	48.5	43.0	35.8	24.9	11.0
Percentage of transfers resulting in live births (all ages) – using donor eggs or embryos					
	Fresh Embryos Fresh Eggs		**Fresh Embryos Frozen Eggs**		**Frozen Embryos**
Singleton	45.1		39.4		39.5
All	55.3		46.7		46.5

[v] A retrieval represents an ART cycle in which at least one egg was retrieved.

[vi] A transfer means at least one egg or embryo transfer was retrieved from the patient in 2016 and was transferred within 12 months of the start of a cycle (in 2016 or 2017). The eggs or embryos can be either fresh or previously frozen or thawed.

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.[49] Ultimately, the choice of treatment will depend on a balance of the chances of conceiving with or without treatment—and with more-complicated or less-complicated treatments—and on other factors such as duration of infertility and the woman's age.[50]

Estimated Marginal Cost of the Mandate

Carrier responses indicated the Massachusetts infertility benefit mandate drives coverage decisions for these services in the fully insured market in the Commonwealth. However, the mandate was enacted in 2005. Therefore, the benefits are EHBs in the state ACA benchmark plan, and the state mandate is superseded by federal statute in the individual and small-group markets. BerryDunn therefore estimated the marginal cost of this mandate as the estimated MA APCD sample RDC for services related to infertility diagnosis and treatment for fully insured Massachusetts residents (unlike other mandates, this mandate applies only to members resident in Massachusetts; it does not extend to nonresidents covered by Massachusetts employers) in large group products in the state in 2018.

To estimate 2018 costs, BerryDunn first calculated PMPM paid claim expenses from the MA APCD Release 8.0 for the years 2016 to 2018. These results are displayed below in Table 4.

Table 4

Infertility Mandate

Sample PMPM Claim Expenses by Service Year

In Raw and 2018 Dollars

Cost	2016	2017	2018
Sample Paid PMPM	$ 4.02	$ 4.57	$ 4.57
Paid PMPM, 2018 $	$ 4.44	$ 4.79	$ 4.57

To set a likely impact range for the mandate, BerryDunn trended these annual PMPM paid expenses forward by medical inflation,[51] taking the resulting minimum ($4.44 PMPM) and maximum ($4.79 PMPM) results as the ends of the range. These results are shown in Table 4 above. Applying this study's estimated large group fully insured 2018 retention factor of 14.5% to the ends of the range and calculating the resulting percent contribution to premium using this study's estimated large group fully insured 2018 premium of $539 results in a mandate impact range of 0.96% to 1.04%. These results are displayed in Table 5 below.

Table 5

Infertility Mandate

Impact Range Calculation

Measures	Minimum	Maximum
Paid PMPM	$ 4.44	$ 4.79
Paid PMPM With Admin	$ 5.20	$ 5.61
Percent of Total Premium	0.96%	1.04%

BerryDunn chose the midpoint of the percent of premium range, one percent of large group fully insured premium, or $5.41 PMPM,[vii] as the point estimate of marginal mandate impact for purposes of this study. Deflating this figure by the large group fully insured retention factor results in a paid claim expense PMPM impact estimate of $4.61. Multiplying the estimated PMPM paid claim expense and premium (paid claim expense plus administrative loading) by twelve months of estimated average monthly Massachusetts-resident health insurance membership subject to the mandate results in a total estimated paid claim impact of $76 million and estimated premium impact of $87 million. These results and related statistics are displayed in Table 6 below. Recall that the population percent of total premium figure in each of the final mandate result exhibits includes all fully insured and self-insured GIC membership and uses the estimated all-market fully insured and self-insured GIC premium estimate of $512.

Table 6

Infertility Mandate

Contribution to Premium

Measures	Sample Estimate
Sample Average Members	727,882
Paid PMPM	$ 4.61
Paid PMPM With Admin*	$ 5.41
Allowed PMPM	$ 4.84
	Premium Impact Estimate
Insured Population	1,379,741
Contribution to Total Annual Claims	$ 76,383,282
Contribution to Total Annual Premium	$ 87,226,087
Percent of Total Premium	0.611%

*$5.41 PMPM represents large group FI premium. The equivalent amount is $5.27 when including SI GIC, as is the case in the premium impact estimate section of the exhibit.

Chiropractors

The chiropractor provider mandate requires coverage by general health insurance corporations for chiropractic services, whether performed by a physician or by a chiropractor. A related statute (M.G.L. c. 176B § 7) prohibits a medical service corporation from discriminating against chiropractors in providing chiropractic services. Chiropractors

[vii] The exact midpoint of the premium impact range is 1.0031 percent. BerryDunn used this figure to calculate the estimated premium impact PMPM.

provide both chiropractic services and non-chiropractic services, and chiropractic services are provided by both chiropractors and other providers.[52]

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.[53] The goals of chiropractic care include improved joint motion and function, with an emphasis on the body's ability to heal itself.[54] In theory, by aligning spinal joints, chiropractors improve the function of the body's nervous system and improve overall health.[55] Chiropractors treat patients of all ages with a variety of health conditions, and are well known for their expertise in caring for patients with back pain, neck pain, and headaches.[56]

Chiropractors typically complete nearly four years of pre-medical undergraduate education, followed by four to five years at a chiropractic college, where the curriculum includes at least 4,200 hours of classroom, laboratory, and clinical experience.[57] The chiropractic course of study is approved by the Council on Chiropractic Education, an accrediting body fully recognized by the United States Department of Education.[58] For licensure in Massachusetts, graduates of a chiropractic college must pass Parts I, II, III, and IV—and the special Physiotherapy section—of the board exam administered by the National Board of Chiropractic Examiners, as well as the Massachusetts jurisprudence examination administered by the state Board of Registration of Chiropractors.[59] Massachusetts also requires chiropractors to complete at least 12 hours of continuing education annually to maintain and renew licensure.[60]

Licensed chiropractors are recognized by Medicare for payment as a physician only for manual spinal manipulation treatment of spinal subluxation.[61,62] Medicare does not cover other services or tests ordered by chiropractors.[63] As a result, for Medicare beneficiaries, chiropractors are not eligible to order and/or refer for Part B services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS),[64] but they might act as a supplier of durable medical equipment.[65]

Few studies exist on the prognostic value of demographic, clinical, or psychosocial factors on long-term outcomes for patients with chronic low back pain.[66] In one study, chiropractic care compared favorably to medical care with respect to long-term pain and disability outcomes.[67] 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.[68] The same study found that costs were lowest for primary care providers, and patient satisfaction highest for chiropractors.[69] A more recent article examining the costs of care between chiropractors and other providers was equivocal in its conclusions and called for additional research.[70]

Estimated Marginal Cost of the Mandate

As noted above, this mandate's reach is limited to general health insurance corporations. HMOs are regulated under a separate chapter of Massachusetts law that does not require the benefit. Therefore, this analysis estimates the marginal cost of this mandate as the difference between the PMPM costs of chiropractor services reported in the MA APCD for non-HMO products subject to the mandate and the 2018 PMPM costs of chiropractor services reported in the MA APCD for HMO products.

To derive the estimate, BerryDunn first limited the sample data to the three major sample carriers reporting both HMO and non-HMO products. BerryDunn then extracted and summarized MA APCD claims for the years 2016 to 2018 where the billing or servicing provider National Provider Identifier (NPI) reported on the claim had a National Plan and Provider Enumeration System (NPPES) primary taxonomy indicating the provider was a doctor of chiropractic (defined as "111N" appearing as the first four characters of the taxonomy code). Next, claims overlapping with the chiropractic services mandate analysis and impact were removed from the sample (i.e., claims reported by Blue Cross/Blue Shield of Massachusetts (BCBSMA) for chiropractic procedures subject to the chiropractic services mandate) to avoid double-counting mandate marginal impacts.

BerryDunn next calculated sample PMPM paid and allowed costs for chiropractor services for the two product types for paid claims with service dates in years 2016, 2017, and 2018. Non-HMO paid PMPM costs were consistently higher throughout the period. Table 7 below shows these results.

Table 7

Paid Cost and Allowed Cost PMPM, 2016 – 2018

HMO Products vs. Non-HMO Products Subject to the Chiropractor Provider Mandate

	2016		2017		2018	
Cost	Non-HMO Sample Amount	HMO Sample Amount	Non-HMO Sample Amount	HMO Sample Amount	Non-HMO Sample Amount	HMO Sample Amount
Paid PMPM	$ 1.18	$ 0.66	$ 1.29	$ 0.63	$ 1.06	$ 0.59
Allowed PMPM	$ 1.60	$ 0.97	$ 1.72	$ 0.94	$ 1.47	$ 0.90

Difference	2016	2017	2018	Mean
Paid PMPM	$ 0.52	$ 0.66	$ 0.47	$ 0.55
Allowed PMPM	$ 0.62	$ 0.78	$ 0.57	$ 0.66

Noting the consistency of the PMPM cost differences for 2016 and 2017 followed by the drop observed in 2018, BerryDunn utilized the average of the observed PMPM differences over the three years to calculate the chiropractic services marginal cost estimate, providing a measure of conservatism for the estimate. This difference, or the marginal cost of the mandate, may be attributable to increased utilization, variation in population characteristics, referral requirements by primary care physicians in the HMO population, or other factors. While isolating the individual effects of these factors is beyond the scope of this analysis, BerryDunn conservatively assumes the entire cost difference is driven by higher utilization in the non-HMO group.

The average annual difference in allowed PMPM costs between the two product types was found to be $0.66 for these services. To calculate the marginal direct cost impact of the mandate, BerryDunn then multiplied this difference by 74%, the average annual ratio, over the period 2016 to 2018, of plan paid amounts to plan allowed amounts for plans subject to the mandate.[viii] This resulted in an estimated marginal claims cost impact of $0.48, or $0.57 including administrative loading. Because this mandate only applies to the small population of fully insured members in non-HMO products, the total estimated 2018 premium impact of this mandate is approximately $5.6 million, or 0.04% of

[viii] The analogous figure for HMO Blue plans in the sample was 35%.

2018 Commonwealth fully insured premium. Therefore, the impact of this mandate relative to the total fully insured population is not material. Table 8 below displays a summary of these results and related statistics.

Table 8

Chiropractor Provider Mandate

2018 Contribution to Premium

Measures	2018 Non-HMO Sample Amount	2018 HMO Sample Amount	2018 Premium Impact Estimate*
Sample Average Members	234,631	1,070,543	234,631
Paid PMPM	$ 1.06	$ 0.59	$ 0.48
Paid PMPM With Admin	$ 1.23	$ 0.69	$ 0.57
Allowed PMPM	$ 1.47	$ 0.90	$ 0.66

	Impact
Insured Population	831,041
Contribution to Total Annual Claims	$ 4,820,985
Contribution to Total Annual Premium	$ 5,635,616
Percent of Total Premium	0.039%

*Net amounts *exclude* overlap between mandated services between the chiropractic services mandate and the chiropractor provider mandate.
The impact is calculated as the average of the differences between the HMO and non-HMO PMPMs for the years 2016-2018.
Removing overlapping claims from BCBS Blue products only reduces the BCBS Blue allowed amount such that the overall weighted sample allowed amount for non-HMO products is lower than the HMO products weighted average sample allowed amount. This measure is not useful and therefore is not presented above.

Acute Treatment Services (ATS) and Clinical Stabilization Services (CSS)

Among the provisions of Chapter 258 of the Massachusetts Acts of 2014, two place restrictions on the ability of health insurance carriers to require authorization for substance use disorder services. Carriers generally require providers to obtain prior authorization for substance use disorder services or the carrier will deny payment. In addition, for facility services, the carrier may review the necessity of continuing the treatment (in a "concurrent review") and may sometimes terminate authorization for an ongoing stay. Chapter 258 eliminates preauthorization across the spectrum of substance use disorder services, and for two intensive facility-based services, eliminates carriers' ability to terminate authorization for the first 14 days of a treatment episode involving those two services. Specifically, these provisions of the law require:

- Prior authorization for substance abuse treatment: "Any [health insurance] coverage…shall not require a member to obtain preauthorization for substance abuse treatment if the provider is certified or licensed by the department of public health." The law further defines substance abuse treatment to include "early intervention services for substance use disorder treatment; outpatient services including medically assisted therapies; intensive outpatient and partial hospitalization services; residential or inpatient services, not covered [elsewhere in the law]; and medically managed intensive inpatient services, not covered [elsewhere in the law]."[71]

- Prior authorization and concurrent review for ATS and CSS: Health insurance plans "shall provide…coverage for medically necessary acute treatment services[ix] and medically necessary clinical stabilization services[x] for up to a total of 14 days and shall not require pre-authorization prior to obtaining acute treatment services or clinical stabilization services; provided that the facility shall provide the carrier both notification of admission and the initial treatment plan within 48 hours of admission; provided further, that utilization review procedures may be initiated on day 7. Medical necessity shall be determined by the treating clinician in consultation with the patient and noted in the patient's medical record."[72]

Effect of the Mandate on Health

Substance Use Disorder, Dependence, and Addiction

According to the Diagnostic and Statistical Manual of Mental Disorders (DSM), published by the American Psychiatric Association to describe mental disorders, "substance use disorder" is a "cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems."[73] Symptoms may include some combination of "impaired control, social impairment, risky use and [tolerance and/or withdrawal]."[74] While not a diagnostic term in the DSM, substance addiction as defined by the National Institute of Drug Abuse (NIDA) is a chronic illness affecting "multiple brain circuits, including those involved in reward and motivation, learning and memory, and inhibitory control over behavior."[75] The term "substance use disorder" has largely replaced "substance abuse" in the literature. Both are used interchangeably herein.

Substance Use in Massachusetts Compared to the United States

In 2018, there were 67,367 drug overdose deaths in the United States, with nearly 70% involving opioids.[76] In the same year, approximately 88% of drug overdose deaths involved at least one opioid in Massachusetts, for a total of 1,991 opioid-related deaths (a rate of 29.3/100,000 individuals). The following are substance use-related indicators as measured through the National Survey on Drug Use and Health (NSDUH) and the National Survey of Substance Abuse Treatment Services (N-SSATS), sponsored by the Substance Abuse and Mental Health Services Administration (SAMHSA).[77]

During 2017-2019, among young adults 18 – 25 in Massachusetts, the annual average prevalence of:[78]

- Marijuana use disorder was 5.8% (or 46,000), compared to the national average of 5.6%
- Opioid use disorder was 1.2% (or 9,000), compared to the national average of 1.0%
- Illicit use disorder was 8.3% (or 65,000), compared to the national average of 7.5%
- Alcohol use disorder was 13.9%, compared to the national average of 9.8%

[ix] "Acute treatment services," as defined in Chapter 258: "24-hour medically supervised addiction treatment for adults or adolescents provided in a medically managed or medically monitored inpatient facility, as defined by the department of public health, that provides evaluation and withdrawal management and which may include biopsychosocial assessment, individual and group counseling, psychoeducational groups and discharge planning."

[x] "Clinical stabilization services," as defined in Chapter 258: "24-hour clinically managed post detoxification treatment for adults or adolescents, as defined by the department of public health, usually following acute treatment services for substance abuse, which may include intensive education and counseling regarding the nature of addiction and its consequences, relapse prevention, outreach to families and significant others and aftercare planning, for individuals beginning to engage in recovery from addiction." CSS may be used without detoxification, for example for cocaine addiction.

- Substance use disorder was 19.0%, compared to the national average of 14.7%

During 2017 – 2019, among people aged 12 or older in Massachusetts, the annual average prevalence:[79]

- Marijuana use disorder was 2.2% (or 132,000), compared to the national average of 1.6%
- Heroin use was 0.47% (or 28,000), compared to the national average of 0.30%
- Prescription pain reliever misuse was 2.9% (or 171,000), compared to the national average of 3.7%
- Opioid use disorder was 1.0% (or 59,000), compared to the national average of 0.7%
- Illicit use disorder was 3.6% (or 213,000), compared to the national average of 2.9%
- Alcohol use disorder was 6.2% (or 369,000), compared to the national average of 5.3%
- Substance use disorder was 8.7% (or 516,000), compared to the national average of 7.4%

Other significant statistics:

- On a single day in March 2019, there were 66,912 people in Massachusetts enrolled in substance use disorder treatment (compared to 45,438 people on a single day in 2015):[8081]
    - 56.7% received treatment for a drug problem only
    - 14% received treatment for an alcohol problem only
    - 28.7 received treatment for both drug and alcohol problems
- On a single day in March 2019, there were:[82]
    - 19,830 people in Massachusetts receiving methadone in opioid treatment programs as part of substance use treatment, compared to 17,633 on a single day in 2015
    - 11,316 people in Massachusetts receiving buprenorphine in opioid treatment programs as part of substance use treatment, compared to 4,113 on a single day in 2015

Despite 10% of U.S. adults having substance use disorder at some point in their lives, 75% report not receiving any form of treatment.[83] Individuals with substance use disorder are significantly more likely to have psychiatric disorders, including mood, anxiety, post-traumatic stress and personality disorders.[84]

Treatment for Substance Use Disorder

Summarizing treatment for substance use disorder is challenging, in that the spectrum of services is broad, and the variables that affect an individual's treatment are multifaceted. Chapter 258 includes the following service categories in its definitions of substance abuse services:

- Early intervention
- Outpatient
- Intensive outpatient and partial hospitalization
- Residential or inpatient (including CSS)
- Medically managed intensive inpatient (including ATS)

Treatment can begin anywhere within this spectrum of services, depending in large part on the individual and on the substance that has been abused. For cases that are immediately life-threatening, patients often enter services in

detoxification (ATS). It is important to distinguish between detoxification[xi,85] and substance use disorder treatment,[xii, 86] as "[d]etoxification, in and of itself, does not constitute complete substance abuse treatment."[87] The process of detoxification focuses on helping a patient to withdraw safely from acute intoxication or dependency, and includes evaluation, stabilization, and preparation for entry into treatment, but does not necessarily wholly encompass substance abuse treatment.[88] According to the NIDA, however, in current practice:

> Third party payors sometimes prefer to manage payment for detoxification separately from other phases of substance abuse treatment, thus treating detoxification as if it occurred in isolation from that treatment. This "unbundling" of services can result in the separation of services into scattered segments. In other instances, reimbursement and utilization policies dictate that only detoxification can be authorized. This detoxification often does not cover the nonmedical counseling that is an integral part of substance abuse treatment.[89]

Comprehensive, effective treatment provides appropriate access to the whole spectrum of services. Experts emphasize the importance of tailoring treatment approach and duration to the needs of the individual patient. The American Society of Addiction Medicine (ASAM) advises that the length of service in any level of care "varies with the severity of the patient's illness and his or her response to treatment," and "always depends on individual progress and outcome."[90] ASAM guidelines consistently call for individual treatment plans with flexible lengths of stay or treatment, cautioning against mandated lengths of stay.[91] They further advise that "[p]rograms that have predetermined lengths of stay or overall program lengths of stay that must be achieved in order for a patient to 'complete treatment' or 'graduate' are inconsistent with an individualized and outcomes-driven system of care."[92] SAMHSA stresses that patients should be treated in the least restrictive setting.[93] In its guidelines, ASAM also supports individualized treatment in "the most efficient and effective level of service."[94] Moreover, according to its outlined Principles of Effective Treatment, NIDA states that "[n]o single treatment is appropriate for everyone."[95] Accordingly, treatment should be individualized along a spectrum of services and focused on long-term sustained abstinence and recovery.

Medical Efficacy of Substance Use Disorder Treatment

Substance use disorder treatment has been evaluated and found overall to be effective compared to non-treatment. A meta-analysis combined the effects of 78 studies of drug treatment, and "…analyses indicated that drug abuse treatment has both a statistically significant and a clinically meaningful effect in reducing drug use and crime."[96] There is also extensive literature on the characteristics of treatment that are most effective, including treatment duration, treatment continuity, and patient-specific characteristics related to health and living situation.

Duration and continuity of treatment are associated with patient outcome. Overall, studies have found that clients retained for longer periods in substance abuse treatment have better outcomes than those with shorter treatment duration.[97, 98] One study found that longer residential stays resulted in lower readmission rates for substance abuse treatment. These researchers concluded that their "findings highlight the value of providing adequate amounts of residential and outpatient care for patients in substance abuse treatment…."[99] Research has shown that continuing treatment along the spectrum of services, individualized to a patient's specific needs, is beneficial, finding that

[xi] Detoxification is a set of interventions aimed at managing acute intoxication and withdrawal. It denotes clearing toxins from the body of the patient who is acutely intoxicated and/or dependent on an abused substance.

[xii] Treatment/rehabilitation…involves a constellation of ongoing therapeutic services ultimately intended to promote recovery for substance abuse patients.

"retention, duration, and increased aftercare" were important to the effectiveness of inpatient substance abuse treatment.[100] The benefit of continuing treatment from inpatient to outpatient was reinforced in another study, which found that, especially for patients with both mental health and substance abuse issues (dual-diagnosis), those entering outpatient care directly have "somewhat worse outcomes" than those who enter treatment directly from "an immediately prior episode of inpatient care."[101] And a study of residential treatment programs for patients with both substance abuse and mental health diagnoses cited program flexibility and duration of treatment as "critical features of successful treatment…."[102]

There is also clear evidence that patient characteristics are an important aspect of appropriate treatment, with effectiveness depending in part on the individual patient's overall health and social support system.[103,104] In general, patients with more problems at the start of treatment, including co-occurring psychiatric and substance use disorder diagnoses and/or psychosocial problems, have been found to experience better outcomes with longer and more intensive treatment.[105] Other research found that "[p]atients with high psychiatric severity and/or a poor social support system are predicted to have a better outcome in inpatient treatment, while patients with low psychiatric severity and/or a good social support system may do well as outpatients without incurring the higher costs of inpatient treatment."[106] These findings highlight the importance of an individualized approach to treatment.

In summary, evidence indicates that effective treatment for substance use disorder and addiction must recognize the chronic nature of the illness, the likelihood of relapse, and the social factors affecting the progression of the disease and recovery. Furthermore, it suggests that better treatment is individualized along a spectrum of services, with consideration given to the patient's individual characteristics, to co-occurring psychiatric and medical conditions, to the social, emotional, and behavioral health of the patient, and to the social support system in which the patient must pursue recovery.

Understanding how general findings on the efficacy of substance use disorder treatment inform the efficacy of Chapter 258's provisions limiting care management requires understanding current insurance coverage and management for substance use disorder services and how Chapter 258 will alter them.

Chapter 258 and access to treatment for substance use disorder

Chapter 258 expands existing laws not only by requiring certain group health insurance plans to include a range of treatment options, but also by enabling providers to control initial access to these benefits and limiting the ability of insurers to restrict access with prior authorization requirements or medical necessity review. The primary effect of these specific sections of Chapter 258 is to shift the balance of decision-making about admission to various levels of substance use disorder services from the insurer to the provider; under the new law, the provider determines into which level of service a patient is admitted without need for prior authorization from an insurer. For ATS and CSS services, the law goes further and transfers to the provider the ability to both define and determine the medical necessity of treatment for the first 14 days of a treatment episode. If the shift from insurer to provider for determining the necessity of treatment increases access to appropriate and adequate services, then Chapter 258 should positively affect outcomes for privately insured patients with these illnesses. It is also possible that utilization for some services could increase beyond appropriate levels, though the use of standardized criteria would encourage appropriate decisions regarding utilization of services at the least restrictive level of care.

Changes in determining medical necessity

Chapter 258 prohibits insurers from requiring providers to obtain prior authorization before admitting patients to substance abuse services, shifting initial medical necessity determination from carriers to providers. This is a significant change as the respective definitions of medical or treatment necessity held by commercial insurers and substance use disorder treatment providers are often different. Insurers define their own medical necessity criteria, some of which are proprietary. Services are generally determined based on diagnosis, and are intended to restore an individual to a level of functioning present prior to an acute episode, illness, or injury. In the case of substance use disorder services, most often, authorization for admission or continuation of treatment after utilization review is determined by a patient's withdrawal symptoms and severity, as well as the severity of co-occurring biomedical conditions, such as psychiatric disorders and/or other acute or chronic medical disorders. In some cases, serious emotional, behavioral, or cognitive conditions and complications may be considered. These medical necessity criteria are focused on a patient's acute detoxification, withdrawal, and medical stabilization.

For providers, one widely used standard set of criteria for service placement, continued stay, and patient transfer/discharge is published by ASAM (ASAM criteria), which recommends a much broader set of assessment parameters to determine treatment services needed by an individual.[107] Six "dimensions" are included in this assessment "to create a holistic, biopsychosocial assessment of an individual."[108] The Massachusetts Department of Public Health refers to these criteria in its regulations for certain services within the spectrum of care for substance use disorder programs.[109] The six dimensions include not only medical conditions,[110] but also an individual's readiness to change (Dimension 4); relapse, continued use, or continued problem potential (Dimension 5); and the recovery/living environment (Dimension 6). Aligned with this point of view, one of the three "essential components" of the detoxification process as defined by SAMHSA, "patient readiness for and entry into treatment," affects whether a patient is discharged from a given level of care into another type of service or treatment.[111] How these arguably broader criteria are interpreted by providers and applied to commercially insured patients with substance use disorders plays an important role in determining the impact of Chapter 258 provisions regarding access to the various levels of treatment.

Medical Efficacy of Changes to Coverage

As discussed, there is clear evidence that substance use disorder treatment can be effective when appropriately delivered. There is evidence that sufficient duration of and retention in treatment, in settings tailored to the individual's needs, including inpatient, residential, and/or outpatient services, were found to be important indicators of improved outcomes. To the extent that Chapter 258 promotes individualized treatment regimens that consider a broader set of patient assessment parameters, appropriately use services across the spectrum of substance use treatment, and account for the patient's medical and psychosocial conditions as well as recovery support system, the results of the cited studies suggest the law will enhance treatment results for the fully insured population. Whether the specific mechanisms found in the law—the removal of prior authorization requirements and the transfer of initial medical necessity definition and determination to the provider for ATS and CSS—drive that improvement in efficacy depends on whether carrier-driven decisions resulted in treatment that meets this standard, and on the manner in which the mechanism is implemented in practice by providers with the discretion the law provides to them. Removing carrier utilization review increases the possibility of overutilization of ATS and CSS services, especially if providers

standardize lengths of stay beyond an individual patient's need (which can be detrimental to the patient). However, removing the carrier utilization review simultaneously reduces the possibility of underutilization to the extent that carrier policies were inappropriately restrictive. If overly long stays restrict access to a broader set of services, or treatment plans do not consider a patient's entire medical and social condition, the result may be continued relapses and repeated utilization of certain services without related recovery (e.g., readmission for detoxification). Therefore, any improvements in outcomes depend on provider decisions about adequate and appropriate care for privately insured patients, and whether or not these decisions improve on decisions currently made by carriers.

Estimated Marginal Cost of the Mandate

Carrier survey responses indicated acute treatment and clinical stabilization services would generally be covered in the absence of the mandate, but that they would be subject to prior authorization and utilization review performed by the carriers. To study the cost of the mandate, BerryDunn reviewed claims for acute treatment and clinical stabilization services in detail starting in 2014, prior to the effective date of the mandate. Chapter 258 took effect on October 1, 2015, and impacted coverage for members once their health coverage renewed after that date. Because employers can renew health coverage at any time during the year, the last plans to add Chapter 258 coverage were plans with a September 2016 renewal. Thus, 2017 was the first calendar year that Chapter 258 was fully implemented. Overall admissions increased by about 10.9% in 2015 and 2016, and by 5.2% in 2017, the year that Chapter 258 was fully implemented. It is uncertain how many of the additional admissions were due to Chapter 258 versus increases because of the growing opioid epidemic. BerryDunn conservatively assumes all of the 5.2% increase was attributable to Chapter 258.

After Chapter 258 passed, new out-of-state providers expanded bed capacity in the Commonwealth. Based on APCD data, these providers had a higher average length of stay (ALOS). Because the new providers were not in the market prior to Chapter 258, BerryDunn removed the new providers' experience (claim data) prior to calculating the ALOS, to obtain a consistent pre- and post-implementation comparison. Excluding the new providers, the ALOS increased by approximately 0.8 days, or 15.4%. Again, it is uncertain how much of the additional length of stay was due to Chapter 258 versus increases because of the growing opioid epidemic. BerryDunn conservatively assumes all of the 15.4% increase was attributable to Chapter 258.

BerryDunn calculated a 21.4% increase, or 4,014 additional residential bed days, attributable to Chapter 258. Based on changes in covered members, BerryDunn estimated 4,060 additional bed days in 2018. Next, using the APCD, BerryDunn calculated a 2018 average paid cost per day of $610 for acute treatment and clinical stabilization services. BerryDunn multiplied the incremental number of days by the average cost per day and divided by the corresponding member months to calculate the marginal paid claims cost of $0.13 PMPM. Adjusted for administrative loading, BerryDunn estimates this mandate has a $0.15 PMPM, or 0.03%, impact on total Commonwealth premium. Table 9 displays the results.

Table 9

Acute Treatment and Clinical Stabilization Mandate

2018 Contribution to Premium

Measures	Sample Amounts Plans Subj. to Mandate
Sample Average Members	1,596,982
Paid PMPM	$ 0.13
Paid PMPM With Admin	$ 0.15
Allowed PMPM	$ 0.15

	Upper Bound Impact
Insured Population	2,326,947
Contribution to Total Annual Claims	$ 3,610,607
Contribution to Total Annual Premium	$ 4,155,826
Percent of Total Premium	0.029%

If the additional length of stay from the out-of-state providers and the increase in admissions over a two-year period were considered, BerryDunn's paid claims cost impact estimate would increase to $0.33 PMPM. However, this approach overstates the cost of the mandate by including the impact of the opioid epidemic.

The cost impact of the broad requirement "Any [health insurance] coverage…shall not require a member to obtain preauthorization for substance abuse treatment if the provider is certified or licensed by the department of public health," is estimated under "Substance Abuse Treatment Prior Authorization."

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 regardless of etiology. Coverage includes all related services prescribed by an audiologist or hearing instrument specialist, including the initial hearing aid evaluation, fitting and adjustments, and supplies, including ear molds.[112]

Effect of the Mandate on Health

Hearing loss can occur in a variety of ways and at any time during life when any part of the ear—including the inner, middle, or outer ear—the acoustic nerve, or the auditory system is not functioning properly.[113] Hearing loss in infants might be caused by one or more factors, including genetics (approximately 50% of cases); maternal infections during pregnancy, complications after birth, or head trauma (25%); or unknown causes (25%).[114,115] About 33% of infants with genetic hearing loss have a syndrome or condition in addition to the hearing loss, such as Down syndrome or Usher syndrome.[116]

Hearing loss is categorized in a variety of ways, including:[117]

- 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 sensorineural issues.
  - Auditory neuropathy spectrum disorder: Damage to the inner ear or nerve disrupts the brain's ability to organize sound.
- Degree:
  - Mild: Might 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 occurs 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 in life.

Prior to newborn screening programs, "hearing loss in infancy or childhood often resulted in difficulties later in life, including problems with listening and speaking skills, literacy skills, academic performance, and long-term job opportunities."[118] Without screening programs, hearing impairment was typically not recognized until children were 2½ to 3 years old; and for many children, hearing impairment was not recognized until they were 5 or 6 years old.[119]

Estimates of the prevalence of hearing loss in children vary. One study found almost 15% of children ages 6 to 19 had low or high hearing loss in one or both ears at 16 decibels.[120] A study of 8-year-old children concluded that 1.4 per 1000 suffered bilateral hearing loss at 40 decibels or more.[121] In Massachusetts, recent findings estimate that 12.2% of infants screened are found to have hearing loss, or 2.1 per 1000 newborns; these numbers are higher than the national figures of 10.4% and 1.7 per 1000.[122]

There are many different options for children with hearing loss, including early intervention to assist in language and other important skills, as well as technology, medications, and surgery.[123] Medications and surgery might be used to correct some conductive hearing loss, especially those caused by infection or malformation of the outer and/or middle ear.[124] Although technology cannot cure hearing loss, it might help a child make up most of their residual hearing.[125] Hearing aids can maximize the hearing that remains, while children with severe to profound hearing loss might benefit from a cochlear implant, a device surgically implanted into the ear to conduct sound directly to the auditory nerve.[126]

Hearing aids are designed to amplify sounds and might be worn by people of any age, including infants.[127] 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.[128] 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.[129] 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.[130]

Studies have found that hearing aids improve communication outcomes for children[131], and the early provision of hearing aids to children with mild to severe hearing loss results in better speech and language development.[132] Likewise, quality of life indicators improve for hearing-impaired children and their families with use of hearing aids.[133] 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.[134] 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.[135]

Estimated Marginal Cost of the Mandate

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.[136] In previous comprehensive mandate studies, CHIA has included routine childhood hearing screenings in the RDC of this mandate in light of the statute language requiring coverage for all hearing aid-related services prescribed by an audiologist or hearing instrument specialist. However, routine hearing tests and screening for children overlap with other zero-cost Massachusetts mandates (e.g., preventive care for children to age six and early intervention services) and are broadly mandated by ACA preventive care requirements, so they are therefore removed from consideration of incremental impact here. In addition, the hearing aids for children mandate, effective since January 2013, is an ACA EHB in the Massachusetts ACA benchmark plan in force in 2018. Therefore, any incremental impact of the state mandate is limited to the large group population, as shown in Table 10 below.

To calculate the incremental effect of the mandate, BerryDunn first summarized 2018 MA APCD sample claims for fully insured children for hearing aid devices, dispensing fees, fittings, and accessories in large group products, and capped the cost per child at the mandated benefit requirement of $2,000. Although the mandate reaches the self-insured GIC membership, as discussed in CHIA's prospective mandated benefit review report, the GIC voluntarily offered child hearing aid coverage prior to the mandate,[137] and thus, self-insured GIC costs for these benefits are not incremental to the state mandate. BerryDunn also reduced the incremental cost estimate to exclude costs from one carrier that indicated it would provide the mandated benefits even in the absence of the mandate.

Table 10

Hearing Aids for Children Mandate

Contribution to Premium

Measures	Sample Amount Plans Subj. to Mandate
Sample Average Members	1,131,808
Paid PMPM	$ 0.12
Paid PMPM With Admin	$ 0.14
Allowed PMPM	$ 0.13

	Upper Bound Impact
Insured Population	1,281,109
Contribution to Total Annual Claims	$ 1,836,923
Contribution to Total Annual Premium	$ 2,149,091
Percent of Total Premium	0.015%

As summarized in Table 10 above, these steps resulted in an estimated incremental PMPM paid claim impact of $0.12, with a total PMPM cost, after administrative loading, of $0.14 (or 0.02% of the Commonwealth total premium).

Oral Chemotherapy Treatment of Cancer

The oral chemotherapy 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.[138]

Effect of the Mandate on Health

Chemotherapy is a drug treatment that uses powerful chemicals to kill fast-growing cells in the body. It is most often used to treat cancer since cancer cells grow and multiply much more quickly than most cells in the body; the treatment is intended to stop the rapid growth and reproduction common to cancer cells.[139] Chemotherapy drugs may be referred to as cytotoxic, meaning the drugs can kill tumor cells, and the treatment is considered systemic because the drugs travel throughout the body with the ability to kill cancer cells that have spread (metastasized) away from the original (primary) tumor.[140,141] For the cancer patient, there are three main goals associated with chemotherapy treatment: to cure by destroying all cancer cells so that the cancer goes away and does not come back; to control by shrinking tumors and/or stopping the cancer from growing and spreading to help the patient feel better and live longer; and to improve the quality of life by easing symptoms caused by advanced stages of cancer.[142]

In use since the mid-20th century, chemotherapy is most often given as an infusion into a vein (intravenously) where the chemotherapy drugs are introduced into the blood stream through a catheter with a small needle inserted into a vein in the forearm or into a device in a vein in the chest called a port, which can remain in place for weeks, months,

or years.[143,144,145] Chemotherapy can include a single drug, but often several drugs are used together, referred to as combination therapy.[146] Ordinarily, cytotoxic infusions happen at a clinic, doctor's office, or hospital and are typically given in a treatment period referred to as a cycle; e.g., a patient might receive chemotherapy on the first day and then have three weeks of recovery before repeating the treatment.[147] Several cycles make up a course of chemotherapy and vary based on the type and stage of the cancer.[148] In the majority of cases, the most effective doses and schedules of drugs to treat specific cancers have been found through clinical trials, and it is important, when possible, to get the full course of chemotherapy, the full dose, and keep the cycles on schedule to provide the patient the maximum benefit.[149]

The treatment schedule is necessary to kill cancer cells during different phases of the cell cycle. However, chemotherapy drugs cannot differentiate between healthy cells and cancer cells, which causes normal cells to be damaged along with the cancer cells, and can cause side effects.[150] Chemotherapy side effects can vary depending on the chemotherapy drugs given, with most side effects subsiding after treatment ends.[151] There are currently several approaches to reduce the side effects of chemotherapy, including new drugs, combinations of drugs, and delivery techniques; novel approaches that target drugs more specifically at the cancer cells; and drugs to reduce side effects, such as colony-stimulating factors, chemoprotective agents, and anti-emetics (to reduce nausea and vomiting).[152]

As treatment regimens have developed and improved, new routes of chemotherapy administration now include oral (taken by mouth) and topical (rubbed on the skin).[153] Oral chemotherapy is usually taken at home and the drug may be a pill, capsule, or liquid like other medicines; like intravenous chemotherapy, oral chemotherapy is sometimes given in rounds or cycles.[154] Over the past decade, a growing number of oral medications have been used for cancer treatment[155] and have received approval by the United States Food & Drug Administration (FDA).[156] Most patients prefer oral chemotherapy for the convenience of a home-based therapy,[157] which allows them to avoid multiple office visits and gives them a sense of control over their own cancer care.[158]

While patients gain convenience and control, oral chemotherapy requires patients to strictly comply 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.[159] In addition to the safety and adherence issues associated with the use of oral chemotherapy, some traditional roles and responsibilities of oncologists, nurses, and pharmacists shift to patients and caregivers.[160] Providing comprehensive medication therapy management, including education on oral chemotherapy agents, concurrent medications, and symptom management, as well as understanding food and drug interactions, must be continuously reinforced to assure maximum treatment effectiveness and to decrease the rate of adverse events.[161,162] Research has found that as patients shift from a passive to a more active treatment role, as required with oral chemotherapy, a need is created to provide them with more information and support to help them comply with their treatment regimens.[163 ,164,165,166]

Although comparisons of oral chemotherapy drugs with their intravenous forms are limited, studies comparing intravenous 5-fluorouraci (5-FU) with oral 5-FU have demonstrated that efficacy, safety, and quality of life are not compromised by the use of the oral therapy.[167] Further, in addition to oral chemotherapy seeming to be more convenient in terms of administration and reduced time lost for work or other activities for patients, current evidence

suggests oral chemotherapy is cost-effective, mainly due to reduced need of visits and/or hospital stays for the administration of the drug and/or the management of adverse events.[168]

Estimated Marginal Cost of the Mandate

The marginal impact of 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 National Drug Code (NDC) code indicating an orally administered cancer medication between 2012 (prior to implementation of the law) and 2018 (after implementation of the law). The decrease in patient cost-sharing increases the carrier cost and is the marginal cost of the mandate. The decrease in PMPM patient cost-sharing was calculated by developing an estimate of the 2018 carrier-paid expenses in the absence of the mandate by applying the ratio of carrier-paid expenses to allowed expenses in 2012 to the 2018 PMPM allowed expenses, and subtracting it from the 2018 PMPM carrier-paid expenses. This mandate, in force since 2013, is an EHB in the Massachusetts ACA benchmark plan. Therefore, the present analysis applies the impact of the state mandate to large group plans only. BerryDunn used the 2012 estimate obtained from MA APCD Release 4.0 and utilized as the "before" period in the analysis of this mandate in CHIA's 2016 comprehensive mandate review.[xiii,169] 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 2018 than 2012 in the absence of the mandate, the effect of the mandate is understated by this methodology.[xiv]

The estimated PMPM cost impact amount was $0.08, with a total PMPM cost, after administrative loading, of $0.09 (or 0.013% of the Commonwealth total premium). Table 11 below displays a summary of these results and related statistics.

[xiii] MA APCD Release 8.0 includes data for the years 2014 to 2018.

[xiv] That is, if patient cost sharing is measured at $0.06 PMPM in 2012 and $0.01 PMPM in 2018, but in the absence of the mandate patient cost sharing in 2018 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 2018 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.

Table 11
Oral Cancer Drugs Mandate
Contribution to Premium

Measures		Sample Amount*
Sample Average Members		1,131,808
Decrease in Cost Sharing PMPM, 2012 to 2018	$	0.08
Decreased Cost Sharing with Admin	$	0.09

		Upper Bound Impact
Insured Population		1,600,876
Contribution to Total Annual Claims	$	1,572,681
Contribution to Total Annual Premium	$	1,795,927
Percent of Total Premium		0.013%

Low-Protein Foods

The low protein foods mandate requires coverage for low protein food products needed to treat insured individuals with inherited diseases of amino acids and organic acids.[170]

Effect of the Mandate on Health

Hereditary metabolic disorders are genetic conditions that children inherit from their parents' genes that cause problems with metabolism.[171] Metabolism is a complicated process impacting the breakdown and conversion of substances ingested and is carried out by chemical substances called enzymes, which are made by different cells in the body.[172] If a genetic abnormality affects the function of an enzyme or causes it to be deficient or missing, various metabolic disorders can occur and might result in the following:

- Inability to break down a substance that should be broken down, allowing a toxic intermediate substance to build up
- Inability to produce some essential substance[173]

Although both amino acid and organic acid disorders are metabolic disorders, the manner in which they impact metabolism is different. Because key enzymes either are not produced by the body or do not work properly, amino acid disorders affect the body's ability to use protein from food for growth, energy, and repair.[174] Organic acid disorders result in too much of certain organic acids building up in the body because the particular enzymes that are normally used to break down the organic acids are not functioning properly.[175] There are a number of different amino and organic acid metabolic disorders including:

Amino Acid Disorders[176]

Argininemia
Arginosuccinic Aciduria
Benign Hyperphynlalaninemia
Biopterin Defect in Cofactor Biosynthesis
Biopterin Defect in Cofactor Regeneration

Organic Acid Disorders[177]

2-Methyl-3-Hydroxybutyric Aciduria
2-Methylbutyrylglycinuria
3-Hydroxy-3-Methylglutaric Aciduria
3-Methylcrotonyl-CoA Carboxylase Deficiency
3-Methylglutaconic Aciduria

Carbamoylphosphate Synthetase Deficiency
Citrullinemia Type I
Citrullinemia Type II
Classic Phenylketonuria (PKU)
Gyrate Atrophy of the Choroid and Retina
Homocystinuria
Hypermethioninemia
Hyperornithinemia-Hyperammonemia-Homocitrullinuria Syndrome
Hyperprolinemia Type I
Hyperprolinemia Type II
Maple Syrup Urine Disease
Ornithine Transcarbamylase Deficiency
Remethylation Defects
Tyrosinemia Type I
Argininosuccinic Aciduria
Ethylmalonic Encephalopathy
Formiminoglutamic acidemia
Glutaric Acidemia Type I
Holocarboxylase Synthase Deficiency
Isobutyrylglycinuria
Isovaleric Acidemia
Malonic Acidemia
Methylmalonic Acidemia (Methylmalonyl-CoA Mutase)
Methylmalonic Acidemia (Cobalamin Disorders)
Propionic Acidemia
β-Ketothiolase Deficiency

Each of these disorders is caused by a different single enzyme deficiency, causing a block in the respective metabolic pathway.[178] Although hereditary metabolic disorders are individually rare, the overall number of known disorders is probably as large as the number of presenting symptoms that might indicate a metabolic disturbance,[179] with an inborn error of metabolism occurring in one out of every 1,500 births.[180] Collectively, these disorders are an important cause of mortality and morbidity in infants and children.[181]

The first opportunity to address hereditary metabolic disorders occurs with testing of asymptomatic parents.[182] Certain populations have increased carrier rates for inborn errors of metabolism, and preconception screening has been shown to decrease disease prevalence.[183] Some hereditary metabolic disorders, such as PKU, can be diagnosed before birth with amniocentesis or chorionic villus sampling, whereas many are detected after birth with newborn screening tests.[184,185]

Once hereditary metabolic disorders are diagnosed, dietary therapy is the mainstay of treatment for PKU, maple syrup urine disease, homocystinuria, galactossemia, and glycogen storage disease (Type I/III)[186] where the modified diet is essential for the patient's survival and adequate mental development.[187]

An individual with maple syrup urine disease is unable to properly process certain protein building blocks (amino acids). The condition, which begins in infancy, is characterized by poor feeding, vomiting, lack of energy, seizures, and developmental delay.[188] Maple syrup urine disease is managed through diet with severe protein restriction and can be life threatening if left untreated.[189]

Individuals with PKU have 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.[190,191,192] Untreated, PKU can lead to microcephaly, growth failure, seizures, intellectual impairment, and behavioral abnormalities caused by the accumulation of toxic by-products of Phe.[193,194] The low-Phe diet includes medical food and formulas, minimal animal products, and consists mostly of fruits and vegetables that are high in carbohydrates and low in saturated and polyunsaturated fat and cholesterol.[195] 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.[196,197]

Early diagnosis and treatment of metabolic disease is important to reduce disease severity and delay or prevent the onset of the disease.[198] Although optimal long-term outcome depends on early diagnosis and good metabolic control, due to the rarity and severity of conditions, randomized controlled trials are scarce.[199]

Estimated Marginal Cost of the Mandate

This 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. Given that the mandate has been in effect since 2005 and is therefore in the ACA benchmark plan, the impact of this state mandate is limited to large group products. Carrier survey responses did not indicate that these products would be consistently covered in the absence of the mandate; the marginal cost estimate was based on sample data from those carriers that indicated they would not cover low-protein foods absent the mandate. The marginal cost of the mandate was estimated as the sum of paid amounts from claims incurred in the study period for procedure codes indicating the purchase of low-protein food products. The estimated PMPM paid claim amount was $0.03, with a total PMPM cost, after administrative loading, of $0.04 (or 0.01% of the Commonwealth total premium). There is significant overlap between the products covered by the low-protein foods mandate and the nonprescription enteral formula mandate. Those overlap amounts have been deducted from the impact estimate for the nonprescription enteral formula mandate, below. Table 12 below displays a summary of these results and related statistics.

Table 12
Low-Protein Foods Mandate
Contribution to Premium

Measures		Sample Amounts Plans Subj. to Mandate
Sample Average Members		971,352
Paid PMPM	$	0.03
Paid PMPM With Admin	$	0.04
Allowed PMPM	$	0.03

		Upper Bound Impact
Insured Population		1,600,876
Contribution to Total Annual Claims	$	595,712
Contribution to Total Annual Premium	$	685,668
Percent of Total Premium		0.005%

Chiropractic Services

The chiropractic services mandate requires coverage for chiropractic services.[200] Note that 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. The mandate applies to medical service corporations only; that is, the mandate applies to BCBSMA only. In addition, BCBSMA HMO Blue products are licensed as HMOs and are therefore regulated under a separate chapter of Massachusetts law. That is, the mandate applies only to BCBSMA plans that are *not* HMO Blue plans.

Effect of the Mandate on Health

Chiropractic is a form of healthcare that focuses on the relationship of the body's structure, particularly the spine, to its function.[201] The goals of chiropractic care include improved joint motion and function with an emphasis on the body's ability to heal itself.[202] In theory, by aligning spinal joints, chiropractors improve the function of the body's nervous system and overall health.[203] Spinal manipulation is practiced by a variety of healthcare professionals, including physical therapists; naturopathic and osteopathic physicians; chiropractors; and some medical doctors.[204] Practitioners perform manipulation by applying controlled force to a spinal joint, using their hands or a device.[205] Treatment goals include relieving pain and improving physical functioning.[206]

The use of chiropractic care is common, with annual rates among U.S. adults estimated between 8 percent and 14 percent.[207] Chiropractic care is also the predominant type of complementary and alternative medicine (CAM) service used by adults.[208] The National Institutes of Health (NIH) defines CAM as a group of diverse medical and healthcare systems, practices, and products that are not presently considered part of conventional Western medicine.[209] The use of CAM in Western medicine has grown dramatically in recent decades,[210] and numerous studies have demonstrated relatively high patient satisfaction with CAM services.[211] Chiropractic care is the most common and established of CAM modalities;[212] most adults who see a chiropractor have health insurance coverage for chiropractic care.[213] The use of spinal manipulation for acute low back pain has been integrated into the clinical guidelines of the American College of Physicians and the American Pain Society.[214]

According to the NIH National Center for Complementary and Integrative Health (NCCIH), spinal manipulation might benefit some people with low back pain, sciatica, neck pain, and headaches; it might also be used to treat other conditions, such as fibromyalgia, children's ear infections, and chronic obstructive pulmonary disease (COPD).[215] The most common side effects of spinal manipulation are temporary muscle soreness, stiffness, and temporary increases in pain.[216] Serious complications, such as strokes and artery tears, as well as death and delays in the diagnosis of serious illnesses, have been associated with spinal manipulation, but are very rare.[217]

Research has been largely conducted on singular treatment modalities or conditions, and has not focused on the entirety of chiropractic medicine.[218] 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 time frame 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).[219] 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.[220]

Although chiropractic care encompasses many treatments, spinal manipulation is the most common treatment provided.[221] Recent systematic reviews of spinal manipulation have indicated a low-to-moderate treatment effect,[222] while other studies indicate it is an effective strategy for managing back pain.[223] Most research points to mild to moderate short-term benefits of chiropractic care for acute low back pain,[224,225] although these results were sometimes similar to those obtained through other treatments, such as physiotherapy, patient educational materials, oral medications, acupuncture, or steroid injections.[226,227,228]

Summarized in Table 13, a study into the effectiveness of manipulation/mobilization therapies found evidence of the following:[229]

Table 13

Effective	Inconclusive	Not Effective
Acute, subacute, and chronic low back pain Migraine and Cervicogenic[xv] headache Cervicogenic dizziness Extremity joint conditions Acute/subacute neck pain (thoracic manipulation/mobilization)	Neck pain (cervical manipulation/ mobilization) Middle 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

Research has found that people report positive experiences and reduced pain as a result of receiving spinal manipulation.[230]

Estimated Marginal Cost of the Mandate

As noted above, this mandate applies to medical service corporations only; that is, BCBSMA products that are *not* HMO Blue products. This analysis thus estimates the marginal cost of this mandate as the difference between the PMPM costs of chiropractic services reported in the MA APCD for BCBSMA products subject to the mandate and the 2018 PMPM costs of chiropractic services reported in the MA APCD for BCBSMA HMO Blue products. To derive the estimate, BerryDunn first calculated sample PMPM paid and allowed costs for chiropractic manipulative treatment[xvi] for the two product types for paid claims with service dates in years 2016, 2017, and 2018. Non-HMO BCBSMA paid

[xv] Although pain is felt in the head, a cervicogenic headache is caused by referred pain from the cervical spine (neck) or base of the skull region.

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

and allowed PMPM costs for chiropractic services were consistently higher throughout the period. Table 14 below shows these results.

Table 14

Paid Cost and Allowed Cost PMPM, 2016 – 2018

BCBSMA HMO Blue Products vs. BCBSMA Products Subject to the Chiropractic Services Mandate

	2016		2017		2018	
Cost	Blue License Sample Amount	HMO Blue License Sample Amount	Blue License Sample Amount	HMO Blue License Sample Amount	Blue License Sample Amount	HMO Blue License Sample Amount
Paid PMPM	$ 1.10	$ 0.52	$ 1.09	$ 0.52	$ 1.05	$ 0.54
Allowed PMPM	$ 1.96	$ 1.47	$ 1.97	$ 1.48	$ 1.96	$ 1.53

Difference	2016	2017	2018	Mean
Paid PMPM	$ 0.57	$ 0.57	$ 0.50	$ 0.55
Allowed PMPM	$ 0.49	$ 0.48	$ 0.43	$ 0.47

Noting the consistency of the PMPM cost differences for 2016 and 2017 followed by the drop observed in 2018, BerryDunn utilized the average of the observed PMPM differences over the three years to calculate the chiropractic services' marginal cost estimate, providing a measure of conservatism for the estimate. The paid cost PMPM difference exceeds the allowed cost PMPM difference in each year, which might at first appear counterintuitive. Additional analysis of the sample data showed this result is driven by higher average copayment levels for HMO Blue products.

The average annual difference in allowed PMPM costs between the two product types was found to be $0.47 for these services. To calculate the marginal direct cost impact of the mandate, BerryDunn then multiplied this difference by 55%, the average annual ratio over the period 2016 to 2018 of plan paid amounts to plan allowed amounts for plans subject to the mandate.[xvii] This resulted in an estimated marginal claims cost impact of $0.26, or $0.30 including administrative loading. Because this mandate only applies to the small population of fully insured members in non-HMO Blue BCBSMA products, the total estimated 2018 premium impact of this mandate is approximately $600,000, or 0.004% of 2018 Commonwealth fully insured premium. Table 15 below displays a summary of these results and related statistics.

[xvii] The analogous figure for HMO Blue plans in the sample was 35 percent.

Table 15

Chiropractic Services Mandate

2018 Contribution to Premium

Measures	2018 Blue License Sample Amount	2018 HMO Blue License Sample Amount	Premium Impact Estimate*
Sample Average Members	172,158	736,257	172,158
Paid PMPM	$ 1.05	$ 0.54	$ 0.26
Paid PMPM With Admin	$ 1.22	$ 0.64	$ 0.30
Allowed PMPM	$ 1.96	$ 1.53	$ 0.47

	Impact
Insured Population	172,158
Contribution to Total Annual Claims	$ 531,151
Contribution to Total Annual Premium	$ 620,903
Percent of Total Premium	0.004%

*Net amounts include overlap between mandated services between the chiropractic services mandate and the chiropractor provider mandate.

The chiropractor provider mandate results and cross-mandate total results are presented *net* of the overlap amounts.

Sample totals displayed are the 2018 utilization and costs. The impact, however, is calculated as the average of the differences between the Blue-license and HMO Blue PMPMs for the years 2016-2018.

Nonprescription Enteral Formulas

The nonprescription enteral formula mandate requires coverage for nonprescription enteral formulas for home use for which a physician has issued a written order and which are medically necessary for the treatment of malabsorption caused by Crohn's disease, ulcerative colitis, gastro-esophageal reflux, gastrointestinal (GI) motility, chronic intestinal pseudo-obstruction, and inherited diseases of amino acids and organic acids.[231]

Effect of the Mandate on Health

Enteral nutrition (EN) generally refers to any method of feeding that uses the GI tract to deliver part or all of a person's caloric requirements with liquid formula (enteral formula) or food that has been liquefied in a blender (blenderized food).[232,233] As commonly defined, EN can be the oral intake of dietary food, the use of liquid supplements, or the delivery of part or all of the daily nutritional requirements by use of a tube (tube feeding).[234,235,236] However, some sources refer to EN as only tube feeding using an enteral formula.[237,238] With tube feeding, nutrition is provided through the nose, mouth, stomach or small intestine via a tube, catheter, or a surgically made hole into the GI tract.[239,240,241]

EN is provided to patients whose energy and nutrient needs cannot be met by regular food intake.[242,243] Enteral formulas can vary by caloric content as well as the composition of different sources of carbohydrates, fat, protein, and micronutrients, with some specialty enteral formulas used to meet specific nutritional or disease requirements.[244] EN administered to outpatients with tube feeding is known as home enteral nutrition (HEN).[245] HEN may be an option for patients who require life-sustaining nutrition care with a long-term alternative to oral nutrition but who are

otherwise able to live outside an acute-care hospital facility[246], and it is often used for patients whose intestinal tract is functional but who have some degree of failure in the esophagus or throat.[247]

Many adult patients who receive HEN have difficulty with swallowing; these include patients with certain neurological problems or head and neck cancers,[248] while other adult patients include those with certain GI diseases, eating issues caused by dementia or psychological disorders, or those whose energy demands cannot be met with oral nutrition, such as some acquired immunodeficiency syndrome (AIDS) patients.[249,250] For children, the most common medical conditions that require long-term HEN are: prematurity, failure to thrive, congenital heart defects, metabolic disorders, malformations/diseases of the GI tract, genetic syndromes, psychosomatic and/or psychiatric illnesses, conditions with neurological impairment, malformations/diseases of the respiratory tract, cancer, and renal problems.[251]

Tube feeding is not without complications, such as GI complications, infections at the site of tube insertion through the skin, irritation in the nose or throat with nasogastric placement, electrolyte abnormalities, and quality of life impact.[252,253] However, despite these complications, a number of studies have shown that tube feeding does increase nutritional intake and thus improve nutritional status.[254,255] Most studies look at the efficacy for EN for specific conditions or diseases; for example, a number of studies have reported the benefits of EN in the treatment of Crohn's disease.[256,257]

Malnutrition is a serious complication of many diseases, and tube feeding, when appropriately prescribed and used, can prevent complications; produce other clinical, functional, and financial benefits; and be life-saving in some situations.[258] 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.[259] According to the American Gastroenterological Association, tube feeding should be considered for patients who cannot or will not eat, have a functional gut, and have an identified method of access that can be safely obtained.[260] HEN is a life-sustaining therapy for patients with a functional GI tract who are unable to meet their nutrient needs by oral intake and who are able to remain in their own home.[261]

Estimated Marginal Cost of the Mandate

Carrier survey responses indicated nonprescription enteral formulas would generally not be covered in the absence of the mandate because the formulas are considered food products, which are generally not covered by health insurance. The services required by this mandate overlap with those required by the low-protein foods mandate. BerryDunn performed an overlap analysis, the results of which are presented below for the nonprescription enteral formulas mandate *net* of the overlap amounts to avoid double-counting. These costs are included in the low-protein foods impact estimate and in the overall mandate impact estimate.

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 mandate cost. The mandate was enacted in 2005

and is included in the Massachusetts ACA benchmark plan; it is therefore considered an EHB under the ACA. The state mandate therefore impacts only large group plans.

The estimated PMPM paid claim amount was $0.02, with a total PMPM cost, after administrative loading, of $0.03 (or 0.003% of the Commonwealth total premium). Table 16 below displays a summary of these results and related statistics.

Table 16

Nonprescription Enteral Formula Mandate

Contribution to Premium

Measures		Sample Amount*
Sample Average Members		1,087,091
Paid PMPM	$	0.02
Paid PMPM With Admin	$	0.03
Allowed PMPM	$	0.02

		Upper Bound Impact*
Insured Population		1,600,876
Contribution to Total Annual Claims	$	437,801
Contribution to Total Annual Premium	$	499,948
Percent of Total Premium		0.003%

*Net amounts *exclude* overlap between mandated services between the nonprescription enteral formula mandate and the low protein foods 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."[262]

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.[263] 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.[264] If the tissue around the lips does not join completely, an opening known as a cleft lip can result, which might range from a small slit to a large gap through the lip into the nose; this might occur on one or both sides, or

more rarely, in the middle.[265] During the sixth to ninth weeks of pregnancy, the bone, muscle, and other tissue on the roof of the mouth form to create a palate; if these do not join completely together, a cleft palate is formed. This can include the front, back, or both parts of the palate.[266]

Children with orofacial clefts often have problems with their teeth, feeding, clear speaking, ear infections, and hearing.[267] 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.[268,269] A recent study found that children born with orofacial clefts might have poorer academic outcomes in elementary school than their peers, but that more analysis 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.[270]

Orofacial clefts are one of the most frequently observed congenital anomalies occurring in the United States.[271] It is estimated that 6.35 babies per 10,000 are born annually with only a cleft palate (1 in 1574), and 10.6 babies per 10,000 are born with a cleft lip with or without a cleft palate (1 in 940).[272,273,274] Comparably, as of 2014, 9.75 babies per 10,000 are born in Massachusetts with an orofacial cleft (a cleft lip with or without a cleft palate).[275] 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% of total cases of children with birth defects.[276]

Although a common birth defect, orofacial clefts have complex etiology and can occur in isolation or as part of a broad range of chromosomal, Mendelian, or teratogenic syndromes, with the non-syndromic forms thought to be the result of a combination of genetic and environmental factors.[277] 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.[278,279] A mother's healthy diet in the year before pregnancy reduces the risk of orofacial cleft,[280] as does adequate intake of folic acid.[281]

Treatment of orofacial clefts vary based on the cleft's severity, the child's age, the child's needs, and other birth defects or syndromes that might be present.[282] 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).[283] Additional surgeries are often necessary as the children age, including those to improve breathing, hearing, speech, language development, and appearance.[284] Treatment by otolaryngologists, audiologists, dentists, orthodontists, and speech or language therapists might also be necessary.[285] Some children and families also benefit from peer and other emotional support resources.[286] The American Cleft Palate-Craniofacial Association recommends that children with orofacial clefts receive treatment through specialized cleft and craniofacial teams that can coordinate the variety of services needed throughout infancy, childhood, adolescence, and if necessary, adulthood.[287] Interdisciplinary teams include health professionals from medical, dental, surgical, and allied health disciplines.[288] According to the American Cleft Palate-Craniofacial Association, there are four such teams in Massachusetts: three in Boston and one in Worcester.[289]

While no study was found evaluating the spectrum of services required for treatment of orofacial clefts as a whole, the individual services outlined within the mandate have been proven effective for the specific symptom or condition they address.[290]

Estimated Marginal Cost of the Mandate

BerryDunn's interviews with providers and carrier survey responses confirmed the finding in the prospective benefit review report for this mandate that medical services (such as surgery) for these conditions were well-covered prior to its implementation.[291] Therefore, costs of previously uncovered dental, orthodontic, and prosthodontic services provided to treat cleft palate and lip comprise the marginal impacts of the mandate. Owing to limitations in the ability to identify these services in the MA APCD, BerryDunn calculated the estimated 2018 marginal premium impact of this mandate by estimating an annual average per-case cost, or case rate, of these previously uncovered services and multiplying the case rate by an estimate of the under-18, fully insured Massachusetts population with cleft lip and palate in 2018.

To estimate a case rate for these services, BerryDunn compiled a list of typical dental treatments for children younger than 18 years from fact sheets on dental, orthodontic, and prosthodontic care needs of people with craniofacial clefts from a state university's school of dentistry[292] and a nonprofit advocacy organization focused on cleft and craniofacial conditions.[293] Using expert-reviewed price estimates for these services developed for a recent prospective mandated benefit review study on services for other genetic craniofacial conditions,[294] BerryDunn estimated a mid-range case rate of $24,000. The analytical team then compared the estimate to the 2009 case rate of $18,500 utilized in the 2009 prospective mandate review of this mandate[295] by inflating the 2009 case rate to 2018 dollars using monthly dental care inflation rates published by the U.S. Department of Labor Bureau of Labor Statistics (BLS).[296] This calculation resulted in a 2018 case rate estimate of $23,176. Given the consistency of these two results, BerryDunn utilized $24,000, or $1,333 per year, as its estimated case rate for cleft lip and palate dental services for patients under age 18.

BerryDunn then reviewed data on births of children with cleft lip and palate for the years 2000 to 2015 from the Massachusetts Executive Office of Health and Human Services (EOHHS),[297] and calculated an average of 101 births per year of children with a craniofacial cleft. Multiplying this figure by the 18-year age range covered by the mandate (ages 0 to 17, inclusive), BerryDunn estimated a total of 1,818 children with a craniofacial cleft in the state in 2018. Dividing BerryDunn's estimate of 2018 fully insured and GIC self-insured Massachusetts commercial health insurance membership for this age range by a U.S. Census Bureau estimate of 2018 Massachusetts population in the same age range[298] resulted in an estimated proportion of children in the age range covered by fully insured commercial insurance or self-insured GIC policies of 28%. Applying this percentage to the estimate of Massachusetts children with craniofacial clefts resulted in an estimate of 510 children with fully insured commercial or self-insured GIC health coverage in 2018.

This benefit, enacted in 2011, is included in the Massachusetts ACA benchmark plan, and is therefore considered an EHB under the ACA. The state mandate thus impacts only large group plans. According to CHIA's 2019 annual report on the performance of the Massachusetts health care system, 64% of the combined fully insured and self-insured GIC members are in large group plans.[299, xviii] Applying this percentage to the estimate of 510 fully insured and self-insured GIC member children with a craniofacial cleft resulted in an estimate of 328 children in the mandate population. Multiplying $1,333 per year by 328 children yielded an estimate of approximately $440,000 in paid claim

[xviii] 100% of GIC membership is large group and 58% of fully insured membership is large group.

costs, or $500,000 with administrative loading. Dividing this impact estimate by the total 2018 Massachusetts large group fully insured membership estimate resulted in a 2018 PMPM marginal impact estimate for this mandate of $0.02 in claims cost and $0.03 with administrative loading. The estimated impact on total 2018 Massachusetts fully insured market premium is 0.003%. These results are summarized below in Table 17.

Table 17

Cleft Lip and Palate Mandate

Contribution to Premium

2018 Measures	Estimated Impact	
[a] Per Case Cost, 0-17	$	24,000
[b] Cost per Case per Year	$	1,333
[c] Estimated Massachusetts Cases		1,818
[d] Percent of Cases FI + GIC-SI		28%
[e] Percent of FI + GIC-SI in LG		64%
Contribution to Total Annual Claims = [b] x [c] x [d] x [e]	$	437,106
Contribution to Total Annual Premium	$	499,155
Insured Population		1,600,876
Paid PMPM	$	0.02
Paid PMPM With Admin	$	0.03
Percent of Total Premium		0.003%

HIV[xix]-Associated Lipodystrophy Treatment

The HIV-associated lipodystrophy syndrome mandate requires coverage for medical or drug treatments to correct or repair disturbances of body composition caused by HIV-associated lipodystrophy syndrome, including, but not limited to, reconstructive surgery such as suction-assisted lipectomy, other restorative procedures, and dermal injections or fillers for reversal of fat lipoatrophy syndrome.[300] Coverage requires a statement from a treating provider that the treatment is necessary for correcting, repairing, or ameliorating the effects of HIV-associated lipodystrophy syndrome. Benefits may not be subject to any greater deductible, coinsurance, copayments, or out-of-pocket limits than any other benefit provided by the insurer.

Effect of the Mandate on Health

The term "lipodystrophy" is defined as a redistribution of adipose tissue, which can present as lipohypertrophy, or accumulation of adipose tissue in central areas, and/or lipoatrophy, or loss of peripheral adipose tissue that is commonly seen in extremities, malar (cheek region), and temple regions.[301] Because there is no uniform presentation for patients experiencing HIV lipodystrophy, lipohypertrophy and lipoatrophy are considered distinct entities, although frequently overlapping, with different risk factors and metabolic processes underlying their development.[302,303] HIV-

[xix] HIV (human immunodeficiency virus) is a virus that attacks the body's immune system. If HIV is not treated, it can lead to AIDS (acquired immunodeficiency syndrome). CDC. Centers for Disease Control and Prevention. What is HIV? https://www.cdc.gov/hiv/basics/whatishiv.html.

associated lipodystrophy (LDHIV) occurs secondary to antiretroviral (ARV) therapies given to treat HIV-infected individuals[304] and is associated with the development of insulin resistance, hyperlipidemia (an abnormally high concentration of fats or lipids in the blood), and endothelial dysfunction (a type of non-obstructive coronary artery disease).[305]

Causes of LDHIV

LDHIV is a side effect of ARV therapies, although the exact cause is unknown.[306] Older ARV therapies using the thymidine analog nucleoside reverse inhibitors (NRTI), such as zidovudine and stavudine, have been linked to the development of lipoatrophy.[307] Switching patients to newer ARV therapies, such as abacavir and tenofovir, has successfully stopped the worsening of lipoatrophy.[308] In contrast, lipohypertrophy sometimes occurs with protease inhibitors (PI).[309] Switching or discontinuing PI has not been shown to reverse fat accumulation.[310]

Prevalence of LDHIV

From 2000 – 2014, the number of annual HIV diagnoses in Massachusetts decreased by 47%.[311,312] As of December 31, 2015, a total of 34,001 individuals were ever diagnosed with HIV infection and reported in Massachusetts, with or without an AIDS diagnosis, of which 40% (13,729) have died and 60% (20,272) were living with HIV/AIDS.[313] In addition, there are 3,814 individuals living in Massachusetts with HIV/AIDS who were first diagnosed in a state other than Massachusetts.[314] Taking into consideration these numbers, residents infected with HIV who do not yet know their status, and cases that have not yet been reported, the Massachusetts Department of Public Health (MDPH) estimates that the total number of residents living with HIV/AIDS in Massachusetts is between 26,000 and 27,000.[315]

The exact prevalence of LDHIV in Massachusetts or nationally is unknown, as there is a lack of uniformity in defining LDHIV as well as the methods of diagnosis (e.g., patient report versus objective provider measurements).[316] LDHIV prevalence estimates range broadly from 10% to 80% of people living with HIV worldwide.[317]

Diagnosis of LDHIV

Patients on ARV therapies should be monitored for the development of LDHIV. Abdominal girth, hip, and mid-upper-arm circumferences should be measured and monitored regularly.[318] Body weight and body mass index monitoring is critical to identify LDHIV early, as early intervention is more likely to be effective at reversing abnormal fat distribution.[319]

Diagnosis of LDHIV is made based on the characteristic physical appearance of the patient.[320] However, due to the increased incidence of metabolic abnormalities in patients with LDHIV, lipid profile and glucose tolerance should be evaluated, ideally before the initiation of ARV therapy, and repeated every six months. Liver and kidney function tests should be repeated at regular intervals.[321]

Complications

LDHIV can cause significant psychological stress and correlates with depression, decreased self-esteem, and social isolation.[322] Patients might become noncompliant with their ARV related to LDHIV.[323] Metabolic complications include hyperlipidemia and hyperglycemia due to insulin resistance, which subsequently increases the risk of atherosclerotic

cardiovascular disease.[324] Neck pain and sleep apnea might be caused by neck enlargement. Increased abdominal girth related to increase in visceral fat accumulation can lead to abdominal distention and gastroesophageal reflux.[325]

Treatments for LDHIV

LDHIV often leads to feelings of stigmatization, depression, isolation, and poor body image.[326] Treatment of LDHIV can improve the patient's cosmetic appearance, self-esteem, and compliance with ARV.[327] It can also prevent dyslipidemia, abnormal glucose metabolism, atherosclerosis, and diabetes mellitus associated with LDHIV.[328] Depending on the individual patient, different combinations of the following treatments might be recommended: [329]

- Modification of ART
- Use of thiazolidinediones (i.e., a class of oral medication used for the treatment of type 2 diabetes)
- Surgery including administration of fillers, fat transplants, and/or removal of adipose tissue (e.g., liposuction)
- Lifestyle modifications, including diet and exercise
- Medical therapies with metformin for patients with HIV and type 2 diabetes to reduce visceral, abdominal, and subcutaneous fat
- Growth hormone releasing factor injections

Currently, no cure exists for LDHIV. Early intervention and prevention are recommended as the best approaches to the condition, including modifying ARV therapy regimens. However, modifying antiviral treatment is not always an option for patients, because other ARV therapies might not be able to maintain virological control. Furthermore, switching therapies after lipodystrophy has progressed offers only limited benefit.

Surgical interventions (i.e., liposuction, lipectomy, implants, and fillers) provide varying durations of effects with common recurrence.[330] Currently available facial fillers have proven to be helpful, although temporary fillers only last six – 24 months and need to be injected multiple times. Permanent fillers have the possible side effect of cyst and/or granuloma formation. With all fillers, the purity of the injectable project and provider skill are important for positive aesthetic outcomes. Combinations of fillers and surgical procedures are frequently used to achieve the best aesthetic results.[331]

Transfer of an individual's fat from one area to another area is a popular and effective method for patients with suitable donor sites, although touch-ups are frequently required, and side effects might include hypertrophy of the cheeks, bleeding, bruising, facial redness and swelling, contour irregularities, and infection.[332]

Certain areas of excess fat accumulation are amenable to being surgically removed.[333] Unfortunately, abdominal fat accumulation with HIV is visceral (i.e., stored near vital organs), so lipoplasty is not an option. Some areas, such as the dorsocervical area (behind the shoulder blades), are suitable for suction-assisted assisted lipectomy. However, the area might re-accumulate fat.

Conclusion

HIV was once considered a fatal disease. However, with ARV therapies, patients survive to near-normal life expectancies. Older ARV therapies are mostly associated with fat distribution abnormalities, which can cause significant psychosocial problems. Both lipoatrophy and fat accumulation can lead to feelings of stigmatization,

depression, isolation, and poor body image, and as a result, noncompliance with ARV therapies. Fortunately, newer ARV therapies appear to cause fewer fat distribution problems. Restorative dermatologic and surgical interventions can assist patients to maintain a normal appearance and lifestyle and lessen stigma and psychosocial distress.

Estimated Marginal Cost of the Mandate

The HIV-associated lipodystrophy treatment mandate became effective in November 2016. Therefore, BerryDunn estimated the impact of the mandate by comparing MA APCD sample paid claim PMPM costs of lipodystrophy treatments (both medical and pharmacy treatments) for members with HIV for 2015 (prior to the mandate) and 2018 after controlling for medical inflation.[334] The cost is expected to decrease over time related to improved ARV therapies resulting in decreased lipodystrophy prevalence and severity.

The observed cost increase, summarized in Table 18 below, was $0.01 PMPM in paid claims, and $0.01 PMPM in premium impact after administrative loading. This represents a 0.001% impact on the Commonwealth premium.

Table 18

HIV-Associated Lipodystrophy Treatment Mandate

Contribution to Premium

Measures		Sample Amount
Sample Average Members		1,726,476
Paid PMPM	$	0.01
Paid PMPM With Admin	$	0.01
Allowed PMPM	$	0.01

		Upper Bound Impact
Insured Population		2,326,947
Contribution to Total Annual Claims	$	182,638
Contribution to Total Annual Premium	$	210,217
Percent of Total Premium		0.001%

2.0 Aggregated Results of Mandates with Positive Estimated Marginal Direct Cost

The aggregated results of the marginal impact estimates judged to have potential marginal direct cost, with overlap (double-counting) between mandates removed, are summarized in Table 18. Overlaps between mandates were netted out of individual mandate results, as described in the individual mandate analysis sections above, so the results of the mandate marginal impact calculations are additive. The resulting marginal premium cost estimate is $3.71 PMPM over the entire fully insured and self-insured GIC commercial population, or 0.7% of Commonwealth

premium. That is, the additional cost of mandated services in commercial plans subject to the mandates represents approximately three quarters of one percent of premium. Table 19 below displays a summary of these results.

Table 19

All Benefit Mandates Total Contribution to Premium

Measures	Premium Impact Estimate
Insured Population	2,326,947
Paid PMPM	$ 3.24
Paid PMPM With Admin	$ 3.71
Contribution to Total Annual Claims	$ 90,408,886
Contribution to Total Annual Premium	$ 103,478,438
Percent of Total Premium	0.72%

Table 20 below shows these results at the mandate level.

Table 20

Summary of Estimated Costs for Massachusetts Mandated Benefits as of 2018

Dollars in Millions (000,000s)

Mandate	Marginal Claims Estimate	Marginal Premium Impact	Percent of Premium
Unduplicated Total All Mandates	$ 90.41	$ 103.48	0.72%
Massachusetts State Mandates with Potential Direct Marginal Cost			
Infertility Services	$ 76.38	$ 87.23	0.61%
Chiropractors	$ 4.82	$ 5.64	0.04%
Acute Treatment and Clinical Stabilization Services	$ 3.61	$ 4.16	0.03%
Child Hearing Aids	$ 1.84	$ 2.15	0.02%
Oral Cancer Drugs	$ 1.57	$ 1.80	0.01%
Low Protein Foods	$ 0.60	$ 0.69	0.00%
Chiropractic Services	$ 0.53	$ 0.62	0.00%
Nonprescription Enteral Formulas	$ 0.44	$ 0.50	0.00%
Cleft Palate and Lip	$ 0.44	$ 0.50	0.00%
HIV-Associated Lipodystrophy Treatment	$ 0.18	$ 0.21	0.00%

The first result column in Table 20 shows this study's estimated marginal paid claims cost impact for each mandate, and the total (top results row). The second column shows this amount adjusted for carrier retention, or the marginal contribution to Commonwealth fully insured commercial health insurance premium. Finally, the third result column calculates the retention-adjusted amount from the second result column as a percentage of total Commonwealth premium (calculated as the sum of total estimated fully insured member months and self-insured GIC member months multiplied by this study's estimate for average monthly premium expense for such plans).

3.0 Mandates with Zero or Unmeasurable Estimated Marginal Cost

As discussed in the Executive Summary, the following mandates were deemed to have zero marginal direct cost impact for one or a combination of the following reasons:

- In the survey administered for this study, Massachusetts health insurance carriers indicated they would cover the health benefits regardless of whether they were mandated
- Federal law superseded the state-mandated benefit, thus erasing any incremental effect of the Massachusetts statute
- Measuring their impact is not feasible
- BerryDunn's analysis resulted in an estimate of zero marginal direct cost
- The net estimated material impact of the mandate was zero after subtracting overlaps with other state mandates
- The mandated services had become clinically obsolete

In each mandate-specific results section that follows, BerryDunn presents the unique reason for its zero-cost determination.

Abuse-Deterrent Opioids

Massachusetts Chapter 258 of the Acts of 2014[335] requires in part that health insurance plans "shall provide coverage for abuse-deterrent opioid drug products…on a basis not less favorable than non-abuse-deterrent opioid drug products that are covered…An increase in patient cost sharing shall not be allowed to achieve compliance with this section."

Effect of the Mandate on Health

Opioids

Opioids are a class of drugs that reduce pain and relax the body, decreasing one's perception of and reaction to pain.[336,337,338] Most opioids are prescribed to alleviate moderate to severe pain, and some opioids may be used to treat coughing and diarrhea.[339] Because opioids can cause people to feel very relaxed or "high," they are sometimes taken for nonmedical reasons.[340] Taking opioids for nonmedical reasons can be very dangerous because opioids can be highly addictive, and overdoses and death are common.[341] Heroin is the most dangerous opioid, and it has never been used as a medication in the United States. Possible side effects of opioid use include drowsiness, mental confusion, nausea, constipation, euphoria, and slowed breathing.[342] Slowed breathing can cause hypoxia, or too little oxygen to the brain.[343] Hypoxia can lead to coma, permanent brain damage, or death.[344]

Common prescription opioids include morphine, codeine, oxycodone (including brand names OxyContin® and Percocet®), hydrocodone (including brand name Vicodin®), and fentanyl.[345] Prescription opioids are generally safe when taken for a short time and as prescribed by a doctor, but they can be misused. Some people misuse prescription opioids by:[346]

- Taking the medicine in a way or dose other than prescribed
- Taking someone else's prescription medication
- Taking the medication to "get high" rather than for its prescribed purpose

Sometimes individuals misuse opioid medications by crushing pills or opening capsules, dissolving the powder in water, and injecting the liquid into a vein.[347] Sometimes the powder is snorted or chewed.[348]

Tolerance, Dependence, and Addiction

After long-term opioid use, some people might develop a tolerance to the medication, meaning that a higher dose and/or increased frequency of doses is needed to get the desired effects.[349] Tolerance can develop even when taken as prescribed by the doctor.[350] With repeated use, neurons adapt to opioids so that they only function normally in the presence of opioids.[351] Patients with chronic pain might become dependent on opioids with long-term use and require medical support to discontinue taking them.[352] Any person who takes opioids is at risk of developing addiction.[353] Addiction is a chronic medical disease characterized by compulsive, or uncontrollable, drug seeking and use despite harmful consequences and long-lasting changes in the brain.[354,355]

Opioid Use Disorder Impact

In 2019, nearly 71,000 people in the United States United States died from drug overdose; over 70% of these deaths involved an opioid.[356] From 1999 – 2019, nearly 500,000 people in the United States died from drug overdoses involving any opioid, including prescription and illicit opioids. There have been three distinct waves of overdose deaths:[357]

- 1990s: an increase in prescription overdose deaths related to natural and semi-synthetic[358] opioids and methadone
- 2010: an increase in heroin overdose deaths
- 2013: an increase in synthetic opioid overdose deaths, including fentanyl

In Massachusetts, approximately 88% of the 1,991 drug overdose deaths in 2018 involved at least one opioid; heroin was involved in 475 deaths, and prescription opioids were involved in 331. There were 1,806 fatalities involving synthetic opioids[359] other than methadone (mainly fentanyl and fentanyl analogs)—over 90% of the opioid-involved deaths. In the first nine months of 2020, there were 1,517 confirmed opioid-related deaths in Massachusetts. Compared to the same timeframe the previous year, there were 33 additional deaths in 2020. This increase in opioid-related deaths coincided with the COVID-19 pandemic.[360]

In 2012, U.S. healthcare providers wrote 259 million prescriptions for opioid pain medications. Regional variations in prescribing patterns were identified during this time, although the factors causing them were unknown.[361] In 2016, the CDC released a guideline with recommendations on prescribing opioids for chronic pain not related to active cancer treatment, palliative care, or end-of-life care.[362] The guideline addressed 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use. In 2018, Massachusetts providers wrote 35.3 opioid prescriptions for every 100 persons, compared to the U.S. average rate of 51.4.

Abuse Deterrent Opioids (ADOs)

The U.S. Food & Drug Administration (FDA) encourages the development of prescription opioids with abuse-deterrent formulations to help combat the opioid crisis."[363] While recognizing that ADOs are not abuse- or addiction-

proof, the FDA supports ADOs as a step to help reduce opioid abuse.[364] ADOs "target the known or expected routes of abuse associated with opioids, such as crushing in order to snort or dissolving in order to inject, for the specific drug substance." The following opioids are opioids with FDA-approved labeling describing abuse-deterrent properties:[365]

- Oxycontin®
- Hysingla ER
- Xtampza ER®
- RoxyBond®
- [Generic] Hydrocodone bitartrate (reference listed drug: Hysingla ER)

Effectiveness of Abuse-Deterrent Formulations and Technology

ADOs do not prevent individuals from taking prescription drugs in higher doses than prescribed (the most common opioid abuse), change the addictive property of the drugs, or prevent other adverse, multisystem effects of opioids.[366] The technology for engineering ADOs is still relatively new and developing, and post-market studies are still in their infancy.[367]

In a systemic review of 44 reports, the author found that only oxycodone extended release (ER) had information available to evaluate abuse deterrence of ADOs in the community. In Australia, Canada, and the United States, reformulation of oxycodone ER was followed by a significant reduction in measures of abuse, although the precise extent of reduced abuse could not be calculated due to heterogeneous data sets.[368] In a large study utilizing electronic health records from 56 U.S. healthcare organizations, researchers followed patients one year after being prescribed either an abuse-deterrent formulation (ADF) oxycodone or non-ADF oxycodone.[369] To be included in the study, patients could not have had a history of substance use disorder or oral oxycodone in the year prior to being prescribed the ADF or non-ADF oxycodone.[370] After propensity score matching, 89,802 patients were included.[371] One year after the ADF or non-ADF oxycodone, there were 1,445 diagnoses of opioid use disorder or opioid poisoning in the ADF cohort (34.8/1,000 person-years) and 765 diagnoses of opioid use disorder or opioid poisoning in the non-ADF cohort (18.2/1,000 person-years) leading the author to conclude that patients with a new prescription of ADF oxycodone may be at increased risk of opioid-related harm.[372]

Conclusion

Research on the safety and efficacy of ADOs is ongoing. It is important to note that even if the abuse-deterrent properties perform as intended (i.e., deter or dissuade an individual from chewing the drug, or using it for inhalation or intravenous [IV] abuse), ADOs continue to carry significant risks. First, such formulations do not alter the potential for dependence, an individual's physical adaptation to prescribed opioids, or the potential for addiction. Second, while some formulations might deter or make certain methods of abuse less likely, not all risk can be eliminated; drug diversion and intentional misuse of prescription drugs might not be affected by the new abuse-deterrent technologies, which are aimed at making drug product manipulation more difficult or at making abuse of the manipulated product less attractive or rewarding.[373] Third, prescription drug abusers might replace their current drug of choice with other forms of opioids, including heroin, with its risk of overdose or death. Fourth, the term, "abuse-deterrent" might be misleading in relation to the risk of opioid-related harm.[374] For these reasons, the literature supports continued ADO

efficacy studies, specific ADO guidelines, and comprehensive intervention strategies to address the opioid crisis.[375,376]

Estimated Marginal Cost of the Mandate

Responses to the carrier survey consistently indicated that these products would be covered in the absence of the state mandate. In addition, a review of MA APCD data indicated that the cost of both abuse-deterrent and non-abuse-deterrent opioids has trended down since the mandate went into effect. In particular, the average annual allowed PMPM trend for abuse-deterrent opioids from 2016 – 2018, was approximately negative 15%. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Autism Spectrum Disorders

The autism mandate requires coverage for the diagnosis and treatment for Autism spectrum disorders (ASDs)[xx] in individuals on a nondiscriminatory basis, meaning on the same terms as coverage for medical/surgical conditions. As defined in the mandate, treatment of ASDs include: habilitative or rehabilitative care, pharmacy care, psychiatric care, psychological care, and therapeutic care. The mandate's primary effect is to require coverage for medically-necessary habilitative or rehabilitative care.[xxi,377]

Effect of the Mandate on Health

ASDs are a group of developmental disabilities with symptoms that must be present in early childhood (but may not become fully manifest until social demands exceed limited capacities) that limit and impair everyday functioning characterized by: 1) persistent deficits in social interaction and social communication and 2) restricted and repetitive patterns of behavior, interests, or activities.[378,379,380] This definition of ASDs as set forth in the Diagnostic and Statistical manual of Mental Disorders (DSM-5) incorporates several previously distinct diagnoses, including autism, Asperger's disorder, childhood disintegrative disorder, and pervasive developmental disorder not otherwise specified.[381]

In general, children with autism are less able to interpret non-verbal social and emotional cues, as they have difficulty interpreting 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.[382] While these behaviors and symptoms may change over time, adults with ASDs continue to

[xx] Pursuant to Massachusetts General Laws (M.G.L). c.175 §47AA, an ASDs shall have the following meaning: any of the pervasive developmental disorders as defined by the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders, including autistic disorder, Asperger's disorder, and pervasive developmental disorders not otherwise specified.

[xxi] Pursuant to M.G.L. c.175 §47AA, habilitative or rehabilitative care shall have the following meaning: professional, counseling and guidance services and treatment programs, including, but not limited to, applied behavior analysis supervised by a board certified behavior analyst, that are necessary to develop, maintain and restore, to the maximum extent practicable, the functioning of an individual.

struggle throughout life with: language, especially perspective, nuance, humor, and implied meanings; self-sufficiency; and social skills.[383] 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.[384] Outcomes and behaviors for individuals change over time, but most patients remain on the spectrum as adults. The literal interpretation of language and difficulty in understanding the intent of other people might lead to behavioral challenges in some people with ASDs and affects success in school, leisure activities, and employment.[385] Additionally, co-occurring conditions such as seizures, sleep disorders, gastrointestinal disorders, and obesity have a significant effect on the health and quality of life for patients with ASDs, and these conditions must also be addressed through appropriate medical management.[386]

ASDs are difficult to diagnose, as they are neurodevelopmental disabilities or phenomenological disorders, not a specific disease.[387] Moreover, while initial signs and symptoms are usually apparent early in a child's development, the behavioral patterns and social deficits might not be identified as symptoms of ASDs until a child is unable to meet social, occupational, educational, or other important developmental milestones.[388] 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[389] – concluded in its report on screening for ASDs in young children that the current evidence is insufficient to determine the long-term benefits or harms of screening children who don't have obvious symptoms or whose parents or health care provider have not raised concerns about their development.[390,391] However, the American Academy of Pediatrics (AAP) recommends developmental screenings at 9, 18, and 30 months and screening for autism at ages 18 and 24 months.[392,393,394]

Despite the diagnostic challenges, estimates of the prevalence of ASDs—such as those below from the Autism and Developmental Disabilities Monitoring (ADDM) Network[xxii]—have risen dramatically since 2000:

Table 21

Prevalence of Autism Spectrum Disorders among Children Aged 8 Years[395]

Year	2000	2004	2008	2012	2016
Prevalence	1 in 150	1 in 125	1 in 88	1 in 69	1 in 54
Per 1000 children	6.7	8.0	11.3	14.5	18.5

Information for these estimates prior to 2016 was collected on eight-year-old children because previous work had shown that most children with ASDs have been identified for services by that age.[396] The 2016 findings draw on data on both eight-year-old and four-year-old children and show that more children are being evaluated and identified with autism at younger ages, with boys being four times as likely to be diagnosed with autism as girls.[397] While the rate of identification of white children and black children with ASDs was the same for the most recent reporting period,

[xxii] The ADDM Network is an active surveillance system based on health and special education records that provides estimates of the prevalence of ASDs among children aged 8 years whose parents or guardians reside within 11 ADDM sites in the United States (Arizona, Arkansas, Colorado, Georgia, Maryland, Minnesota, Missouri, New Jersey, North Carolina, Tennessee, and Wisconsin).

diagnosis of Hispanic still lagged; and both black and Hispanic children tend to be diagnosed later than white children.[398]

A recent Centers for Disease Control and Prevention (CDC) press release attributes some of the increase in autism prevalence as possibly being due to the way children are identified, diagnosed, and receiving services in their communities as well as reflecting reductions in racial differences in identification of autism.[399] Other factors include substantial improvements in the number of children who had their first developmental screening by the age of 36 months, which is important because the earlier children are identified with autism, the sooner they can be connected to services that can improve outcomes and lead to better quality of life.[400,401]

According to the AAP, the goals of treatment of children with ASDs are to:[402]

- Minimize core deficits (social communication and interaction and restricted or repetitive behaviors and interests) and co-occurring associated impairments
- Maximize functional independence by facilitating learning and acquisition of adaptive skills
- Eliminate, minimize, or prevent problem behaviors that may interfere with functional skills

As well as being based on sound theoretical constructs and objective scientific evidence of effectiveness, interventions should be individualized, developmentally appropriate, and intensive, with performance data relevant to treatment goals in order to evaluate and adjust interventions.[403] Research has made clear that early intervention can improve learning, communication, social skills, and underlying brain development, making early identification and diagnosis of ASDs important to treatment outcomes.[404,405,406,407,408]

Although no treatment has currently been shown to cure ASDs, several interventions have been developed and studied for use in young children.[409] The interventions might reduce symptoms, improve cognitive ability and daily living skill, and maximize the ability of a child to function and participate in the community.[410] The therapies available include: behavior and communication approaches, medication, dietary approaches, and complementary and alternative medicine.[411] Behavioral and communication interventions provide structure, direction, and organization for the child in addition to family participation.[412] Broadly, they address communication, social, daily-living, play, and leisure skills, as well as academic achievement and maladaptive behaviors.

Some behavioral and communication approaches include: Applied Behavioral Analysis (ABA); assistive technology such as communication board and electronic tablets; Developmental, Individual Differences, Relationship-Based Approach (also called “Floortime”); Treatment and Education of Autistic and Related Communication Handicapped Children (TEACCH); occupational therapy; social skills training; and speech therapy.[413] TEACCH uses visual cues to teach skills, as an example, using picture cards to show a child how to get dressed by breaking the information down into small steps.[414] Early intensive behavioral intervention is an immersive behavioral therapy recommended for preschool to early school aged children with ASDs.[415]

As a widely accepted type of behavioral therapy treatment approach for ASDs among healthcare professionals,[416] ABA interventions encourage positive behaviors and discourage negative behaviors to improve a variety of skills, and track and measure a child’s progress.[417] 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.[418] Some examples of the different types of ABA are: Discrete Trial Training (DTT); Early Intensive Behavioral Intervention (EIBI); Early Start Denver Model (ESDM); Pivotal Response Training (PRT); and Verbal Behavior Intervention (VBI).[419] Through ESDM, parents and therapists use play and joint activities to help children who are 12 - 48 months of age advance their social, language, and cognitive skills, while another popular method, DTT, teaches behaviors and responses step-by-step.[420] ABA interventions vary from highly structured adult-directed approaches (e.g., DTT, VBI) to interventions in natural environments that may be child led in the context of play activities or daily routines and are altered on the basis of a child's skill development (e.g., PRT).[421] 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.[422] ABA encompasses a wide array of behavioral interventions; some of these services have been shown to be effective in treating certain symptoms in specific patients with ASDs. Comprehensive ABA interventions are aimed on teaching specific skills to improve intellectual, social, and adaptive functioning, while focused ABA interventions are more time-limited and aimed at changing specific behaviors, most often including those associated with aggression, self-injury, or other challenging behaviors.[423]

The effectiveness of ABA-based interventions in ASDs has been well documented through five decades of research.[424] This research shows that children who receive early intensive behavioral treatment make substantial, sustained gains in IQ, language, academic performance, and adaptive behavior as well as some measures of social behavior, with significantly better outcomes than those of children in control groups.[425] Common factors in combined developmental and behavioral approaches include use of principles of ABA to reinforce skill building; a systematic approach with a manual for training practitioners who would use the intervention in a standard fashion; individualized treatment goals for the child and means of measuring progress; child-initiated teaching, imitation, and modeling; and adult prompting that fades over time to promote independence.[426] Although research has found that these ABA methods can teach certain skills, they cannot be generalized for spontaneous use in natural environments because the highly structured teaching environment is not representative of natural adult-child interactions.[427]

Currently, there are no medications available to cure or treat the composite symptoms of ASDs.[428,429] However, medications, such as aripiprazole and risperidone, have been approved by the United Stated Food and Drug Administration for the treatment of ASD-associated irritability.[430] Pharmacologic interventions might also be used to treat other 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, anxiety, hyperactivity, inattention, destructive behavior, or other disruptive behaviors.[431] Since all medications carry risks, families should work closely with their child's healthcare provider to help ensure the safe use of any medication.[432]

Although dietary approaches and alternative medicine therapies are widely used, in general, research has not proven their effectiveness.[433,434] Moreover, for a variety of reasons, children with ASDs may not get the nutrition they need for healthy growth and development based on eating habits or a restricted diet in hopes of reducing ASD symptoms.[435,436] Complementary, alternative, and integrative therapies used for the treatment of ASDs can be grouped into three general areas: (1) natural products (including herbs, vitamins and minerals, and probiotics), (2) mind and body practices (including yoga, chiropractic, massage, acupuncture, progressive relaxation, and guided imagery), and (3) other therapies (including traditional medicine and naturopathy).[437] Complementary therapies are attractive to families because they are often purported to correct putative biological causes of behavioral symptoms

and may be discussed with an optimism about an outcome that is often not conveyed with the recommendation for conventional therapies; as a result, between 28% and 74% of children with ASDs are given at least one, and usually more than one, complementary therapy.[438] Despite their appeal to families, some alternative therapies, such as intravenous chelation of heavy metals, have been shown to be dangerous.[439]

Additional supports are also used by those diagnosed with ASDs, and may change over time depending on individual age and need, including educational, vocational, residential, and housing support services.[440] Families play a key role in effective treatment for children with ASDs. Recognition that individuals who are affected and their families are partners with the professionals in all aspects of planning a personal, local, and national agenda for ASDs has emerged and has shaped approaches to community services as well as research planning.[441] Although prognosis is heavily affected by the severity of diagnosis and the presence of intellectual disability, children with optimal outcomes receive earlier, more intensive behavioral interventions and less pharmacologic treatment.[442] As research progresses, genetic testing may contribute to identifying effective interventions related to specific etiologies.[443]

Estimated Marginal Cost of the Mandate

The responses to the carrier survey consistently indicated these services, worth approximately 0.30% of Commonwealth fully insured premium in RDC, would be covered in the absence of the state mandate. In the absence of the mandate, it is possible carriers would intensify their utilization management practices and/or reduce quantitative limits for these services, in which case one could argue that this mandate has some marginal premium impact. Within the scope of the present study, there is no clear way to measure these secondary effects, which are a fraction of a percent of Commonwealth premium. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Bone Marrow Transplant (BMT) 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.[444]

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[xxiii] 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.[445,446]

The use of HDC-ABMT for treatment of breast cancer was most often considered experimental.[447,448] Some already-concluded and ongoing trials have shown the potential application of this treatment for more narrowly defined groups of patients[449,450,451452] and/or with an adjustment to the previously used chemotherapy regimen, as these treatment protocols with HDC-ABMT might increase the disease-free survival rate for certain patients.[453,454,455]

[xxiii] Autologous means the individual is both the donor and the recipient.

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.[456,457,458,459,460,461,462,463] The National Comprehensive Cancer Network has excluded HDC-ABMT from its clinical practice guidelines since 1996.[464]

A systematic review of 14 randomized controlled trials has shown high-quality evidence of increased treatment-related mortality and little or no increase in survival by using HDC-ABMT for women with early poor prognosis breast cancer.[465] Given that newer agents, such as taxanes and monoclonal antibodies, have shown benefits in both the adjuvant and metastatic settings without large increases in toxicity, little role remains for HDC-ABMT in the treatment of breast cancer.[466]

Estimated Marginal Cost of the Mandate

Given that HDC-ABMT is most often considered experimental and newer breast cancer treatments are now available without the increased toxicity associated with the use of HDC-ABMT, the direct cost impact of the BMT mandate is estimated as $0 and 0% of Commonwealth fully insured premium.

Cardiac Rehabilitation

The cardiac rehabilitation (CR) mandate requires coverage for the expenses related to CR. For the purposes of this mandate, CR shall mean the multidisciplinary, medically necessary treatment of people with documented cardiovascular disease provided in either a hospital or other setting which meets the standards promulgated by the Commissioner of Public Health.[467]

Effect of the Mandate on Health

Based on the most recent mortality data available, over 640,000 Americans died from diseases of the heart in 2017, accounting for 23% of all deaths that year. [468] In the United States, heart disease is the leading cause of morbidity and mortality in the country,[469] with 12.1% of adults having diagnosed heart disease.[470] Currently, an estimated 92.1 million adults in the United States have at least one type of cardiovascular disease, which may lead to myocardial infarction (MI), stroke, or death, [471] and in 2030, 43.9% of the U.S. adult population is projected to have some type of cardiovascular disease.[472]

CR is a medically supervised program designed to improve a patient's cardiovascular health if the patient has experienced a heart attack, heart failure, angioplasty, or heart surgery.[473] For people of all ages with heart disease, sometimes referred to as cardiovascular disease (CVD)[474], CR is a multidisciplinary intervention that combines exercise, education, and psychological support in medically supervised programs to help patients recover more quickly after a cardiac event and stay healthy by focusing on: improving physical, mental, and social functioning; reducing health risks and disability; fostering and encouraging compliance with healthy behaviors; and promoting active lifestyles.[475,476] To meet these objectives, CR has three equally important parts:[477]

- Exercise counseling and training
- Education for heart-healthy living

- Behavioral counseling to reduce stress

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.[478] As a result, CR is not only an important part of recovery from a heart attack or other heart problem, but it can also help prevent another heart problem in the future.[479] In addition to being cost effective, research has shown CR reduces hospital readmissions, secondary events, morbidity, and mortality while improving exercise capacity, lipid profiles, quality of life, and psychological well-being.[480,481] These positive outcomes are similar in both center- or home-based CR programs;[482,483] however, longer-term studies on the impact of home-based CR on clinical events are needed.[484,485]

Recognizing the benefits of CR, international and evidence-based guidelines from the American Heart Association (AHA) and the American College of Cardiology Foundation (ACCF) include referral to CR for the management and prevention of coronary heart disease.[486,487] However, despite the evidence that CR saves lives and reduces healthcare costs, only 20% of the nearly 1 million Americans who experience a qualifying event each year participate in CR.[488] Some factors found to be associated with low participation rates in CR programs include: the qualifying event (e.g., acute myocardial infarction without procedure vs. coronary artery bypass surgery only), misunderstanding the reasons for onset of coronary heart disease, financial cost, low self-efficacy, lack of perceived benefits, misunderstanding of the purpose of CR, distance and/or lack of transportation, self-concept, self-motivation, family composition, social support, race, occupation, and no referral.[489, 490,491,492] In addition, adherence to a CR program once enrolled also represents a significant concern; factors associated with non-adherence are being older and female, having fewer years of formal education, perceiving few benefits of CR, having angina, and being less physically active during leisure time.[493]

In order to increase utilization of CR, the Million Hearts Cardiac Rehabilitation Collaborative developed a road map to improve CR use, including increasing participation rates to ≥70% by 2022.[494] To accomplish this goal, the U.S. Centers for Disease Control and Prevention (CDC) and the American Association of Cardiovascular and Pulmonary Rehabilitation released the Million Hearts Cardiac Rehabilitation Change Package which focuses on improving awareness of CR value, increasing referral of eligible patients, and reducing system and patient barriers to participation and adherence.[495,496] These are all critical steps in improving the referral, enrollment, and participation rates in CR programs.[497,498] Further supporting these efforts, the Agency for Healthcare Research and Quality (AHRQ) recently announced a $6 million, three-year project designed to save lives by increasing patient participation in CR after cardiovascular events such as heart attacks, heart failure, angioplasty, or heart surgery.[499]

Estimated Marginal Cost of the Mandate

Responses to the carrier survey consistently indicated these services are clinically appropriate and cost-effective care that would be covered in the absence of the mandate. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Certified Nurse Midwives (CNMs)

The CNM mandate requires plans to pay for services rendered by CNMs for the same services that are reimbursed when performed by any other practitioner and are within the lawful scope of practice of CNMs.[500]

Effect of the Mandate on Health

CNMs are Advanced Practice Registered Nurses (APRNs)[501] who provide a full range of healthcare services for women, from adolescence beyond menopause.[502] These services include the independent provision of: primary care; gynecologic and family planning services; preconception care; care during pregnancy, childbirth, and the postpartum period; care of the normal newborn; the ordering of laboratory and diagnostic tests; and the prescription of medications, including contraceptives.[503] CNMs are legally recognized to practice in all 50 states and in the District of Columbia, though CNMs are regulated at the state level.[504] In Massachusetts, CNMs have independent practice and prescribing authority,[505] but are not recognized as primary care providers.[506] Reimbursement in all state Medicaid programs, as well as in Medicare, is mandatory for CNMs at 100% of the physician reimbursement rates.[507]

CNM services focus primarily on reproductive health and gynecological and obstetrical care, but also might be provided to male partners for treatment of sexually transmitted diseases and to normal newborns during the first 28 days after birth.[508] In 2017, CNMs and certified midwives attended almost 351,968 births in the United States.[509] Today, approximately 500 CNMs are licensed in Massachusetts,[510] and over 12,000 are licensed nationwide.[511] CNMs are often also registered nurses or bachelor's degree-prepared nurses who have completed an undergraduate program in nursing, as well as, at minimum, a graduate program in midwifery, and have passed the national certifying exam offered by the American Midwifery Certification Board (AMCB).[512] Although many programs require that applicants be registered nurses or have a bachelor's degree in nursing, 22 programs currently have options for non-nurses.[513]

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 APRN Regulation in an attempt to create consistent regulations and legislation across the United States.[514] The group is attempting to standardize licensure to practice, APRN program accreditation, national certification requirements, and educational requirements.[515] Today, many states have adopted portions of the model, but there are still variations in the regulation of APRN roles from state to state.[516]

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.[517] 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."[518]

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."[519] These results were also found in a large outcomes study of CNM-attended homebirths that 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."[520] A study of spontaneous and episiotomy-caused perineal injury during birth found both severity and prevalence were significantly lower in CNM-attended births.[521]

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 healthcare 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 promote the highest standard for education, national professional certification, and licensure; stated the need for options and preferences of women in healthcare; stated 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.[522]

Estimated Marginal Cost of the Mandate

The CNM mandate requires plans to pay for services rendered by CNMs when the same services are reimbursed when performed by any other practitioner and are within the lawful scope of practice of midwives. The primary effect of the mandate, as noted by one major carrier in BerryDunn's survey, is to shift utilization from physicians to CNMs. As CNMs are generally lower-cost providers than physicians, and it is unlikely fully insured members would base childbearing decisions on the availability of coverage to receive services from CNMs as opposed to physicians, this study estimates the 2018 marginal, direct cost impact of this mandate to be $0 and 0% of Commonwealth fully insured premium.

Certified Registered Nurse Anesthetists (CRNAs)

The CRNA mandate requires plans to pay for services rendered by CRNAs if the same services are reimbursed when performed by any other practitioner and are within the lawful scope of practice of CRNAs.[523]

Effect of the Mandate on Health

CRNAs are advanced practice registered nurses (APRNs).[524] CRNAs administer anesthesia and provide care before, during, and after surgical, therapeutic, and obstetrical procedures; they might also provide pain management and some emergency services.[525] There are more than 40,000 CRNAs[526] practicing in the United States, providing over 49 million anesthetics to patients annually.[527] There are over 1,100 CRNAs employed in Massachusetts.[528] According to the American Association of Nurse Anesthetists, CRNAs are the primary anesthesia providers in rural America, enabling healthcare in underserved areas to offer trauma stabilization, as well as surgical, obstetrical, and pain management services.[529]

CRNAs are required to complete a bachelor's or graduate degree in nursing and a minimum of a master's degree from an accredited nurse anesthesia educational program.[530] They must also pass a national certification exam following graduation.[531] CRNAs must be licensed as a registered nurse (RN) and/or an APRN in the United States, and have a minimum of one year of work experience as an RN in a critical care setting.[532] In Massachusetts, CRNAs are certified to practice as APRNs within their authorized specific clinical category.[533] In 2008, the National Council of State Boards of Nursing (NCSBN) adopted the Consensus Model for APRN Regulation in an attempt to create consistent regulations and legislation across the United States.[534] The group is attempting to standardize licensure to practice, APRN program accreditation, national certification requirements, and educational requirements.[535]

The federal Centers for Medicare and Medicaid Services (CMS) requires that CRNAs be supervised by a physician, unless they are located in a state that has exempted CRNAs from the supervision requirements pursuant to the November 13, 2001, CMS rule set forth in the Federal Register.[536,537] As of 2020, 18 states and Guam have formally opted out of the CMS supervision requirements.[538]

In Massachusetts, CRNAs do not have independent prescribing authority. Instead, they must have a written agreement outlining physician supervision of their prescriptive practice;[539,540] 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 Massachusetts Board of Registration in Medicine.[541542] CRNA prescriptive practice is also limited to the immediate perioperative care of a patient.[543] Massachusetts and Maine are the only New England states that do not grant CRNA full practice authority.[544,545]

In a review of seven years of Medicare inpatient claims data analyzing safety outcomes for patients, researchers found that the CMS policy allowing states to opt out of the physician supervision requirements was not associated with increased risks to patients.[546] Other studies comparing rates of complications for obstetrical anesthesia between CRNAs and anesthesiologists found no difference between the two staffing models.[547,548] A recent study comparing scope of practice laws governing CRNAs provided strong evidence of differences in the likelihood of anesthesia complications by patient characteristics, patient comorbidities, and the procedures being administered, but virtually no evidence that the odds of a complication differ by scope of practice or delivery model.[549]

Estimated Marginal Cost of the Mandate

The CRNA mandate requires plans to pay for services rendered by CRNAs when the same services are reimbursed when performed by any other practitioner and are within the lawful scope of practice of nurse anesthetists. The primary effect of the mandate, as noted by multiple carriers in BerryDunn's survey, is to shift utilization from physicians to CRNAs. As CRNAs are generally lower-cost providers than physicians, and it is unlikely fully insured members would base care decisions on the availability of coverage to receive services from CRNAs as opposed to physicians, this study estimates the 2018 marginal cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Clinical Trials for Treatment of Cancer

The clinical trials for treatment of cancer mandate requires coverage for services for patients enrolled in a qualified clinical trial to the same extent that the services would be covered if the patients were not receiving care in a qualified clinical trial. To require coverage, a qualified clinical trial must be intended to treat cancer and must meet the other criteria set forth in the law.[550]

Effect of the Mandate on Health

According to the National Cancer Institute, a clinical trial is "a type of research study that tests how well medical approaches work in people. These studies test new methods of screening, prevention, diagnosis, or treatment of a disease."[551] The National Cancer Institute defines the different types of clinical trials to be for treatment, prevention, screening, or quality of life/supportive/palliative care.[552] Clinical trials are categorized into phases. If a treatment is successful in one phase, it will proceed to the next phase. There are three main phases of clinical trials; although they are explained in the context of drug treatment trials, the same concepts apply to most types of clinical trials:

- Phase I clinical trials typically enroll 15 to 30 participants, and seek to determine: a safe dose; optimal mode of administration; and how the treatment affects the human body and fights cancer.[553]
- Phase II clinical trials usually enroll less than 100 participants, and attempt to determine: if the treatment has an effect on a certain cancer and how the treatment affects the body and fights cancer.[554]

- Phase III clinical trials typically enroll from 100 participants to several thousand participants, and compare the new treatment or use of the new treatment with the current standard treatment.[555]

The early Phase 0 clinical trials, and the later Phase IV clinical trials, are less common.[556] Phase 0 clinical trials are very small and help researchers decide if a new agent should be tested in a Phase I clinical trial.[557] In Phase 0 clinical trials, patients face lower risk but will not benefit from the clinical trial; these clinical trials are used to study how the cancer, body, and treatment interact, and are intended to hasten and streamline the approval process.[558] Phase IV clinical trials look at long-term safety and effectiveness, and take place after a new treatment has been approved and is on the market.[559]

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.[560] Clinical trial participants are randomized into treatment or control groups. The control groups typically receive the standard of care currently being used, while the treatment groups receive the new treatment intended to improve the current standard.[561] Most cancer clinical trials do not use placebos except in instances where there is no proven effective treatment for the type of cancer being studied.[562] The American Cancer Society (ACS) points out that participation empowers patients to actively decide their cancer treatment, and provides an opportunity to help others and advance research.[563] Participation drawbacks might be that the new treatment is not as effective for an individual as the current standard, or might cause different or more severe side effects than the standard treatment protocol; likewise, clinical trials also might require more testing or clinical appointments than standard treatment.[564]

A 2017 study on public and patient perspectives of clinical trials found that 88% of participants were "interested in learning more about taking part in clinical trials," and 80% of participants "would like to participate in a clinical trial."[565] Yet ACS reports that the biggest barrier to the completion of clinical trials is that fewer than 5% of adults participate in them, with the most common reason being that patients did not know the studies were an option for them.[566] Of patients aware of their eligibility, only 25% reported participating.[567] Participants do report a high rate of satisfaction, especially with the quality of their care; over 75% report that they would recommend participation to others.[568] Approximately 60% of children under age 15 participate in clinical trials, and this has been credited as one reason childhood cancer survival rates have increased so dramatically in the last few decades.[569]

Estimated Marginal Cost of the Mandate

Responses to the carrier survey consistently indicated these services would be covered in the absence of the mandate. In addition, multiple carriers indicated this coverage is required by the ACA. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

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.[570]

Effect of the mandate on health

The United States has an estimated 61 million women ages 15 – 44;[571] of these, 70% are sexually active but do not want to become pregnant.[572] In the United States, nearly half (45% or 2.8 million) of all pregnancies are estimated to be unintended.[573] Estimates for 2014 indicate that the percentage of women reporting that their pregnancies occurred too soon or were unwanted was 33% in Massachusetts.[574]

Family planning was 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, and it continues to be in Healthy People 2030.[575] 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."[576]

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.[577] Additionally, contraceptive use might decrease menstrual period pain and bleeding and reduce gynecological disorder risks, including those for ovarian and endometrial cancers.[578] The negative consequences of unintended pregnancies are numerous. They include: delays in initiating prenatal care; the reduced likelihood of breastfeeding; increased risk of maternal depression; and increased risk of violence.[579] Some studies show that children born from an unintended pregnancy might be more likely to suffer from poor physical and mental health in childhood, and they might attain lower educational and behavioral outcomes.[580, 581, 582, 583, 584, 585, 586]

Similarly, outcomes are worse for unintended pregnancies in teen mothers; 82% of pregnancies among mothers age 15 – 19 are unintended.[587] An adolescent female who experiences an unintended pregnancy is less likely to graduate from high school or attain a GED by age 30, and will earn approximately $3,500 less per year on average than her peers who delay having children; teen fathers experience similar lower educational achievement and income.[588] Teen mothers, on average, receive twice as much federal aid for twice as long as non-parent teens.[589] Finally, children of teenage parents 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.[590]

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 a woman's health, as well as some pre-term births and their associated birth defects.[591]

Contraceptive Effectiveness

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% of women do not need a contraceptive method,[592] 10% of women are at risk of unintended pregnancy but are not using contraception.[593] 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.[594]

Slightly less than half of pregnancies in the United States each year are unintended; of these, research shows that 95% were experienced by women either not using contraception or using it inconsistently.[595] Most women who use contraception (72%) rely on nonpermanent methods, while the remainder rely on male or female sterilization.[596]

Contraception success rates depend on either permanency or consistency of use; permanent sterilization methods result in a failure rate of less than 1% with typical use, while other methods vary widely, from 1% failure rates for implants to 28% 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."[597] Table 22 summarizes the estimated number of users of each type of contraception and the expected proportion of pregnancies expected for each assuming typical use.

Table 22

Contraceptive Method Choice: Most Effective Method Used in the Past Month by U.S. Women, 2014[598]

Method	Number of Women	% of Women Aged 15 – 44	% of Women at Risk of Unintended Pregnancy	% of Contraceptive Users	% of Women Who Experience Unintended Pregnancy Within the First Year of Typical Use[599]
Pill	9,572,477	15.6%	22.7%	25.3%	7%
Tubal (Female) Sterilization	8,225,149	13.4%	19.5%	21.8%	0.5%
Male Condom	5,496,905	8.9%	13.0%	14.6%	13%
Intrauterine Device	4,152,344	7.2%	10.6%	11.8%	0.1 – 0.8%
Vasectomy (Male Sterilization)	2,441,043	4.0%	5.8%	6.5%	0.15%
Withdrawal	3,042,724	5.0%	7.2%	8.1%	22%[600]
Injectable	1,481,902	2.4%	3.5%	3.9%	4%
Vaginal Ring	905,896	1.5%	2.1%	2.4%	7%
Fertility Awareness-Based Methods	832,216	1.3%	2.0%	2.2%	2 – 23%
Implant	965,539	1.6%	2.3%	2.6%	0.1%
Patch	69,106	0.1%	0.2%	0.2%	7%
Emergency Contraception: Pill or Intrauterine Device (IUD)	69,967	0.1%	0.2%	0.2%	Varies with regimen used and time between unprotected intercourse and treatment[601]
Other Methods*	234,959	.04%	0.6%	0.6%	Varies
No Method, at Risk of Unintended Pregnancy	4,408,474	7.2%	10.5%	NA	85%
No method, not at risk	19,302,067	31.4%	NA	NA	NA
Total	67,491,766	100.0%	100.0%	100.0%	NA

*****Includes diaphragm, female condom, foam, cervical cap, sponge, suppository, jelly/cream and other methods. NOTE: "At risk" refers women who are sexually active, not pregnant, not seeking to become pregnant or postpartum, and not contraceptively sterile. NA=Not applicable.*

The Role of Access

For nonpermanent means of contraception, consistency of use directly impacts success in preventing unintended pregnancy; in particular, for oral contraceptives (OCPs), use must be continuous to be effective. Barriers to

consistent use for OCPs include associated out-of-pocket costs; dispensing restrictions such as monthly pharmacy visits, which many women find inconvenient; and other access issues.[602,603] The American College of Obstetricians and Gynecologists (ACOG) supports improved access to contraceptives to improve access and encourage consistent use.

Overall, insurance coverage is associated with increased use of contraception.[604] Since implementation of the ACA's contraceptive coverage as a preventive service, fewer women have to pay out-of-pocket for contraceptives.[605] Research has shown that when the copay for contraceptives has fallen to $0, contraceptive use has risen among women, and there is an increased probability of these women choosing a long-term contraceptive method above the general increasing trend for these methods. [606] No-cost contraception has been shown to increase use of effective birth control methods, and reduce unintended pregnancy and abortion.[607]

However, in one prospective study that removed financial barriers and offered women their choice of OCPs for three years, many women were still inconsistent in filling their prescriptions.[608] Research indicates that women are less consistent in their contraceptive use when they are not involved in the choice of contraception prescribed by their doctor, and that, to improve consistent use and thus efficacy, addressing women's contraceptive preferences and needs should consider their social, emotional, and sexual lifestyles.[609]

For long-acting reversible contraception (LARC) methods, which are the most effective nonpermanent contraceptive methods, ACOG recommends increasing access to, and removing barriers to providing, contraceptive implants and IUDs.[610] These methods are associated with the highest continuation rates of contraceptives, requiring "a single act of motivation for long-term use, eliminating adherence and user dependence from the effectiveness equation."[611] However, research has found that out-of-pocket costs are a barrier to use, even for privately insured women,[612, 613] with one analysis finding that once these barriers were removed, the majority of women choose LARC methods for contraception.[614] These studies, though, were conducted prior to the implementation of the ACA, which has significantly reduced out-of-pocket expenses for these methods and may increase their utilization.[615, 616]

Research on utilization of permanent sterilization focuses most often on the postpartum period (first six – 12 months following childbirth), when women are more likely to choose these methods. A study examining women's contraception in this period found that, while 78% preferred either sterilization or LARC, only 30% accessed these methods.[617] These researchers concluded that "[w]omen's contraceptive needs could be better met by counseling about all methods, by reducing cost barriers, and by making [LARC and permanent sterilization] available at more sites."[618] In a study comparing long-term contraceptive choices for women based on insurance status, researchers found that, of women who received a LARC IUD placement or sterilization within one year of pregnancy, those with public insurance (Medicaid) were more likely to choose permanent sterilization over LARC.[619] Other researchers found that the use of sterilization and LARC varied widely geographically, possibly due to "state policies and funding for family planning services, local medical norms surrounding contraceptive practice, and women's and couples' demand or preference for different methods."[620] These researchers found that women with Medicaid coverage for their delivery were more likely to access female sterilization, LARC, or injectables in the postpartum period than were women with private insurance.[621] Again, however, these studies used data prior to the implementation of the ACA and the mandated expansion of insurance to include permanent sterilization methods for women without cost-sharing.

Conclusion

In general, when used correctly and consistently, contraceptives are effective at preventing unintended pregnancies and the 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 LARCs. Consistent and correct 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.

Estimated Marginal Cost of the Mandate

The Massachusetts contraceptive services mandate in effect throughout 2018[xxiv] 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 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 $0 and 0% of Commonwealth fully insured premium.

Cytological Screening (Pap Smear)

The cytological screening mandate requires coverage for cytological screening annually for women 18 years and older.[622]

Effect of the Mandate on Health

A Pap test, also called a Pap smear or Papanicolaou test, removes cells from the cervix so they might be checked under a microscope for cervical cancer or cell changes that might lead to cervical cancer.[623] 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 Pap test, which detects cervical cancer and precancerous lesions."[624,625,626] Further, the survival rate for women with precancerous lesions diagnosed through a Pap test is nearly 100%, as cancer is prevented altogether, and women with localized cervical cancer, most often detected early, have a five-year survival rate of 92%.[627628,629] 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 56%, while the five-year survival rate for distant-stage cervical cancer is only 17%;[630] most women diagnosed at these stages have not had a Pap test within the five years prior to diagnosis.[631]

While the Pap test has been extremely helpful in identifying precancerous lesions and early-stage cancer in women who are screened, cervical cancer is still prevalent; it is the fourth most common cancer for women worldwide.[632]

[xxiv] This report addresses mandates in force throughout 2018. It does not address Chapter 120 of the Acts of 2017 "An Act Relative to Advancing Contraceptive Coverage and Economic Security in our State" the relevant portions of which were not effective until July 2018, leaving insufficient time for the Act's provisions to have an effect measurable under this report's methodology.

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).[633] HPV infection is common, but it is usually cleared by the body and does not cause cancer. However, persistent HPV infection causes almost all cervical cancers; 90% of anal cancers; and 60% – 70% of oropharyngeal, vaginal, vulvar, and penile cancers.[634] This new understanding of the causes of these cancers has led to a shift from a strategy mostly focused on screening for precancerous lesions and cancers, to approaches that include vaccination against HPV to prevent infection, as well as screening not only for precancerous lesions and cancers, but also for HPV itself, as reflected in the 2012 updates to the American Cancer Society's cervical cancer screening guidelines.[635]

Initial infection with HPV is common in young women within their first decade of sexual activity.[636] However, less than 10% of these infections persist and, relatively slowly, become precancerous lesions, most often between 5 and 10 years after initial infection.[637] From these, a minority of cases progress to invasive cancer; this also often takes many years or decades, with the risk highest in women 35 – 55 years old.[638]

Given these statistics, agreement is near universal on the benefits of cytological screening for women. Many U.S. government agencies and medical societies now agree on a single set of recommendations regarding testing methods and intervals the U.S. Preventive Services Task Force (USPSTF) released in August 2018. These recommendations call for less frequent screening, as researchers have found that:

> [S]creening more frequently than every 3 years with cytology alone confers little additional benefit, with a large increase 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 adverse effects, including the potential for cervical incompetence and preterm labor during pregnancy. Evidence from randomized clinical trials, observational studies, and modeling studies suggest that a 5-year screening interval for primary hrHPV testing alone or cotesting offers the best balance of benefits and harms. Screening more frequently than every 5 years with primary hrHPV testing alone or cotesting does not substantially improve benefit but significantly increases the number of screening tests and colposcopies.[639]

The USPSTF assigns a letter grade for each of its recommendations based on the certainty of the evidence and on the balance of benefits and harms of a preventive service. The grades range from "A," having high certainty and substantial net benefit for the preventive service, to "D," having zero or negative net benefit regardless of the level of certainty for the preventive service.[640] As of 2018, the USPSTF gives the recommendations for women age 21 – 65 a grade of "A," and the recommendations for women under 21 and over 65 a grade of "D."[641] Under the Affordable Care Act (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 co-payments). [642]

Table 23
Cytological Screening Recommendations[643]

General Recommendations	Women Age	
	21 – 65	65+
• Screening more frequently than every 3 years with cytology confers little benefit • No screening for women under age 21 • No screening for women who have had a hysterectomy with removal of the cervix and do not have a history of a high-grade precancerous lesion • Routine screening should continue for women found to have a high-grade precancerous lesion within the past 20 years, regardless of age	• For women 21 – 29 years, screening for cervical cytology alone every 3 years • For women age 30 – 65, screening every 3 years with cervical cytology alone, and every 5 years with high-risk human papillomavirus (hrHPV) testing alone or • For women age 30 – 65, screening every 5 years with hrHPV testing in combination with cytology (cotesting)	• No screening for women who have had adequate prior screening and are not otherwise at high risk for cervical cancer

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.

Estimated Marginal Cost of the Mandate

Responses to the carrier survey consistently indicated these cancer screening services are clinically and cost-effective care that would be covered in the absence of the Massachusetts mandate. In addition, carriers noted coverage for cytological screening for cervical cancer is required by the ACA, though at a lesser frequency than required by the Massachusetts mandate. Carriers also noted the services were covered prior to the mandate, an additional indicator that the state mandate does not increase health insurance costs. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Dentists

This mandate requires a dentist to be considered a physician for purposes of reimbursement for any services covered by the medical policy/contract that dentists are licensed to perform.[644]

Effect of the Mandate on Health

Dentists are doctors of oral health who are focused on the diagnosis, treatment, and prevention of diseases of the mouth and maxillofacial area.[645] To practice general dentistry, dentists must complete an undergraduate degree, as well as four years of dental school.[646] Residency training is required, spanning an additional two to eight years, depending on the specialty or the area of advanced dental education.[647]

To obtain a license, dentists must pass Part I and Part II of the National Board Dental Examinations written tests, which cover basic biomedical sciences, dental anatomy, ethics, and other clinical subjects, including patient management.[648,649,650] Most states also require an additional clinical examination.[651] For states that do not require the clinical examination, alternative requirements including postgraduate education programs are in place.[652] In Massachusetts, the licensure requires successful completion of a Board-approved regional or state clinical examination.[653] Applicants for dental licensure in Massachusetts must also pass the Massachusetts Dental Ethics and Jurisprudence Exam.[654] In addition, effective November 3, 2017, each dentist must enroll with MassHealth as an Ordering, Referring and Prescribing (ORP) non-billing provider (if not already enrolled as an approved billing provider) before applying for an initial dental license or seeking to renew an existing dental license.[655] Within the practice of dentistry, there are 10 specialties recognized by the National Commission of Recognition of Dental Specialties and Certifying Boards, including: dental public health; dental anesthesiology; endodontics; oral and maxillofacial pathology; oral and maxillofacial radiology; oral and maxillofacial surgery; orthodontics and dentofacial orthopedics; pediatric dentistry; periodontics; and prosthodontics.[656]

Dentists are recognized as physicians by Medicare when providing medically necessary services while acting within the scope of the dental license.[657] Dental services are generally excluded from Medicare coverage, i.e. procedures primarily provided for the care, treatment, removal, or replacement of teeth or structures supporting the teeth.[658] In contrast, services that might be considered as medical, even when performed by a dentist, are included in Medicare coverage.[659] These services are defined as any otherwise covered services that might legally and alternatively be performed by doctors of medicine, osteopathy, and dentistry—such as dental examinations to detect infections prior to certain surgical procedures; treatments of oral infections and interpretations of diagnostic X-ray examinations in connection with covered services; and extractions performed in preparation for radiation treatment for neoplastic disease involving the jaw.[660,661]

A comparison of patient visits to emergency departments (EDs), physician offices, and dental offices for the management of dental problems found that patients visiting EDs and physician offices typically did not receive definitive care, and subsequently visited a dental office for treatment.[662]

Estimated Marginal 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 that dentists are licensed to perform. Responses to the carrier survey consistently indicated these services would be covered in the absence of the mandate. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Diabetes-Related Services and Supplies

The diabetes mandate requires coverage for a wide range of services and supplies related to diabetes treatment that have been prescribed by a health professional, including: blood glucose monitors; blood glucose monitoring strips; ketone strips; lancets; insulin; insulin syringes; prescribed diabetes medications that influence blood sugar levels; laboratory tests; insulin pumps; therapeutic shoes and inserts; supplies and equipment approved by the U.S. Food & Drug Administration (FDA); and outpatient self-management education, including medical nutrition therapy.[663]

Effect of the Mandate on Health

Diabetes is a significant public health challenge of the 21st century.[664] It is one of the most common and costly chronic diseases in the United States.[665] A total of 30.3 million Americans (9.4% of the population) have diabetes, including 23.1 million diagnosed individuals and an estimated 7.2 million undiagnosed individuals.[666] In 2015, over 1.5 million new cases were diagnosed, and diabetes was the seventh-leading cause of death.[667] An estimated 33.9% of adults aged 18 years or older have pre-diabetes, and nearly half of adults aged 65 years or older have prediabetes, 48.3%.[668] In Massachusetts, 8.3% of adults have been diagnosed with diabetes as of 2016, and 7.2% have pre-diabetes, lower than the national figure of 8.5% for adults diagnosed with diabetes.[669]

Diabetes mellitus is caused when the body cannot produce enough or appropriately respond to insulin, the hormone used to absorb and utilize glucose as fuel for the body's cells to produce energy.[670] The three most common types of diabetes are:

- Type 1 diabetes is thought to be caused by an autoimmune reaction that stops the body from producing insulin. About 5% of people with diabetes have type 1. Currently, no one knows how to prevent type 1 diabetes, and individuals must take insulin every day to survive.
- Type 2 diabetes results when the body does not utilize insulin well and cannot keep blood sugars within a normal range. Type 2 diabetes can be prevented or delayed with lifestyle changes, such as losing weight, eating healthy food, and being active.
- Gestational diabetes develops in pregnant women who have never had diabetes, and usually goes away after the baby is born but increases the mother's risk for type 2 diabetes later in life.[671]

Consistently high blood glucose levels can lead to serious diseases, and people with diabetes have a higher risk of developing infections.[672] Diabetes reduces median life expectancy by 8 years[673] and increases the risk of:[674,675,676]

- Cardiovascular disease, leading to heart attack or stroke (two to three times more likely in people with diabetes)
- Kidney disease (experienced by up to 40% of people with diabetes)
- Non-traumatic lower limb amputation (likelihood is 25 time greater for people with diabetes)
- Pregnancy complications, including major birth defects, spontaneous abortion, and excessively large babies, as well as putting the child at an increased risk for type 2 diabetes in adulthood.[677]

- 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.[678] Key objectives to address the diabetes public health challenge include reducing: the annual number of new cases of diagnosed diabetes in the population; the death rate among persons with diabetes (all-cause, diabetes-related, and cardiovascular disease-related); and lower-extremity amputations, in part through the following measures (this list is not exhaustive):[679]

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

For those with undiagnosed diabetes:

- 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 with pre-diabetes and at high risk for diabetes, increase prevention behaviors:

- Increase level of physical activity
- Attempt to lose weight
- Reduce the dietary fat or calories

Maintaining blood glucose levels, blood pressure, and cholesterol at or close to normal levels can help delay or prevent diabetes complications.[680] The supplies and services required under the Massachusetts mandate are necessary to effectively manage diabetes.

Estimated marginal cost of the mandate

Responses to the carrier survey consistently indicated these services are clinically appropriate and cost-effective care that would be covered in the absence of the mandate. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Early Intervention Services

This mandate requires coverage for early intervention services from birth until age three for children who have identified handicapping conditions or who are at risk for developmental delays due to biological, established, or environmental factors.[681] Early intervention services are for the purpose of minimizing the potential for developmental delay and for preventing institutionalization of such children.[682] Early intervention services are developmental services, including, but not limited to, speech, occupational and physical therapy, social work, psychological, educational, and nursing services.[683]

Effect of the Mandate on Health

Neuroscience and behavioral research shows that the architecture of the brain is constructed through an ongoing process that begins before birth and continues into adulthood, with simpler neural connections forming first, followed by more complex circuits.[684] Sensory pathways develop first, including vision and hearing, followed by early language skills, and then higher cognitive skills.[685] In the first few years of life, more than one million new neural connections are formed every second; after this initial period of rapid proliferation, these connections are reduced through a process called pruning so that the brain circuits become more efficient.[686] Neural connections proliferate and prune within prescribed order, with later, more complex brain circuits built upon earlier, simpler circuits.[687] As a result, early experiences affect the nature and quality of the brain's developing architecture with the circuits used during this period being reinforced, while those not used are pruned.[688] The brain develops at its fastest pace during the first three years of life, and babies' brains are primed to respond to everyday loving moments, from affection to comfort to play.[689] Relationships build the foundation for development; as a result, consistent engaging interactions with parents and caregivers strengthen young children's brains.[690] For children born at risk or diagnosed with a developmental delay or disability, these interactions can be compromised, thus affecting lifelong growth and development.

Early intervention services are available to babies and young children with developmental delays and disabilities and their families,[691] and are designed to help children gain physical, thinking, communication, social, and emotional skills.[692] Services often include physical, occupational, and/or speech therapy; services for hearing impairment; family training; and nutrition services.[693,694] Each state provides its own set of programs and services to every eligible child from birth to age three, under Part C of the Individuals With Disabilities Education Improvement Act.[695]

The overall outcomes for babies and young children receiving early intervention services include: increased motor, social, and cognitive functioning; acquisition of age-appropriate skills; reduced negative impacts of their disabilities; and decreased need for special education.[696] Children who receive high-quality and early intervention services have improved outcomes in health, language and communication, cognitive and social/emotional development, academic achievement, labor market success, as well as a reduction in delinquency, crime, and social welfare program use.[697,698,699]

Estimated Marginal Cost of the Mandate

The estimated marginal, direct cost impact of this mandate is $0. Most carriers stated their coverage would not change in the absence of the mandate, citing medical necessity and overlaps with ACA requirements. One large carrier stated that the benefit would be covered in the absence of the mandate, except for certain nonclinical services. However, BerryDunn's clinical expert reviewed a summary by procedure code of 2018 claims extracted from the MA APCD using the carrier-reviewed data pull specification for this mandate and categorized all the services as clinical. As such, this study estimates the 2018 impact of this mandate as $0, and 0 percent of fully insured Commonwealth premium.

Hearing Screening for Newborns

This mandate requires coverage for hearing screening for newborns.[700]

Effect of the Mandate on Health

Hearing loss affects approximately 1.7 infants screened per thousand in the United States each year.[701] In Massachusetts, over 1200 newborns failed a hearing screening before leaving the hospital, and 12% of these newborns were subsequently diagnosed with hearing loss after more extensive testing in 2017.[702] 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."[703] Research suggests that a child's speech and language development is most intensive during the first three years of life, when the brain builds the nerve pathways necessary for "understanding auditory information."[704]

Age at diagnosis influences outcomes for children with hearing loss: The earlier the detection, the more options and opportunity for treatment, and the better the outcome.[705,706] As research continues to describe the rapid development of the brain before the age of three,[707] and positive outcomes are increasingly associated with early enrollment of hearing-impaired children into treatment programs,[708] it becomes more critical to lower the age of diagnosis to as early as possible, and at no later than three months of age.[709]

Universal newborn screening leads to earlier detection and treatment of hearing loss.[710] 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.[711,712,713,714]

The JCIH endorses Early Hearing Detection and Intervention (EHDI) for infants with hearing loss.[715] The goal of EHDI is "to maximize linguistic competence and literacy development for children who are deaf or hard of hearing."[716] The JCIH 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.[717] Before six months of age, those with confirmed hearing loss "should receive appropriate intervention…from health care and education professionals with expertise in hearing loss and deafness in infants and young children."[718] 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."[719]

All states have established EHDI. Forty-three states, as well as the District of Columbia and Puerto Rico, mandate newborn hearing screening programs.[720] In 2016, data collected by the Centers for Disease Control and Prevention (CDC) showed that over 98% of newborns in the United States were screened for hearing loss, and 75% of infants with hearing loss were diagnosed before three months of age.[721] In fact, EHDI surveys show improvement in several measures for diagnosis and treatment of hearing loss from 2005 to 2017.[722,723,724]

Table 24
CDC EHDI Survey Data for 2005 and 2017

	2005	2017	Improvement 2005 to 2017
Infants received hearing screening before age 1 month	80.1%	97.5%	21.7%
Infants with hearing loss enrolled in early intervention	57.8%	65.1%	12.6%

These programs are making progress toward the goal of screening all infants, and diagnosing and enrolling those infants with hearing loss in treatment earlier.

Estimated Marginal Cost of the Mandate

Responses to the carrier survey consistently indicated that these services would be covered in the absence of the mandate. In addition, multiple carriers noted that coverage of hearing screenings is required by the ACA. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Home Health Care

The home health care (HHC) mandate requires coverage for medically necessary healthcare services, including but not limited to, nursing and physical therapy, provided by a home health agency in a patient's residence.[725] Additional services, such as occupational therapy, speech therapy, medical social work, nutritional consultation services, the services of a home health aid and the use of durable medical equipment and supplies are included in the mandate's required coverage, provided these services are determined to be medically necessary components of the nursing and physical therapy services.

Effect of the Mandate on Health

HHC is a term describing a broad range of healthcare services provided in the home.[726] HHC is 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, as well as assistance with essential activities of daily living.[727] HHC is most often provided by licensed practical nurses, registered nurses, licensed social workers, certified nurse assistants, and home health aides.[728]

HHC covers a wide array of services, and can often result in earlier discharge from hospitals and delay the need for institutional services, such as long-term nursing home care.[729,730] Use of HHC continues to grow for a variety of

reasons, including: aging populations; increasing hospital costs; medical advances that allow for better management of chronic and incurable diseases; increased prevalence of chronic diseases; and patient choice.[731]

HHC is medically based, and might include the following types of assistance:[732,733]

- Occupational, physical, and/or speech therapy
- Skilled nursing
- Vital sign (blood pressure, heart rate, temperature, and rate of breathing) monitoring
- Medical social services and counseling
- Psychiatric care
- Medical observations and assessments
- Medication management
- Pain management
- Infusion therapy
- Wound care
- Infection prevention
- Patient and caregiver education
- Assessment and correction of home safety risks
- Assistance with activities of daily living (such as bathing, dressing, and eating)
- Home care support (including housekeeping and cooking)
- Chronic condition and serious illness monitoring

Given the wide variety of available services, summarizing the clinical effectiveness of HHC is especially challenging. However, research has shown that the provision of well-defined, quality HHC can provide significant clinical benefits. Some studies have found that discharge from the hospital to home benefits elderly patients,[734] and that HHC can significantly reduce mortality and admissions for long-term institutional care.[735] Other studies have documented that HHC decreases the rate of decline of functional status,[736] and have found positive health outcomes for pressure ulcers, surgical wounds, and incontinence for patients with severe health problems receiving HHC.[737] According to the Centers for Medicare and Medicaid Services, HHC is usually less expensive, more convenient, and just as effective as care received in a hospital or skilled nursing facility (SNF).[738]

In addition, HHC has been shown to be particularly effective for the care of the terminally ill. Terminally ill patients receiving HHC had fewer hospitalizations, nursing home admissions, and outpatient visits; were more likely to be able to die at home according to their wishes; and expressed significantly higher satisfaction with their care.[739] Moreover, the provision of HHC has led to higher quality of life measures for terminally ill patients and their caregivers, as well as higher satisfaction rates with care for patients with both terminal and non-terminal illnesses.[740]

Estimated Marginal Cost of the Mandate

Responses to the carrier survey consistently indicated these services would be covered in the absence of the mandate. In addition, one carrier indicated these services likely result in cost savings by preventing admissions to acute care hospitals and other forms of residential care. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Hormone Replacement Therapy

The hormone replacement therapy (HRT) mandate requires policies covering outpatient services or outpatient prescription drugs and devices to provide HRT (services and drugs) for peri- and post- menopausal women under the same terms and conditions as for other outpatient services and drugs.[741]

Effect of the Mandate on Health

Menopause is the time in a woman's life in which the ovaries stop making estrogen and menstruation naturally stops, marking the end of the woman's reproductive years.[742] Prior to the onset of menopause, with a median age of 51 in North America,[743] a woman's ovaries produce the hormones estrogen and progesterone to control the menstrual cycle.[744] During perimenopause, the years leading up to menopause, the levels of estrogen begin to fluctuate, causing some women to have a variety of mild to severe symptoms.[745]

Vasomotor symptoms, often referred to as hot flashes, are common during menopause. They result in a sudden feeling of heat that rushes to the upper body and face, and might last seconds to several minutes, causing flushing, chills, clamminess, perspiration, anxiety, sleep disturbances (night sweats), and heart palpitations.[746,747] For women who experience vasomotor symptoms, 87% experience such episodes daily, and 33% experience such episodes at least 10 times per day; the median duration of these vasomotor symptoms for women is from 4 to 10 years.[748,749] In addition, 10%–40% of women also experience vaginal atrophy; symptoms include vaginal or vulvar dryness, discharge, itching, and dyspareunia (difficult intercourse).[750] The urethra might become dry, inflamed, or irritated, which can cause more frequent urination and increase the risk of urinary tract infections.[751] Other menopausal symptoms include osteoporosis, or the loss of bone density that increases the risk of bone fracture most often affecting bones of the hip, spine, and wrist; mood changes; irregular periods; thinning hair; dry skin; weight gain; and slowed metabolism.[752,753]

To help relieve perimenopausal and menopausal symptoms, hormone therapy (HT), also known as HRT,[754] might be used.[755] HT involves taking estrogen, which can be given in many forms. For those women who have never had a hysterectomy and still have an intact uterus, HT comprises taking estrogen and progestin; this is sometimes called combined hormone therapy (CHT).[756,757] Systemic HT is administered in the form of pills, skin patches, and gels and sprays that are applied to the skin; and if progestin is added, it might be given separately or combined with estrogen in the same pill or patch.[758] Women who only experience minor symptoms such as vaginal dryness might be treated with a local estrogen therapy in the form of a vaginal ring, table, or cream.[759]

Systemic estrogen, with or without progestin, HT is the most effective proven treatment for relieving hot flashes and night sweats.[760,761] Systemic estrogen therapy has been shown to protect against bone loss and to prevent hip and spine fracture, while both systemic and local types of estrogen therapy relieve vaginal dryness.[762] In addition, CHT therapy might reduce the risk of colon cancer.[763]

However, HT might increase the risk for certain types of cancer and other conditions.[764] Estrogen therapy alone increases the risk of endometrial or uterine cancer because the treatment causes the lining of the uterus to grow (endometrial hyperplasia); use of progestin in combination with estrogen decreases this risk.[765,766] Estrogen therapy is also associated with a small increased risk of gallbladder disease, with the greatest risk from oral forms of

therapy.[767,768] CHT is associated with a small increased risk of heart attack; this risk is related to a patient's age when she begins therapy and other medical conditions.[769] CHT and estrogen-only therapy are associated with a small increased risk of stroke and deep vein thrombosis (DVT), which might be lessened by using non-oral therapy routes.[770] CHT is also associated with a higher risk of breast cancer, with the risk varying according to the progestin component; the longer the CHT is used, the higher the risk.[771,772,773]

Evidence now exists to support certain non-hormonal treatment of menopausal symptoms, including selective serotonin reuptake inhibitors (SSRIs) and selective serotonin/norepinephrine reuptake inhibitors (SNRIs), which are types of anti-depressants. The non-hormonal drugs which have been shown to be effective for the treatment of hot flashes include citalopram, escitalopram, venlafaxine, desvenlafaxine, and paroxetine.[774] The only U.S. Food and Drug Administration (FDA)-approved, non-hormonal therapies for menopausal symptoms include paroxetine for vasomotor symptoms[775,776] and ospemifene for dyspareunia;[777] both were approved in 2013.[778] The FDA has not approved any bioidentical hormones, herbs, or other natural products for the treatment of menopausal symptoms because it either does not have evidence, or does not know if the products are safe and effective.[779]

The use of HT became controversial during the course of the Women's Health Initiative (WHI) Clinical Trial and Observational Study (WHI Study), conducted by the National Heart, Lung, and Blood Institute. The WHI Study focused on strategies for preventing heart disease, cancer, and osteoporotic fractures in menopausal women through treatment with HT, dietary patterns, and calcium/vitamin D supplementation.[780] The HT component of the WHI Study was stopped early in 2002 when a review of the cumulative data to date found CHT to be associated with an increased risk of breast cancer.[781] Additional similar studies on HT use and the risk of breast cancer included the Collaborative Reanalysis and the Million Women Study (MWS).[782] Review of the evidence from these studies for causality of breast cancer from HT questioned the results.[783,784,785,786,787] This confusion about HT and the risk of developing breast cancer led many clinicians and patients to abruptly end HT, which for some women impacted their reduction in quality of life and led them to seek alternative treatments that had not been studied for safety and efficacy when used for menopausal symptoms.[788] Researchers who retrospectively examined the impact of the WHI Study results on HRT use concluded that questions about the long-term health consequences of HT remain, and that without further study, deciding on the best treatment plan will continue to involve an amount of guesswork.[789] After reviewing the evidence on the use of postmenopausal HRT, the United States Preventative Services Task Force (USPSTF) concluded that, while CHT reduced risks of colorectal cancer and fractures from osteoporosis, it potentially increased risks for coronary heart disease, breast cancer, venous thromboembolism, stroke, and cholecystitis.[790]

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 potential risks and benefits of HT, to individualize HT, and to use the lowest effective dose for the shortest duration.[791] Additionally, the treatment guidelines published by the Endocrine Society recommend screening for breast cancer and cardiovascular risk before initiating HT, and providing the most appropriate therapy depending on the risk/benefit considerations.[792]

Current evidence does not justify the use of HT to prevent postmenopausal chronic conditions, including coronary heart disease, breast cancer, or dementia.[793,794] In the absence of contraindications, systemic HT remains the most effective therapy for the management of vasomotor symptoms in postmenopausal women.[795] The USPSTF

recommends against the use of CHT for the primary prevention of chronic medical conditions in postmenopausal women and estrogen-only therapy for the primary prevention of chronic medical conditions in postmenopausal women for women who have had a hysterectomy.[796] The USPSTF did not include the use of HT for the management of menopausal symptoms, such as hot flashes or vaginal dryness, within the scope of their recommendation statement.[797]

Estimated Marginal Cost of the Mandate

Responses to the carrier survey consistently indicated these services would be covered in the absence of the mandate. In addition, one carrier indicated these services may result in long-term savings by reducing the effects of osteoporosis and preventing cardiac events. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Hospice Care

The hospice care mandate requires coverage for licensed hospice services for terminally ill patients with a life expectancy of six months or less.[798]

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 a program of palliative and supportive care services providing physical, psychological, social, and spiritual care for dying persons, their families, and other loved ones.[799] Services are provided in both home and inpatient settings, and might be provided on a part-time, intermittent, regularly scheduled, or around-the-clock basis.[800] With its origins extending back to the Middle Ages, hospice care uses teamwork and careful listening to patients to achieve relief of pain and suffering; make possible a peaceful death; help the family; and assist in the search for meaning.[801]

Since objective data are lacking on the true experience of dying from the point of view of the patient, a common perception is that a patient's quality of life rapidly deteriorates before death.[802] Despite these difficulties, however, some studies have shown hospice care to be associated with a relatively high and stable quality of life over time;[803] improved pain control; decreased hospitalizations; decreased tube feedings for terminal nursing home patients;[804] improved quality of death;[805] and a reduction in mortality for widowed spouses.[806] A systematic review of research found evidence supporting the use of home-based hospice care in order to increase the number of patients who die at home.[807] Two frequently cited studies dispel the myth that hospice care hastens death, finding that for certain well-defined, terminally ill populations, patients who choose hospice care live longer on average than similar patients who do not choose hospice care;[808] however, the authors point out that more research is needed before generalizing their findings.[809] Another review of studies found a great deal of evidence demonstrating the benefits of hospice care, revealing that hospice services support families to sustain patient care at home, and that hospice day care services generate for the patient a renewed sense of meaning and purpose.[810]

Estimated Marginal Cost of the Mandate

Responses to the carrier survey consistently indicated these services would be covered in the absence of the mandate. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Human Leukocyte Antigen Testing

The human leukocyte antigen (HLA) testing mandate requires coverage for HLA or histocompatibility locus antigen testing necessary to establish the suitability of a bone marrow transplant donor.[811]

Effect of the Mandate on Health

A histocompatibility antigen test looks at proteins called HLAs that are found on the surface of most cells and in large amounts on the surface of white blood cells.[812] HLAs help the immune system tell the difference between body tissue and substances that are not from your own body.[813] HLA testing is used to identify good matches for patients in need of tissue grafts or organ transplants, and might also be used to diagnose some autoimmune disorders, monitor certain medication treatments, and determine parent/child biological relationships.[814] Such transplants might include kidney transplants or bone marrow transplants.[815] A bone marrow transplant replaces unhealthy marrow with healthy marrow.[816] The technical name for blood stem cell transplants is hematopoietic stem cell transplants (HSCTs). This refers to:

- Bone marrow transplants
- Stem cell transplants (or peripheral blood stem cell transplants)
- Cord blood transplants (CBTs)[817]

Bone marrow is the tissue in bones that makes blood-forming cells (blood stem cells), which might also be found in the bloodstream and in umbilical cord blood or discarded placenta of a newborn.[818,819] HSCTs can treat blood cancers, such as leukemia or lymphoma; bone marrow diseases, such as aplastic anemia; and other immune system or genetic diseases, such as sickle cell disease.[820] In addition to the classification based on the source of blood stem cells, HSCTs vary according to who provides the cells for transplant.[821] The three most common types of HSCTs based on source of blood stem cells include autologous, in which a patient's own cells are used for transplant; allogeneic, which uses donor cells; or haploidentical, a type of allogeneic transplant.[822] This mandate specifically refers to bone marrow transplants, and does not include CBTs or the more common peripheral blood transplants in its language.

For allogeneic donations, the best matches for HSCTs are siblings who have identical HLAs.[823] However, sibling matches account for only a portion of BMTs; most patients (about 70%) do not have a matching donor in their family and are in need of an unrelated donation.[824,825] Due to public investment in donor recruitment, most patients likely to benefit from HSCT will have a donor..[826]

The better the HLA match between a patient and a donor, the better a patient's chances for survival.[827] 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[828] (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 (high-resolution matches).[829] Survival after transplant is improving for all donor types.[830] Mismatched HLAs put a patient at risk for acute and chronic graft-versus-host disease, graft rejection, and treatment-related mortality.[831] The NMDP recommends transplant physicians reevaluate alternative treatment options early on in situations where donors do not meet high-resolution match criteria, and decide whether to use a donor with a lower degree of HLA match or select another graft source (e.g., unrelated cord blood transplantation, or partially matched-related donor transplantation).[832]

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."[833] The mandate also includes a reference to Massachusetts General Laws (M.G.L.) Chapter 111 Section 218, which requires HLA testing conform to medical eligibility requirements and other test protocols established by a number of agencies, including the national marrow donor program registry.[834] The NMDP, which oversees the donor registry (Be The Match™), has established HLA matching guidelines.[835] This analysis presumes that the mandate covers testing under the current guidelines in place with the NMDP for bone marrow transplants.

Estimated Marginal Cost of the Mandate

Responses to the carrier survey consistently indicated these services would be covered in the absence of the mandate. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Hypodermic Syringes or Needles

This mandate requires coverage for medically necessary hypodermic syringes or needles.[836] 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 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 syringes or needles. Many illnesses are treated with patient-delivered injectable therapies, including multiple sclerosis,[837] diabetes,[838] infertility,[839] pernicious anemia,[840] iron deficiency,[841] cancer,[842] and human immunodeficiency virus/acquired immunodeficiency syndrome HIV/AIDS.[843] Often, these drugs must be injected, as the specific medication would be destroyed in the digestive process if taken orally.[844] Although some injectable drugs can deliver a particular dosage over a long period of time, up to several months, many still require daily injections.[845] One disadvantage of injection, particularly self-injection, is the risk of infection; patients also might have a fear of needles or might be unable or unwilling to self-administer the drug by injection, making treatment adherence an issue.[846,847,848] Conversely, the ability for a patient to self-administer might 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 might improve adherence.[849,850] The availability of newer technologies for some conditions, such as pre-filled injectable pens, might reduce the use of hypodermic syringes and needles for self-administration; some studies conclude that patients find use of pens easier, more convenient, and less stressful,[851] while use of pens increases the accuracy of the medication dose. [852]

Estimated Marginal Cost of the Mandate

Responses to the carrier survey indicated these products would largely be covered in the absence of the mandate, and noted a high level of overlap between this mandate and the diabetes services and supplies mandate, which this study also estimates as a zero cost mandate. In addition, one carrier indicated this is cost effective coverage, as availability of new syringes and needles prevents costly patient infections. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

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.[853]

Effect of the Mandate on Health

Lead exposure presents a significant health threat to thousands of American children.[854] Until 2012, children were identified as having a blood lead level (BLL) of concern if the test result was 10 micrograms or more in a deciliter (10 µ/dL).[855] (A microgram is one millionth of a gram. A deciliter is about half a cup of liquid).[856] Because their growing bodies are more prone to harm and absorb lead more easily than do adults' bodies, young children face the most danger from exposure to lead.[857] Although the 10 µ/dL had been relied on as a BLL with a level of concern,[858] numerous studies have shown that even BLLs below 10 µ/dL harm children.[859] In childhood, elevated BLLs can significantly impact cognitive function as well as have adverse cardiovascular, immunological, endocrine, and behavioral effects.[860] Pregnant women and women of childbearing age should also avoid exposure to lead because lead ingested by a mother can affect the unborn child.[861]

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.[862] The public health efforts have resulted in a continuous decreasing trend in BLLs in the U.S. population.[863] According to the Centers for Disease Control and Prevention (CDC) 2017 data, the percentage of children in Massachusetts found to have BLLs greater than 10 µ/dL is 0.3%.[864]

Although the risk of exposure has decreased with the removal of lead from gasoline and paint and with the reduction in factory emissions, the risk of exposure continues, particularly in older homes and communities.[865] Lead can remain in household dust, in soil that children unintentionally ingest through normal hand-to-mouth behavior, or in water supplied through lead pipes; it can also be found in some toy jewelry, older toys, ceramics, and glazes made in the United States prior to the 1990s or imported.[866] Other potential sources include older vinyl mini-blinds and imported aluminum cans with soldered seams.[867]

Although exposure risk has decreased across the entire United States population, higher BLLs (BLLs greater than 10 µ/dL), as well as risk of exposure, continue to be more prevalent among children with known risk factors, including minority race or ethnicity, urban residence, living in housing built before the 1950s, and low family income.[868] This information has led to a change in public health advocacy from recommending screening of all children for lead exposure, to a primary prevention strategy aimed at children and families most likely to live in homes with lead hazards. According to the American Academy of Pediatrics (AAP), universal screens or BLL tests are no longer recommended except for high-prevalence areas with increased risk factors as described in a 2012 CDC report, such as older housing.[869] The 2012 CDC report also included updated recommendations regarding BLLs in children and shifted its focus to primary prevention of lead exposure.[870]

Based on updated CDC recommendations, instead of using a BLL of concern, the CDC now uses a blood lead reference value for BLLs (≥ 5 µ/dL), thereby lowering the level at which evaluation and interventions are recommended.[871] As a result, more children will likely be identified as having lead exposure, allowing parents, doctors, public health officials, and communities to take action earlier to reduce the child's future exposure to lead.[872] This new reference value, which the CDC will review every four years, is based on the 97.5th percentile of the National Health and Nutrition Examination Survey's (NHANES') blood lead distribution in children, identifying children ages 1–5 years who are in the highest 2.5% of children when tested for lead in their blood.[873] As a result, in 2014, the CDC revised the Healthy People 2020 BLL target to incorporate the most recent NHANES data for its initiative to reduce BLLs in children aged 1–5 years by 10%.[874] A recent examination of the NHANES survey data has shown that the proportion of children aged 1–5 years with an elevated lead level, defined as 5 µ/dL or greater, decreased from 9.9% in 1999–2000 to 0.5% in 2013–2014.[875]

The current AAP Bright Futures Periodicity Schedule recommends a risk assessment at the following well-child visits: 6 months, 9 months, 12 months, 18 months, 24 months, and at three, four, five, and six years of age.[876,877] BLL screenings are to be performed at the child's 12- and 24-month visits if a patient is identified through screening, lives in a high-prevalence area, or is required by Medicaid rules.[878] Medicaid-eligible patients tend to be at higher risk for lead exposure because many live in these lower socioeconomic areas.[879] As a result, many state Medicaid/Early and Periodic Screening, Diagnostic, and Treatment programs require a universal BLL test at the child's 12-month and 24-month visits, no matter the prevalence of elevated levels, based on factors such as where the patient lives.[880] Although many state Medicaid/Early and Periodic Screening, Diagnostic, and Treatment programs have been directed to transition their requirements to be more in line with prevalence data (targeted screening) rather than requiring testing children at specific ages, most states have not completed these efforts.[881]

In Massachusetts, lead poisoning screening is required by Department of Public Health regulations; all children must be screened for lead poisoning at least once between the ages of 9 and 12 months, and again at ages two and three.[882] In addition, children living in cities and towns identified as high risk for childhood lead poisoning, as determined by the Massachusetts State Program, shall also be screened at age four.[883] Children must have evidence of screening or be screened to fulfill kindergarten entry requirements.[884] Children must be screened for lead poisoning more than once a year when they meet one of the following high-risk criteria or whenever in the sound medical judgment of the health care provider they are at high risk of lead poisoning: [885]

- Living in a pre-1978 home with deteriorated paint or plaster, unless it has been inspected by a lead inspector and found not to contain lead-based paint: Screening at least every six months between the ages of six months and three years, and again at ages four and five
- Having siblings or playmates who are lead poisoned: Screening at least every six months between the ages of six months and three years, and again at ages four and five
- Living in a pre-1978 home undergoing renovation, unless it has been inspected by a lead inspector and found not to contain lead-based paint or plaster: Screening within four weeks of the start of the renovation project, once a month thereafter during its duration, and once after its completion[886]

The U.S. Preventive Services Task Force (USPSTF) final recommendation statement found insufficient evidence to assess the balance between potential benefits and harms of routine screening for elevated BLLs in children at increased risk.[887] However, given that BLLs in young children are an important health issue, monitoring of BLLs at the population level should be continued.[888]

Estimated Marginal Cost of the Mandate

Responses to the carrier survey consistently indicated these services would be covered in the absence of the mandate and is required by the ACA. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Long-Term Antibiotic Therapy for the Treatment of Lyme Disease

The Lyme disease mandate requires coverage for long-term antibiotic therapy for a patient with Lyme disease when determined to be medically necessary and ordered by a licensed physician after making a thorough evaluation of the patient's symptoms, diagnostic test results, or response to treatment. An experimental drug shall be offered as long-term antibiotic therapy if it is approved for an indication by the U.S. Food and Drug Administration (FDA), provided that a drug—including an experimental drug—shall be covered for an off-label use[xxv] in the treatment of Lyme disease if the drug has been approved by the FDA.[889]

Effect of the Mandate on Health

Lyme disease is the most common vector-borne[xxvi] disease in the United States,[890,891] and is the most common tick-borne disease in the northern hemisphere, notably in Europe and North America.[892] In the Unites States, Lyme disease accounts for 82% of cumulative reported tick-borne diseases.[893] Lyme disease is most often caused by the bacterium *Borrelia burgdorferi* and is transmitted to humans through the bite of an infected tick.[894] The blacklegged tick (or deer tick, *Ixodes scapularis*) spreads the disease in the northeastern, mid-Atlantic, and north-central United

[xxv] Off-label use of a drug means the drug is used for a disease or medical condition that it is not approved to treat.

[xxvi] Vector-borne diseases are human illnesses caused by parasites, viruses, and bacteria that are transmitted by vectors. Vectors are blood-feeding insects and ticks capable of transmitting pathogens between hosts.

States, while the western blacklegged tick (*Ixodes pacificus*) spreads the disease on the Pacific Coast.[895] Based on reported cases of Lyme disease from 2009 – 2018, the Centers for Disease Control and Prevention (CDC) classifies Massachusetts as a high-incidence state, having at least 10 confirmed cases per 100,000 persons for the previous three reporting years.[896]

The Massachusetts Department of Public Health (MDPH) discontinued case-based Lyme disease surveillance in 2016,[897] and the most recently available published data from 2014 reported 3,830 confirmed Lyme disease cases and 1,770 probable cases in Massachusetts.[898] The MDPH now produces Monthly Tick-Borne Disease Reports that show seasonal trends in reported tick bites and tick-borne disease diagnoses in Massachusetts residents.[899] Highlights from these reports include

- Although tick activity is weather-dependent, there are two peaks during the year: the first begins in March/April and lasts through August, and the second occurs in October – November.
- The majority of cases of tick-borne disease occur in June – August.
- Tick-borne diseases are more frequently diagnosed in children and older adults.[900]

According to the Annual Tick Report Summary, emergency department (ED) visits in 2019 that resulted in diagnosis of Lyme disease peaked at just under 0.2% of total ED visits.[901]

Early signs and symptoms of Lyme disease include fatigue, headache, fever, chills, muscle and joint aches, swollen lymph nodes, and a characteristic skin rash called erythema migrans (EM).[902,903] The EM rash begins at the site of the tick bite, expands gradually over several days, and sometimes clears as it enlarges, resulting in a "target" or "bull's-eye" appearance.[904,905] Lyme disease can be difficult to diagnose because many of the common symptoms associated with it occur with other diseases.[906] The EM rash is the only manifestation of Lyme disease in the United States that is sufficiently distinctive to allow clinical diagnosis in the absence of laboratory confirmation,[907] and only 70% – 80% of patients present the classic EM "bull's-eye" appearing rash.[908] Consequently, patients with symptoms suspicious for early Lyme disease but lacking the typical EM rash present a diagnostic dilemma because serologic test results at this stage might be negative.[909] According to the CDC, when assessing a patient for Lyme disease, a healthcare provider should consider the signs and symptoms of Lyme disease; the likelihood that the patient has been exposed to infected blacklegged ticks; the possibility that other illnesses might cause similar symptoms; and results of laboratory tests when indicated.[910] The International Lyme and Associated Diseases Society's (ILADS') position on Lyme diagnosis and testing states that a clinical diagnosis must be based on the patient history and physical findings, and supported by appropriate laboratory tests when they are indicated; in addition, the clinician must understand the strengths and limitations of laboratory testing in order to use testing modalities effectively and avoid some of the pitfalls of diagnosis that can result from overreliance on laboratory testing to rule in or rule out an illness.[911]

If left untreated, Lyme disease might progress to later stages involving the musculoskeletal, cardiovascular, and nervous systems.[912,913] The diagnosis of these late stages of Lyme disease is based on clinical examination with serologic confirmation.[914] Although laboratory testing might be supportive of the diagnosis, antibodies can take several weeks to develop; as a result, serologic testing has been found to be problematic in its sensitivity for identifying the Lyme disease in its early stages.[915,916,917] Moreover, while these tests are more likely to accurately

identify Lyme disease in its later stages,[918] treatment is generally more effective when prescribed in an earlier disease stage.[919]

The challenges in making a correct Lyme disease diagnosis can be further complicated by infections by other tick-transmitted organisms; these co-infections might cause additional symptoms or co-morbidities, and prevent the successful treatment of Lyme disease.[920] Likewise, the presence in the patient of autoimmune disorders or previously undiagnosed diseases also makes diagnosis and treatment of Lyme disease difficult.[921]

While the majority of Lyme disease patients are successfully treated with oral antibiotics, approximately 10% – 20% of patients report a range of continuing symptoms, such as fatigue, difficulty in sleeping, arthralgia, myalgia, memory impairment, and headache, collectively called post-treatment Lyme disease syndrome (PTLDS) or post-Lyme disease syndrome (PLDS).[922,923] As reported by the National Institutes of Allergy and Infectious Diseases, studies have found that patients demonstrating PTLDS symptoms have a severe impairment in overall physical health and quality of life.[924] Although the reasons for these symptoms are unknown, causes such as autoimmune disease, persistent infection, other illnesses, or chronic inflammatory processes have all been considered.[925] Chronic Lyme disease (CLD), PTLDS, and PLDS are terms intended to describe patients who have had well-documented Lyme disease and continue to have symptoms that last months or years after antibiotic therapy.[926] However, CLD is also used to describe symptoms in people who have no clinical or diagnostic evidence of a current or past infection with *Borrelia burgdorferi*.[927] As a result, experts no longer support the use of CLD due to confusion in how the term is employed and a lack of a clearly defined clinical definition.[928] Consequently, although the term CLD was used in the original proposed mandate report[xxvii], the term PLDS will be used for this report because it is more widely accepted and is often used interchangeably with the term PTLDS.[929]

According to the Infectious Diseases Society of America (IDSA), the absence of a well-accepted definition of PLDS contributes to the confusion, controversy, and lack of firm data on the incidence, prevalence, and pathogenesis of PLDS.[930] Why some patients experience PLDS is not known; according to the CDC, there are a number of possible PLDS causes proposed by experts, such as:

- An autoimmune response causing symptoms that last well after the infection is gone, similar to the known autoimmune responses that follow other infections (i.e., rheumatic heart disease following strep throat)
- A persistent but difficult-to-detect infection
- Other causes unrelated to the patient's *Borrelia burgdorferi* infection [931]

According to the ILADS, the challenges associated with initially diagnosing Lyme disease also apply to patients with PLDS, causing providers to miss a Lyme disease diagnosis; as a result, patients with symptoms of Lyme disease are commonly misdiagnosed with fibromyalgia, chronic fatigue syndrome, and depression.[932] There are currently no commonly agreed-upon symptoms or laboratory and imaging findings which are sensitive and specific to aid in the clinical evaluation of patients with persistent Lyme disease symptoms; as a result, the clinical diagnosis is primarily

[xxvii] House Bill 989 of the 188th General Court (2013-2014), Commonwealth of Massachusetts.

one of exclusion, and the current illness must be distinguished from other systemic inflammatory, rheumatic, malignant, and infectious conditions, as well as from the effects of co-morbid or pre-existing conditions.[933]

Accompanying the divergence of opinion on the existence or definition of PLDS is significant disagreement on how to treat these patients, including the length of treatment and types of antibiotics. There is currently no known proven treatment for PLDS.[934] While short-term antibiotic therapy is a proven treatment for early Lyme disease, a number of studies have found that long-term outcomes are no better for patients who received additional prolonged antibiotic treatment than for patients who received placebos.[935,936,937] In addition to finding the efficacy of prolonged antibiotic therapy to be of little or no benefit, researchers have emphasized the frequency of adverse events associated with such a regimen.[938] Some of the risks of long-term antibiotic treatment include the development of antibiotic-resistant infection, intractable diarrhea, kidney or liver damage, allergic reactions, gastrointestinal bleeding, and venous thrombosis.[939,940] However, the ILADS maintains it is in the best interest of these patients for clinicians to offer additional treatment.[941] Taking into account the strength of the evidence addressing the effectiveness of antibiotic retreatment, the burden of disease in this patient population, and the risks associated with various antibiotic options, the ILADS concludes that the very real consequences of an untreated chronic Lyme infection far outweigh the potential consequences of long-term antibiotic therapy.[942] Despite the ILADS position on treating PLDS, there are currently no FDA-approved pharmaceutical therapies or commonly agreed-upon treatments for patients who have undergone a recommended course of antibiotics for Lyme disease but who continue to have persistent symptoms.[943]

While agreement exists that a certain portion of patients have symptoms that are ameliorated through short-course treatments of antibiotics, the reasons why some patients experience PLDS are unknown.[944] Further contributing to the confusion is the lack of a well-accepted definition of PLDS,[945] as well as the unknown mechanisms underlying PLDS.[946] Whether this population continues to be ill due to some form of Lyme disease, or symptoms result from other causes, produces further differences on recommended treatments. The dilemma for clinicians is avoiding inappropriate or overtreatment while effectively managing their patients' ailments.

It is likely that the number of new Lyme disease cases will continue to increase, as well as the number of patients with PLDS.[947,948] As suggested by some researchers, a determination should be made as to whether there is a need for optimized first-line drugs that more effectively and immediately limit Lyme disease progression and do not predispose patients to complications.[949] Given the cumulative presence of PLDS, further studies are needed in the Lyme disease field to improve diagnostic tests, increase medical and public awareness, and to accurately define the number of patients infected and chronically ill.[950]

Estimated Marginal Cost of the Mandate

BerryDunn estimated the marginal, direct cost of this mandate by comparing costs of the medical services and pharmaceuticals required by the mandate from the period prior to implementation of the mandate (July 2016) to the period after implementation. BerryDunn extracted from the MA APCD, summarized by service year for the years 2014 to 2018, and separately for each half of calendar year 2016, medical costs of Lyme disease testing and pharmaceutical claim costs. Pharmaceutical claim costs consisted of the costs of prescriptions filled in a given year for antibiotic drugs typically used for long-term antibiotic Lyme disease treatment by members with at least one medical claim with a primary diagnosis of Lyme disease or at least one medical claim with a diagnosis of Lyme disease appearing in the primary, second, or third diagnosis fields. No material difference in claims expense for the

services was observed between the pre- and post-mandate periods. Therefore, this study estimates the 2018 impact of this mandate as $0, and 0 percent of fully insured Commonwealth premium.

Mammography

The mammography mandate requires coverage for one baseline mammogram for women between the ages of 35–40, and for an annual mammogram for women 40 years of age or older.[951]

Effect of the Mandate on Health

According to the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), breast cancer is the most common cancer for women in the United States, and is second only to lung cancer in mortality rate.[952] Mammography can detect asymptomatic breast cancer.[953] At this early asymptomatic stage, breast cancer can be more effectively treated than when clinical signs and symptoms are present.[954] Screening mammography can also reduce breast cancer mortality among women ages 40–74.[955] The U.S. Preventive Services Task Force (USPSTF) states that the number of breast cancer deaths averted increases with age; women ages 40–49 benefit the least, and women ages 60–69 benefit the most.[956]

However, a systematic review found that screening can lead to unnecessary additional tests and treatments, as well as to anxiety, distress, and breast cancer-specific worry associated with false-positive results.[957] False-positive results are more common in women ages 40–49.[958] A significant harm resulting from screening is the detection and treatment of invasive and noninvasive cancer that would never have been detected, or threaten health, in the absence of screening (overdiagnosis and overtreatment).[959]

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 the ages of 40–50. The introduction of digital breast tomosynthesis (DBT) has also added to the controversy regarding the screening recommendations. DBT is often considered the better mammogram based on observed increases in specificity and breast cancer detection compared with digital mammography.[960] Various organizations have changed their breast cancer screening guidelines multiple times; the most recent guidelines of seven leading organizations are reflected in Table 25.

Table 25
Screening for Breast Cancer for Women at Average Risk: Comparative Guideline Table

Issuing Organization	Ages 40–49	Ages 50–74	Ages 75+	DBT
American Academy of Family Physicians (Based on USPSTF)[961]	Decision to have mammogram based on individual decision	Biennial mammogram	Insufficient evidence for recommendation	Insufficient evidence for recommendation

Issuing Organization	Ages 40–49	Ages 50–74	Ages 75+	DBT
American Cancer Society[962] (2020)	Between ages 40–44 have option to screen with mammography annually Beginning at age 45, mammogram annually	Ages 50–54 should receive annual mammograms. Ages 55 and older can switch to biennial mammograms or choose annual mammograms. Screening should continue as long as the woman is in good health and expected to live at least 10 more years		Women should be able to choose between 2D and 3D mammography if they or their doctors believe one would be more appropriate
2003 American Cancer Society Recommendations[963]	Screen with mammography annually	Screen with mammography annually, indefinitely in healthy patients		
American College of Obstetricians and Gynecologists[964] (2017)	Offer mammography starting at age 40, initiate at ages 40–49 Screening interval might be annual or biennial	Recommend mammography at age 50 if patient has not already initiated Screening interval might be annual or biennial.	The decision to discontinue should be based on a shared decision-making process that includes a discussion of the woman's health status and longevity	
American College of Physicians[965] (2019)	Clinicians should discuss whether to screen for breast cancer with mammography.	Clinicians should offer screening for breast cancer with biennial mammography.	Clinicians should discontinue screening for breast cancer in women ages 75 or older or in women with a life expectancy of 10 years or less.	
American College of Radiology[966] (2010)	Screen annually	Screen annually until life expectancy is less than 5–7 years		
USPSTF (2016)[967]	Individual decision	Biennial screening	Insufficient evidence for recommendation	Insufficient evidence for recommendation

In October 2015, after a systematic review of the breast cancer screening literature, the American Cancer Society formulated revised guidelines based on the quality of the evidence and judgment about the balance of benefits and harms.[968] Screening is now recommended annually for women beginning at age 45.[969]

The final recommendations of the USPSTF for mammography screening, released in 2016, give a "B" grade to the recommendation for women ages 50–74; a "C" grade for women ages 40–49; and an "I" grade for women over 76 and the use of DBT.[970] A "B" grade indicates that the USPSTF recommends clinicians offer or provide the service to eligible patients; a "C" grade means that the service be offered or provided only to selected patients, depending on individual circumstances; and an "I" grade indicates that the current evidence is insufficient to assess the balance of benefits and harms of the service and that, if offered, the patient should understand this uncertainty.[971] Based on the USPSTF guidelines, the decision to start screening prior to age 50 should be an individual one, and women who place a higher value on the potential benefit than on the potential harms might choose to begin biennial screening between the ages of 40–49.[972]

Estimated Marginal Cost of the Mandate

Responses to the carrier survey consistently indicated these cancer screening services are clinically and cost-effective care that would be covered in the absence of the Massachusetts mandate. In addition, carriers noted coverage for mammography is required by the ACA, though at a lesser frequency than required by the Massachusetts mandate. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Maternity Care and Minimum Maternity Stay

The maternity care mandate requires coverage for prenatal care, childbirth, and postpartum care to the same extent as provided for medical conditions not related to pregnancy. This includes 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) for a mother and her newborn child.[973] A decision to discharge the mother and infant early (less than 48 hours for vaginal delivery and 96 hours for cesarean delivery) must be made by the attending physician in consultation with the mother.[974] The mandate requires post-delivery care to include home visits, parent education, assistance and training in breast or bottle feeding, and the performance of any necessary and appropriate clinical tests."[975] The first home visit must be conducted by a registered nurse, physician, or certified nurse midwife, with any subsequent clinically necessary visits to be conducted by a licensed healthcare provider.[976]

Effect of the Mandate on Health

Access to prenatal care and education can dramatically improve birth and health outcomes for mothers and their babies.[977] Prenatal care has been practiced widely in the U.S. since the early twentieth century, and plays a significant role in maintaining low maternal mortality rates.[978] Further, inadequate prenatal care has been shown to result in significantly higher fetal, newborn, and perinatal (associated with birth) mortality.[979] Studies have shown improved maternal and birth outcomes for women receiving prenatal care with preeclampsia (pregnancy-related high blood pressure),[980] gestational diabetes,[981] and HIV.[982] Some research also points to a reduction in pre-term delivery for women with adequate prenatal care.[983]

Length of maternity stay

Hospital discharges for newborns at any time $\leq$ 48 hours significantly increase the risk for readmission, including the risk for readmission due to hyperbilirubinemia.[984] According to the American Academy of Pediatrics (AAP) and the

American College of Obstetricians and Gynecologists (ACOG), the hospital stay of a mother and her newborn should be long enough to allow for the identification of problems and to ensure that the mother is sufficiently recovered and prepared to care for herself and her newborn at home.[985] Although neonatal cardiopulmonary problems usually become apparent during the first 12 hours after birth, jaundice, ductal-dependent cardiac lesions, and gastrointestinal obstructions for the newborn, as well as endometritis and other significant maternal complications, might require a longer period of observation to become apparent.[986] Many services are performed in the post-partum/pre-discharge stay, including: newborn screenings and risk assessment; administration of immunizations; maternal and family counseling and assessments; 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 outpatient follow-up care planning for mother and baby.[987]

Post-partum hospital stays for mother and baby have changed significantly over the last five decades, with stays for vaginal delivery dropping from 3.9 to 2.1 days and for caesarian deliveries from 7.8 to 3.1 days between 1970 and 2008. [988,989] Initially, the shorter stays were in response to attempts to "demedicalize" childbirth; however, cost containment efforts by insurers resulted in the length of stay becoming even shorter.[990] In response to concerns raised by both the medical community and the public regarding the trend towards shortened hospital stays in the 1990s, states began passing laws mandating minimum insurance coverage for maternity stays.[991] By the end of 1996, 28 states had passed legislation mandating insurance coverage for postpartum days,[992] with most states following the AAP and ACOG length of stay guidelines.[993] In addition, the federal government enacted the Newborns' and Mothers' Health Protection Act of 1996 (NMPHA), which provides for a minimum maternity stay and became effective in 1998.[994,995] The NMHPA prohibits the restriction of mothers' and newborns' benefits for hospital length of stay in connection with childbirth to less than 48 hours for a vaginal delivery or 96 hours for a cesarean section.[996]

According to the U.S. Department of Labor, many states have enacted their own version of the NMHPA for insured coverage.[997] As a result, state law will apply if there are regulations regarding coverage for newborns and mothers that meet specific criteria and the coverage is provided by an insurance company or HMO.[998,999] This is true in Massachusetts, where the state law pertaining to minimum inpatient stays following birth applies. The Massachusetts statute mandates coverage for the expense of prenatal care, childbirth, and postpartum care to the same extent as provided for medical conditions not related to pregnancy, with a provision to provide coverage of a minimum 48 hours of inpatient care following a vaginal delivery and 96 hours of inpatient care following a caesarean section for a mother and her newborn.[1000]

The most current AAP and ACOG recommendation states that the 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.[1001,1002] The AAP and ACOG guidelines 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 when 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.[1003,1004] An observational cohort study concluded that discharge plans should be individualized and jointly tailored to a family's needs rather than to a set timescale, as being unready at postpartum discharge was associated with increased healthcare use and poorer health outcomes in the first two to four weeks following discharge for the mother and infant.[1005]

In one study, the legislative mandates targeting postpartum length of stay were associated with an increase in average length of stay, although there was significant variation across demographic groups.[1006] Further, evidence has shown that early discharge legislation has decreased risk for infant readmission,[1007,,1008] emergency room visits,[1009] morbidity, and mortality.[1010] Other research suggests that mothers who stayed only one night after vaginal delivery reported more distress, fatigue, and pediatric problems; used more outpatient services following discharge; and were less likely to initiate and/or continue breastfeeding than mothers who stayed two nights.[1011] However, some research suggests that improved mortality and morbidity rates depend on the content of post-partum services, which should be more uniformly defined and administered.[1012,,1013]

Home visits

The mandate further stipulates that post-delivery care shall include home visits, parent education, assistance and training in breast or bottle feeding, and the performance of any necessary and appropriate clinical tests."[1014] The first home visit must be conducted by a registered nurse, physician, or certified nurse midwife, with any subsequent clinically necessary visits to be conducted by a licensed healthcare provider.[1015]

According to the AAP, once the minimum criteria are met before discharge of a newborn, a follow-up visit by a licensed healthcare professional should occur within 48 hours of discharge based on risk factors but no later than 72 hours in most cases, either in the home or clinic setting.[1016] The purpose of the follow-up visit is to: [1017]

- Weigh the infant; assess the infant's general health, hydration, and extent of jaundice; identify any new problems; review feeding pattern and technique; and obtain historical evidence of adequate urination and defecation patterns for the infant
- Assess quality of mother-infant attachment and details of infant behavior
- Reinforce maternal or family education in infant care, particularly regarding infant feeding and safety such as breastfeeding, safe positioning for sleep, and child safety seats
- Review the results of outstanding laboratory tests, such as newborn metabolic screens, performed before discharge
- Perform screening tests in accordance with state regulations and other tests that are clinically indicated, such as bilirubin measurement
- Verify the plan for healthcare maintenance, including a method for obtaining emergency services, preventive care and immunizations, periodic evaluations and physical examinations, and necessary screenings
- Assess for parental well-being including postpartum depression in the mother

Home 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.[1018] Beyond cost-effectiveness, a variety of significant health benefits to both child and mother have resulted from these visits, including a decrease in missed well-infant visits;[1019] identification of psychosocial issues and post-partum depression and improvement in

the maternal-child bond;[1020] a reduction of incidence of child abuse or neglect;[1021] and fewer emergency department visits.[1022,1023] In addition, home visits might encourage more women to exclusively breastfeed their babies.[1024]

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).[1025,1026] For pregnant women and children, mandated preventive services include a wide range of screenings and other services, including breastfeeding support and counseling and maternal depression screening for mothers of infants.[1027,1028]

Estimated Marginal Cost of the Mandate

Responses to the carrier survey consistently indicated these services would be covered in the absence of the state mandate. In addition, as noted above and emphasized by multiple carriers, this coverage is required by the ACA and the NMHPA. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

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, Post Traumatic Stress Disorder (PTSD), 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 also 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.).[1029]

Effect of the Mandate on Health

Mental illness is the leading cause of disability in the United States, accounting for 25% of all years of life lost to disability and premature mortality.[1030] Moreover, suicide, which is most often attributable to mental illness, is the 10th leading cause of death in America, with over 47,000 cases each year.[1031]

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."[1032] 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.[1033] The American Psychiatric Association (APA)'s Diagnostic and Statistical Manual, Fifth 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.[1034]

Major diagnostic categories of mental disorders include:[1035]

- 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

An estimated 20.6% of adults have a mental, behavioral, or emotional disorder, collectively referred to as "any mental illness (AMI)" diagnosed currently or within the past year.[1036] AMI can range from no impairment to severe impairment.[1037] An estimated 5.2% of U.S. adults (approximately 13.1 million) suffer from a serious mental illness (SMI).[1038] Those with an SMI have a mental, behavioral, or emotional disorder resulting in serious functional impairment, which substantially limits one or more major life activities.[1039] Only 65.5% of the adults with SMI received mental health treatment in the past year.[1040] In Massachusetts, 282,000 individuals aged 18 and older suffered from an SMI in the past year; approximately 1.2 million suffered from AMI in the past year.

For children ages 13 to 18 in the U.S., the lifetime prevalence of a mental disorder is 49.5%, and over 20% either currently or at some point in their lives have had a seriously debilitating mental disorder.[1041] Anxiety disorders are the most common condition (31.9%), followed by behavior disorders (19.1%), mood disorders (14.3%), and substance abuse disorders (11.4%); 40% meet the diagnostic criteria for more than one disorder.[1042]

Among the people aged 12 years or older, 20.4 million suffer from a substance use disorder. In this age group, alcohol use disorder is most common (71% or 14.5 million people), followed by illicit drug use disorder (40.7% or 8.3 million people) and an overlapping alcohol use disorder and illicit drug use disorder (11.8% or 2.4 million people).[1043] In Massachusetts, 503,000 of individuals aged 12 or older suffered from a substance use disorder in 2019.[1044]

The ongoing COVID-19 pandemic has negatively impacted many people's mental health and created barriers to access to treatment for individuals diagnosed with mental illness and substance use disorders.[1045] Approximately four in 10 adults in the United States have reported symptoms of anxiety or depressive disorder, compared with one in 10 who reported these symptoms from January to June in 2019.[1046] The increased mental health needs created and exacerbated by the pandemic are expected to persist long after the physical impacts of the pandemic itself.

Treatment

Studies linking physical and mental health issues continue to show that 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 might, in turn, impede treatment and recovery. Treatments generally fall into the broad categories of psychotherapy

and medication, and might incorporate a combination of the two. Psychotherapy is used to help patients understand their illnesses, and it 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.[1047] Other therapies include psychodynamic, light, expressive or creative arts, animal-assisted, and play.[1048] Pharmacological therapy for mental illness generally refers to drugs categorized as antipsychotics, antidepressants, mood stabilizers, antianxiety, and stimulants.[1049] New treatments include brain stimulation therapy, the direct activation or touching of the brain with electricity, magnets, or implants.[1050]

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."[1051] The U.S. Substance Abuse and Mental Health Services Administration provides communities, clinicians, policy makers, and others with information and tools to incorporate evidence-based practices into their communities or clinical settings in their Evidence-Based Practices Resources Center.[1052]

The National Institute on Drug Abuse (NIDA) published its "Principles of Effective Treatment" for substance abuse disorders in 2018, outlining general points that research has shown improve outcomes of treatment for this chronic disease.[1053] In general, NIDA states 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:[1054]

- 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.

Screening

Research continues on the efficacy of specific treatments for specific mental illnesses and co-morbidities, reflected in recommendations such as those from the United States Preventive Services Task Force (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 (e.g., 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.[1055]

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.[1056]

Under the Affordable Care Act (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).[1057,1058] For mental health preventive services, the (USPSTF) currently gives a grade "A" or "B" rating to:

- Screening adults, including pregnant and postpartum women, for depression. Adequate systems should be in place to assure accurate diagnosis, effective treatment, and appropriate follow-up.[1059]
- Screening adolescents (12 – 18 years of age) for MDD. Adequate systems should be in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up. [1060]
- Screening for intimate partner violence (IPV) in women of reproductive age. Provide or refer women who screen positive to ongoing support services.[1061]
- Screening in primary care settings of adults 18 years or older, including pregnant women, for unhealthy alcohol use and providing persons engaged in risky or hazardous drinking with brief behavioral counseling interventions to reduce unhealthy alcohol misuse.[1062]
- Screening adults 18 years or older for unhealthy drug use. Should be implemented when services for accurate diagnosis, effective treatment, and appropriate care can be offered or referred.[1063]
- Screening all adults about tobacco use, advising them to stop using tobacco, providing behavioral interventions, and providing U.S. Federal Drug Administration-approved pharmacotherapy for cessation to nonpregnant adults who use tobacco.[1064]
- Screening all pregnant persons about tobacco use, advising them to stop using tobacco, and providing behavioral interventions for cessation to pregnant persons who use tobacco.[1065]
- Providing interventions by primary care clinicians, including education or brief counseling, to prevent initiation of tobacco use among school-age children and adults. [1066]
- For pregnant and postpartum persons at risk of perinatal depression, providing or referring to counseling interventions.[1067]

Estimated Marginal Cost of the Mandate

The ACA requires coverage for treatment of inpatient and outpatient mental health and substance abuse disorder as an EHB 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. In addition, responses to the carrier survey consistently indicated these services would be covered in the absence of the mandate. Therefore, this analysis assumes the Massachusetts mental health care mandate to be superseded by federal law; the marginal, direct impact of the state mandate is therefore $0 and 0% of Commonwealth fully insured premium.

Nurse Practitioners

The nurse practitioner (NP) mandate requires plans to cover services of NPs if the same services are reimbursed when performed by any other practitioner and are within the lawful scope of practice of NPs.[1068] Also, Chapter 176R of the Massachusetts General Laws allows NPs to serve as primary care physicians and prohibits carriers from subjecting NPs to reduced coverage limits.[1069]

Effect of the Mandate on Health

NPs are advanced practice registered nurses (APRNs) who are licensed practitioners, practicing autonomously and in coordination with healthcare professionals and other individuals.[1070] NPs practice in nearly all health care settings, including clinics, hospitals, emergency rooms, urgent care sites, private practices, nursing homes, and home health.[1071] NPs provide a wide range of health care services, including the diagnosis and management of acute, chronic, and complex health problems; health promotion; disease prevention; health education; and counseling.[1072] There are more than 290,000 licensed NPs in the United States, including over 7,700 in Massachusetts;[1073] 89.7% of NPs are certified in primary care, and 69% of NPs deliver primary care.[1074] NPs practice in diverse settings such as family practice, geriatrics, internal medicine, pediatrics, and women's health care.[1075] Some NP specialty areas include: neonatal health, hematology/oncology, psychiatric/mental health, allergy and immunology, cardiovascular disease, dermatology, orthopedics, neurology, emergency medicine, urology, and pulmonology.[1076] More than one billion patient visits are made annually to NPs.[1077] In Massachusetts, an NP is certified to practice, within a specific clinical category, as an Advanced Practice Clinical Nurse.[1078]

NPs' educational requirements include a master's, post-master's, or doctoral degree, with most graduate candidates holding a Bachelor of Science in Nursing (BSN).[1079,1080] NPs can be licensed and might prescribe medications in all 50 states,[1081,1082,1083] although the scope of practice and physician oversight requirements might vary across states.[1084,1085] In 2008, the National Council of State Boards of Nursing (NCSBN) adopted the Consensus Model for Advanced Practice APRN Regulation in an attempt to create consistent regulations and legislation across the United States, which would standardize licensure to practice, APRN program accreditation, national certification requirements, and educational requirements.[1086]

In Massachusetts, NPs do not have independent practice authority and must have a collaborative agreement with supervising physicians.[1087] The collaboration agreement must also include prescriptive guidelines developed by the supervising physician; 11 items must be outlined in the agreement, including the scope of the NP's prescribing practice and the types of medication that might be prescribed.[1088] These regulations make Massachusetts the only New England state without full practice authority and one of the most restrictive practice environments in the nation.[1089,1090]

In a review of articles comparing the quality and safety of care provided by NPs to the quality and safety of care provided by medical doctors (MDs), researchers found that outcomes for NPs were comparable or better for all 11 outcomes reviewed.[1091] A high level of evidence indicated that patient outcomes on satisfaction with care, functional status, health status, number of emergency department visits, hospitalization rates, blood pressure, blood glucose, serum lipids, and mortality are similar for NPs and MDs.[1092] 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 advanced practice nurses and physicians; for some measures, advanced practice nurse care was

superior.[1093] Another review found that specialized nurses could help improve primary care of patients with chronic disease; achieve health outcomes that were similar to those of MDs; and when working with MDs, reduce hospital visits and improve certain patient outcomes related to diabetes, coronary artery disease, or heart failure.[1094]

Estimated Marginal Cost of the Mandate

. Carrier survey responses consistently indicated carriers would cover nurse practitioner services in the absence of the mandate. Given that nurse practitioners are generally lower-cost providers than physicians, the only potential positive net marginal direct cost effect of this mandate would result from utilization increases driven by an increase in health care provider supply driven by the mandate. However, this study found no evidence that any such effect materially increases commercial fully insured health care premiums in the Commonwealth, resulting in an estimated 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Off-Label Use of Prescription Drugs to Treat Cancer

Pursuant to this mandate, no insurer that provides coverage for prescription drugs may exclude coverage for any such drug on the grounds that the off-label use of the drug has not been approved by the United States Food and Drug Administration (FDA) for that indication, provided that such drug is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature, or by the Commissioner of Insurance based on the recommendations of a panel established to review off-label uses of prescription drugs for the treatment of cancer for medical appropriateness.[1095]

Effect of the Mandate on Health

Off-label drug use refers to the practice of prescribing a drug for a different purpose than what the FDA approved and is called “off-label” because the drug is being used in a way not described on its package insert, known as its “label.”[1096] Pursuant to Chapter 175 Section 47L of the Massachusetts General Laws, the Commissioner shall establish a panel of six medical experts[xxviii] to review off-label uses of prescription drugs for the treatment of cancer not included in any of the standard reference compendia or in the medical literature and to advise the Commissioner in such instances whether a particular off-label use is medically appropriate; as a result, the panel shall make such recommendations from time to time and whenever a particular dispute about payment for such off-label use is referred to the panel by the Commissioner.[1097]

The FDA was created as a federal consumer protection agency with the passage of the Pure Food and Drugs act of 1906 to rein in long-standing, serious abuses in the consumer product marketplace.[1098] To further expand consumer protection, the Federal Food, Drug, and Cosmetics Act of 1938 (Act) tightened controls over drugs and food, included new consumer protection against unlawful cosmetics and medical devices, and enhanced the government’s ability to enforce the law.[1099] Although the Act gave the FDA the authority to regulate drug promotion by pharmaceutical companies, the FDA regulations have attempted to strike a balance between giving physicians the freedom to use their best clinical judgment and preventing drug manufacturers from inappropriately influencing prescribing

[xxviii] The review panel shall be comprised of six medical experts to include: three medical oncologists selected by the state medical oncology association; a physician selected by the Massachusetts medical association; a physician selected by a hospital and medical service corporation; and a physician selected by the Massachusetts association of health maintenance organizations from a member plan.

practices.[1100] As a result, according to FDA regulations, physicians may prescribe drugs for off-label use, but drug manufacturers may not promote such uses.[1101]

When the FDA approves a drug for market, it also approves the labeling for its use.[1102] The FDA-approved drug labeling for healthcare providers gives key information that includes: specific diseases and conditions that the drug is approved to treat; how to use the drug to treat those specific diseases and conditions; information about the risks of the drug; and information that health care providers should discuss with the patients before they take a drug.[1103] Physicians, however, are not limited to prescribing a drug according to its label and may legally prescribe drugs for any use consistent with available scientific data and proper medical practice[1104], which may include off-label uses—a practice that is common, with approximately one in five prescriptions written for off-label use.[1105] Before 1997, marketing of off-label uses by pharmaceutical companies was illegal; however, with the approval of the Food and Drug Administration Modernization Act (FDAMA) in 1997, pharmaceutical companies were permitted to circulate scientifically valid information and to sponsor independent scientific educational activities if certain conditions were met.[1106,1107] The FDAMA stated that the scientific literature could only be distributed if the off-label use discussed was included in a filed or soon-to-be filed supplemental New Drug Application, and companies had to provide the FDA with advance copies of the materials.[1108] With the legality of these restrictions being challenged[1109] and recognizing that in certain circumstances the exchange and distribution of scientific information on off-label uses should be allowed, in January 2009, the FDA issued new guidance about the promotion of off-label uses of drugs, known as "Good Reprint Practices."[1110] While marketing (advertising and promoting) off-label use remains illegal,[1111] this new guidance describes provisions under which pharmaceutical companies may distribute reprints of journal articles describing drug indications that the FDA has not approved.[1112] It is important to note that off-label use is not the same as expanded access[1113] (compassionate use) or right to try[1114], which are FDA processes, outside of clinical trials, allowing patients who are not responding to currently approved treatments other options to investigational treatments not yet FDA-approved.[1115]

In addition to these reforms, the FDA Amendments Act (FDAAA) passed in 2007 made changes to expand the information collected and studied about drugs following approval.[1116] The FDAAA expanded the FDA's authority to monitor safety after approval and provided funding to set up a stronger post-marketing surveillance system as well as an active monitoring system to discover adverse events involving a drug.[1117] Further, manufacturers must now publicly register many of their industry-sponsored studies, making the information on off-label use more robust and available to physicians and the public, and further preventing the industry from concealing unfavorable results.[1118] The FDAAA also empowered the FDA to mandate label changes to reflect newly discovered risks as well as restrict the use of drugs known to be risky by limiting their distribution to physicians with specialized training. [1119]

The current drug approval process can take up to 15 years; it is estimated that from 5,000 to 10,000 compounds, only one new drug reaches the market.[1120] Because of the enormous amount of time and money required to seek FDA approval for a new drug use, manufacturers opt for back-door approaches to developing off-label revenue streams, and off-label uses discourage companies from conducting additional clinical research because they can sell their products without seeking FDA approval.[1121] As a result, with many patients benefiting from receiving drugs or devices under circumstances not specified on the FDA-approved label, off-label prescribing has become an integral part of contemporary medicine.[1122] One study of 29 new drugs approved in 1998 found that 59% of drug therapy innovations came from field discovery and not through clinical trials.[1123] Another study, published in 2006, found that

21% of all estimated uses for commonly prescribed medications in the United States were for off-label drugs.[1124] A 2008 survey found that 80% of oncologists prescribe off-label treatments at least once;[1125] and a recent retrospective observations study found that the National Comprehensive Cancer Care Network frequently recommends uses beyond the FDA-approved indications even for newer branded drugs.[1126]

Although off-label use has gained much interest from the research community in recent years as it could offer safe, timely, and affordable new treatment options for cancer patients with high unmet needs;[1127] off-label use is not without significant risks and controversy with available compendia indicating that only a minority of off-label uses is well supported by evidence.[1128] As a result, despite sufficient evidence justifying some off-label practices, the lack of FDA approval means that the off-label uses are not given the same degree of scientific scrutiny as labeled indications.[1129] The provider community itself is divided; a survey of oncologists regarding off-label use found that their attitudes and practices vary substantially.[1130] Consequently, while off-label use could provide timely access to treatments for patients with urgent medical needs, it also entails important safety, liability, and financial risks for patients, physicians, and society.[1131]

Despite these concerns, many physicians believe it is sometimes appropriate to prescribe drugs for indications the FDA has not approved.[1132] Through its policy statement, 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 off-label indication when such use is based upon sound scientific evidence or sound medical opinion" and affirms the position that, when the prescription of a drug or use of a device represents safe and effective therapy, insurers should cover such therapy and include such appropriate off-label uses of drugs on their formulary.[1133] 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 might not be aware of the treatment's uncertainty and potential risks, nor of the potential additional cost of an off-label treatment that might not be reimbursable. Findings from a 2006 poll "suggest that much of the U.S. public is confused and ambivalent about off-label prescribing, with about half the respondents believing that physicians are permitted to prescribe drugs only for on-label indications and about half believing that physicians should be prohibited from prescribing drugs for off-label indication."[1134] Because disclosure that a prescribed drug is being used off-label is not legally required if it is being given in the patient's best interest and is left to the discretion of the treating physician, the American Academy of Pediatrics Committee on Drugs advises physicians to use professional judgment in deciding whether to discuss with patients and parents a drug's off-label status and acceptance in the medical community.[1135,1136]

Pursuant to the FDA's guidance, "if physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects."[1137] Oncologists rely on compendia for the up-to-date off-label indications and reimbursement information; however, these compendia "lack transparency, cite little current evidence, and lack systematic methods to review or update evidence."[1138] For anti-cancer chemotherapeutic regimens, Medicare law directs the Centers for Medicare & Medicaid Services (CMS) to consider certain listed compendia when deciding whether the use of a drug is medically accepted for the treatment of cancer, and allows CMS to revise the list.[1139]

For cancer treatment, off-label use is common because:

- Certain drugs approved for treatment of specific tumor types are found to be effective against many different kinds of tumors.
- Chemotherapy treatments often combine drugs. These combinations might include one or more drugs not approved for that disease. In addition, drug combinations change over time as doctors study different ones to find out which work best.
- Cancer treatment is continuously changing and improving.
- Oncologists and their patients are often faced with problems that have few approved treatment options. This is especially true for less common types of cancer.
- Oncologists and their patients might be more willing to try off-label drugs than other medical specialties.[1140]

Reimbursement for off-label prescriptions is inconsistent and complex, and many insurance companies will not pay for a drug for an off-label use because the use is experimental or investigational.[1141] Many states, such as Massachusetts, mandate coverage for off-label prescriptions for certain types of drugs, and in 1993, federal legislation was passed to require insurance that covers medically appropriate cancer therapies to include some off-label uses.[1142] Likewise, in 2008, Medicare rules were changed to cover more off-label uses of drugs used for cancer treatment.[1143]

Although patients need access to off-label drug treatments, they also need commensurate protection from risky and/or ineffective interventions.[1144] Health care providers should continually educate themselves about off-label uses to weigh the potential risks and benefits in order to provide the best care for their patients.[1145] Further, although off-label use is common, most uses occur without scientific support; as a result, efforts should be made by policy makers to scrutinize underevaluated off-label prescribing that compromises patient safety or represents wasteful medication use.[1146]

Estimated Marginal 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. 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). 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. This study therefore includes $0 and 0% of Commonwealth fully insured premium in marginal cost related to this mandate.

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

Pursuant to this mandate, no insurer that provides coverage for prescription drugs shall exclude coverage of any such drug for human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) treatment on the grounds that the off-label use of the drug has not been approved by the United States Food and Drug Administration (FDA) for that indication, if such drug is recognized for treatment of such indication in one of the standard reference

compendia or in the medical literature or by the Commissioner of Insurance based on the recommendations of a panel established to review off-label uses of prescription drugs for the treatment of HIV/AIDS for medical appropriateness.[1147]

The general issues arising from the practice of prescribing off-label drugs as well as the role of the FDA regarding off-label drug use are outlined in the preceding section: Off-Label Uses of Drugs for Cancer Treatment.

Effect of the Mandate on Health

Off-label drug use refers to the practice of prescribing a drug for a purpose different from what the FDA approved and is called "off-label" because the drug is being used in a way not described on its package insert, known as its "label."[1148] Pursuant to Chapter 175 Section 47P of the Massachusetts General Laws, the Commissioner of Insurance shall establish an 11-member advisory panel[xxix] to advise the Commissioner on whether off-label uses for HIV/AIDS treatment not included in any of the standard reference compendia or in the medical literature are medically appropriate; as a result, the panel shall make such recommendations from time to time and whenever a particular dispute about payment for such off-label use is referred to the panel by the Commissioner.[1149]

Off-label use of drugs does not comply with the diagnostic or condition indications and/or the administration and dosage requirements approved as safe and effective by the FDA.[1150,1151] Drugs are often used off-label in response to unmet medical needs, the needs of poorly studied populations or populations not studied at all in trials, or urgent public health needs, when it is reasonable to assume that the drugs could effectively treat a given condition.[1152] As explained in the preceding section: *Off-Label Use of Prescription Drugs to Treat Cancer*, off-label drug use is complicated, often by: a lack of information regarding safety and effectiveness; appropriate route, use, and dosage administration; as well as complex reimbursement issues, especially in relation to insurance coverage for non-approved pharmaceuticals.

Early in the history of the U.S. AIDS crisis, off-label indications frequently represented community standards of care, most often being used for the treatment and prevention of HIV-related opportunistic infections.[1153] According to the United States General Accounting Office (GAO), a number of studies from the early to mid-1990s documented that 81% of AIDS patients received at least one drug off-label and 40% of all reported drug treatment in AIDS patients was off-label.[1154] These treatment attempts were sometimes the only hope of survival for a dying patient; as an example, thousands of AIDS patients were saved by the off-label use of various mixtures of antiretroviral and anti-infective drugs.[1155]

[xxix] This 11-member panel shall include: (a) three medical infectious disease specialists selected by the Massachusetts Department of Public Health, (b) two physicians selected by the Massachusetts Department of Public Health, (c) one physician representing a nonprofit hospital and medical service corporation, one physician representing health maintenance organizations, and one physician representing commercial insurers; (d) two consumers selected by the Massachusetts Department of Public Health, and (e) one representative from an AIDS service organization or consumer advocacy group selected by the Massachusetts Department of Public Health.

Primarily in response to the HIV/AIDS crisis, the FDA took several significant steps toward making experimental drugs intended to treat life-threatening diseases more widely available to severely ill patients, as well as toward accelerating the review and approval of applications for these new products:

- In 1987, an "AA" priority category was established to classify all applications for potential AIDS therapies to ensure that these products receive the highest priority in the review process
- In October 1988, interim regulations designed to expedite marketing approval of new drugs intended for life-threatening and severely debilitating diseases were issued
- On December 11, 1992, the final rule was published that accelerated the approval of new drugs for serious and life-threatening diseases when the drug provides meaningful therapeutic benefit over existing products
- On December 12, 1995, the FDA published a report, "Timely Access to New Drugs in the 1990s: An International Comparison," which documents that the FDA's tough standards do not delay consumer access to important new drugs compared to other countries, and that the United States has available valuable drugs as soon as, and in many cases sooner than, its counterparts around the world. For example, six antivirals have received approval for the treatment of HIV: two were approved in three months, three in six months and one in eight-and-a-half months.[1156]

Moreover, the FDA created parallel track mechanisms in 1992 to expand the availability of promising investigational drugs to those persons with HIV/AIDS-related diseases who were without satisfactory alternative therapy and who could not participate in controlled clinical trials.[1157] These systems were established 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. Since the approval of Zidovudine in 1987,[1158] the FDA has approved 32 antiretroviral drugs, 1 pharmacokinetic enhancer, and 21 fixed-dose combinations to treat HIV/AIDS patients.[1159] Treatment with antiretroviral drugs has transformed HIV infection from an almost fatal infection into a manageable chronic condition.[1160] In addition to drugs for treatment of HIV/AIDS, pre-exposure prophylaxis (PrEP) is a way to prevent HIV infection by taking a pill every day for people who do not have HIV but who are at very high risk of getting HIV.[1161]

Given these developments, the availability of more approved treatments, and research regarding their safety and efficacy, it is difficult to determine how widely off-label treatments are currently being used for HIV/AIDS treatment and prevention. Research on off-label use continues to be scarce, as gathering data regarding these applications is challenging.[1162] One long-term study of the use of off-label anti-retroviral drugs for children with HIV/AIDS from 1988 – 2012 concluded that off-label use was common and that frequent incorrect dosing might occur when prescribing off-label.[1163]

Estimated Marginal 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 impact of the mandate is estimated to be $0 and 0% of Commonwealth fully insured premium.

Optometrists

The optometrist mandate requires coverage for services of optometrists if such services are reimbursed when performed by physicians and are within the lawful scope of practice of optometrists.[1164]

Effect of the Mandate on Health

Optometrists, or doctors of optometry, are independent healthcare professionals who examine, diagnose, treat, and manage diseases, injuries, and disorders of the visual system, the eye, and associated structures; they also identify related systemic conditions affecting the eye.[1165] Educational requirements for optometrists include four years of pre-professional undergraduate education and four years of graduate study at a college of optometry.[1166,1167] 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).[1168] In Massachusetts, there are five tests, including applied basic science, patient assessment and management (PAM), clinical skills, treatment and management of ocular disease (TMOD), and state jurisprudence.[1169,1170,1171] Optometrists licensed by examination are automatically eligible for certification to use or prescribe diagnostic pharmaceutical agents (DPA Certification) and therapeutic pharmaceutical agents (TPA Certification); TPA Certification is issued with licenses.[1172] Licenses must be renewed annually[1173] and include evidence of continuing education.[1174]

Medicare considers optometrists to be physicians "with respect to all services the optometrist is authorized to perform under State law or regulation."[1175] This review found no published studies quantifying the efficacy of the work of optometrists or studies 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.

Estimated Marginal Cost of the Mandate

The optometrist mandate requires coverage for services of optometrists if such services are reimbursed when performed by physicians or optometrists and are within the lawful scope of practice of optometrists. The primary effect of the mandate, as noted by multiple carriers in BerryDunn's survey, is to shift utilization from ophthalmologists to optometrists, and there is no evidence of increased utilization of service owing to the mandate. Other carriers stated the mandated services would be covered even in the absence of the mandate. This study therefore estimates the 2018 marginal cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Physician Assistants

The physician assistant (PA) mandate requires carriers to recognize PAs 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. The mandate also allows PAs to serve

as primary care physicians when practicing within the scope of a PA license, including all regulations requiring collaboration with or supervision by a physician.[1176,1177]

Effect of the Mandate on Health

PAs are medical professionals committed to team practice with physicians and other healthcare providers as part of a healthcare delivery team.[1178] Depending on their specialty, experience, and the setting in which they practice, PAs take medical histories; conduct physical exams; diagnose and treat illnesses; order and interpret tests; develop treatment plans; prescribe medications; perform procedures; assist in surgeries; counsel patients on preventive care; manage the care of hospitalized patients; and conduct clinical research.[1179]

PAs are educated at the master's degree level. Most programs last approximately 27 months (three academic years), and include classroom instruction and more than 2,000 hours of clinical rotations.[1180] Students fulfill prerequisite courses similar to those required in medical school; take classes in basic medical sciences, behavioral sciences, and behavioral ethics; and receive clinical education training.[1181] PAs are then required to complete at least 2,000 hours of clinical rotations in family, internal, and emergency medicine; pediatrics; psychiatry; general surgery; and obstetrics and gynecology.[1182]

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; complete training for prescribing controlled substances; 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.[1183,1184,1185,1186] PAs are also required to complete continuing medical education to remain licensed in the Commonwealth.[1187] There are approximately 89,000 professionally active PAs nationally, and 2,100 professionally active PAs in Massachusetts.[1188] The total number of certified PAs nationally and in Massachusetts is approximately 130,000 and 3,500, respectively.[1189]

While PAs must by supervised by a physician,[1190] they are able to independently prescribe medications in Massachusetts following guidelines developed with the supervising physician.[1191] 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.[1192]

Studies of the effectiveness of PAs often include nurse practitioners as well, and researchers might 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, and that they provide safe care in emergency departments, as well as in intensive care, critical care, and neonatal intensive care units.[1193,1194,1195,1196,1197] Over the past 10 years, there has been an increase in the number of studies assessing the impact of advanced practice providers, nurse practitioners, and PAs in acute and critical care settings.[1198] Collectively, these studies identify the value of advanced practice providers in patient care management, continuity of care, improved quality and safety metrics, patient and staff satisfaction, decreasing the cost of care and resource use, and enhancing the educational experiences of residents and fellows. 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.[1199]

The PA mandate requires carriers to recognize PAs as participating providers and include coverage for the care provided by PAs for the purposes of health maintenance, diagnosis, and treatment of patients.[1200] The coverage shall

also include benefits for primary, intermediate, and inpatient care, including care provided in hospitals, clinics, professional offices, home and long-term care settings, mental health or substance abuse programs, or other settings when rendered by PAs who are participating providers practicing within the scope of their licenses.[1201] The mandate deems PAs qualified to be designated as primary care providers in an insurer network.[1202]

Estimated Marginal Cost of the Mandate

Carrier survey responses consistently indicated carriers would cover physician assistant services in the absence of the mandate. Given that physician assistants are generally lower-cost providers than physicians, the only potential positive net marginal direct cost effect of this mandate would result from utilization increases driven by an increase in health care provider supply driven by the mandate. However, this study found no evidence of that any such effect materially increases commercial fully insured health care premiums in the Commonwealth, resulting in an estimated 2018 marginal cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Podiatrists

The podiatrist mandate requires reimbursement for covered podiatric services performed by a physician or a licensed podiatrist within the lawful scope of practice.[1203]

Effect of the Mandate on Health

A podiatrist is a doctor of podiatric medicine (DPM) who diagnoses, treats, and prevents conditions and injuries affecting the foot, ankle, and related structures of the leg (lower extremity).[1204,1205] DPMs are uniquely qualified based on their education, training, and expertise to treat the lower extremity.[1206] Working independently, DPMs utilize x-rays and laboratory tests for diagnostic purposes; prescribe medications; order physical therapies; set fractures; and perform surgeries.[1207] DPMs treat patients with chronic illnesses that can lead to serious foot and ankle problems, such as diabetes, arthritis, obesity, heart disease, and peripheral arterial disease.[1208] An estimated 18,000 DPMs practice in the United States.[1209]

DPMs receive medical education and training comparable to medical doctors or doctors of osteopathic medicine.[1210] To be licensed in Massachusetts, DPMs 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.[1211,1212,1213,1214] Additionally, DPMs must pass oral, written, and/or clinical examinations administered by the Commonwealth,[1215,1216] and complete 15 hours of continuing education annually to renew licensure.[1217] Massachusetts, however, is one of four states nationally that only includes the foot, and does not include the ankle, in the scope of practice for DPMs.[1218]

Medicare considers a DPM a physician "only with respect to those functions which he/she is legally authorized to perform in the State in which he/she performs them."[1219] DPMs are eligible to order and/or refer for Part B and Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) for Medicare beneficiaries.[1220] Further, DPMs 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.[1221]

While no evidence was found comparing the effectiveness of podiatric care provided by DPMs to that provided by nurses, allied health professionals, or non-specialist physicians, some evidence exists that interdisciplinary foot and

wound 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.[1222,1223,1224,1225,1226] Other studies have found that for patients waiting for an evaluation by an orthopedic surgeon, DPMs can provide appropriate triage service, resulting in more timely provision of non-surgical care and better targeted use of orthopedic surgical resources.[1227,1228]

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

Estimated Marginal Cost of the Mandate

Carrier survey responses consistently indicated carriers would cover podiatrist services in the absence of the mandate. In addition, one carrier specified these services were covered prior to the implementation of the mandate; another referred to a study suggesting the mandate might lead to cost savings via avoided amputations among members with diabetes. Therefore, BerryDunn estimated the 2018 marginal cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Prescription Eye Drops

This mandate requires coverage for refills of prescription eye drops in accordance with the Medicare Part D guidelines on early refills of topical ophthalmic products when: (i) the prescribing healthcare practitioner indicates on the original prescription that additional quantities of the prescription eye drops are needed; (ii) the refill requested by the insured does not exceed the number of additional quantities indicated on the original prescription by the prescribing healthcare practitioner; and (iii) the prescription eye drops prescribed by the healthcare practitioner are a covered benefit under the policy or contract of the insured.[1229]

Effect of the Mandate on Health

Prescription eye drops, or topical ophthalmic solutions, are used to treat a wide variety of conditions, both acute and chronic. However, this mandate impacts only prescriptions for which patients require refills. Therefore, this review will not address the efficacy of prescription eye drops, but assumes that these FDA-approved treatments are effective for the conditions for which they are prescribed. Instead, the research presented summarizes studies measuring patient eye drop prescription adherence[xxx], the potential adverse outcomes of non-adherence, and the relationship between patient adherence and insurance coverage rules regarding refills.

Most often treatments with eye drops are for the following conditions, some of which are chronic: glaucoma, uveitis, dry eyes syndrome, conjunctivitis (allergic, infectious, and/or chemical), macular edema, and strabismus.[1230]

[xxx] Patient eye drop adherence reflects the patients' ability to use the volume of the prescription medication as directed.

Understanding the nature of conditions often treated with eye drops is useful in understanding the value of maintaining prescribed treatment regimens; several of these conditions are described below.

- Glaucoma is a group of eye disorders leading to progressive damage to the optic nerve, which can lead to loss of nerve tissue, resulting in loss of vision.[1231] In the United States, glaucoma is the leading cause of preventable blindness and the second leading cause of blindness overall; at least three million people have the disease.[1232,1233] The number of patients with glaucoma in the United States is projected to increase by more than double, from 2.7 to 6.3 million from 2010 – 2050.[1234] According to the American Glaucoma Society (AGS), although not all patients with glaucoma demonstrate elevated intraocular pressure, the current standard glaucoma care is devoted almost exclusively to the reduction of intraocular pressure which can arrest the progression or dramatically slow the course of disease in the vast majority of cases.[1235] The condition is chronic, and can be controlled but not cured through medication compliance and regular physician visits.[1236] Currently available methods for glaucoma pressure-lowering include: medicines (usually eye drops); laser treatment; and surgery.[1237] Of these treatments, prescription eye drops are the most common and often the first treatment typically used to reduce intraocular pressure to prevent further damage to the optic nerve.[1238,1239]

- Uveitis is the swelling and/or irritation of the middle layer of the eye, or uvea, which supplies blood to the retina.[1240] The incidence in the United States is approximately 15 cases per 100,000 per year, or a total of 38,000 new cases per year with an average age at onset of 30.7 years.[1241] Uveitis is the third leading cause of blindness worldwide, and is estimated to be the cause of 10% – 15% of cases of blindness in the United States.[1242] Symptoms of uveitis include eye pain, redness, blurred vision, floating spots, and sensitivity to light.[1243] The condition can result from several causes, including certain autoimmune diseases, trauma, infections, and toxins.[1244] It is often treated with steroid eye drops: to reduce inflammation, to dilate the pupils to prevent muscle spasms in the iris and ciliary body; and to alleviate pain.[1245]

- Chronic dry eye syndrome is a condition in which the eye does not produce enough tears, or when tears don't work correctly, making one's eyes feel uncomfortable; and in some cases, might cause vision problems.[1246] An estimated 4.88 million people over the age of 50 in the United States have dry eyes; of these, over 3 million are women.[1247] Being age 50 or older and female increases the risk of developing dry eye; dry eye may also occur from a variety of causes including: medicines, health problems such as diabetes, thyroid problem and autoimmune disorders; laser eye surgery; windy, smoky, or dry environments; and looking at screens for long periods of time.[1248] Treatment for dry eye usually depends on what is causing symptoms and might include: over-the-counter eye drops; prescription cyclosporine eye drops; lifestyle changes; tear duct plugs; and, in some cases, surgery.[1249]

- Conjunctivitis is an inflammation or infection of the transparent member (conjunctiva) that lines the eyelid, and is commonly caused by a bacterial or viral infection, or an allergic reaction.[1250] A systematic review of the literature in 2013 found that approximately 1% of all patient visits to primary care clinicians are conjunctivitis related with allergic conjunctivitis being the most frequent cause, affecting 15% – 40% of the population.[1251] Conjunctivitis symptoms include redness, tearing, gritty feeling, discharge that

> may form a crust during sleep, and intense itching of one or both eyes.[1252] Treatment depends on the cause and is most often with allergy eye drops for allergic conjunctivitis.[1253]

Eye drop medications, both prescription and over-the-counter, are a mainstay of therapy for treating ocular disorders and are a preferred method of treatment because they are: effective; non-invasive; and, in theory, easy to use.[1254] However, some patients have difficulty administering eye drops in their own eyes; these patients may not instill the correct number of drops successfully in the eye, or they may dispense too many drops at one time. One study of patients instilling eye drops to treat glaucoma found that, while most patients claim to have no problems using the drops correctly, less than one-third were able to actually do so.[1255] Another study found these problems persist even with patients who have significant experience in using drops.[1256] According to a study that assessed patient self-efficacy with general glaucoma medication adherence and eye drop technique, patients who were less than 80% adherent to their glaucoma medication regimen are significantly more likely to have worse visual field defect severity.[1257] These gaps in glaucoma treatment can lead to irreversible vision impairment and blindness.[1258] Supporting these study findings, the American Academy of Ophthalmology (AAO) reported that more than half of the patients with glaucoma skip or improperly administer medications, risking permanent vision loss.[1259]

A known barrier to patient adherence with chronic topical glaucoma treatment is an inadequate amount of medication available between prescription refills.[1260] For patients with coverage for prescription medications, the time interval between refills is often set by their insurance carrier or the insurance carrier's contracted pharmacy benefit manager. Clinicians have indicated these restrictions can prohibit patients who have difficulty administering eye drops from obtaining early refills when they have prematurely exhausted their medication supply, making adherence to their treatment regimens more difficult.[1261,1262] According to a joint statement by the AAO and the AGS, restrictions on medication availability are a component of poor outcomes in glaucoma treatment.[1263] A recently-published analysis of glaucoma patients attempted to measure how often patients ran out of glaucoma eye drops prior to a scheduled refill, finding that 5% of the study survey respondents routinely ran out of their prescription medication between refills, and 25% reported this early exhaustion (bottles did not last until the next allowed refill) at least once yearly.[1264] Another study found that only 10% of glaucoma patients continuously refilled their prescription within 12 months.[1265]

In order to address the challenges associated with early prescription eye drop refills, as well as in response to the complaints filed by patients and providers, in 2010 the Centers for Medicare and Medicaid Services (CMS) issued a guidance memo for all Medicare Part D (pharmacy) plan sponsors, advising them of best practice policy for their Medicare Part D prescription plans for early refill edits for topical ophthalmic products. The guidance stated that:

> CMS recognizes that early refill edits are an important utilization management tool used to promote compliance and prevent waste. However, it is equally important that Part D sponsors implement such edits in a manner that does not unreasonably put beneficiaries at risk of interruptions in drug therapy that potentially have serious consequences.[1266]

As a result, CMS advised insurers to allow refills for topical ophthalmic products at 70% of predicted days of use for both retail and mail-order sources and to allow physicians to authorize even earlier refills for specific patients who may need them.[1267]

Although most insurance carriers have incorporated this guidance on behalf of their Medicare patients, Medicare covers only about half of glaucoma patients. For commercially insured patients, as of 2019, seventeen states have enacted legislation that allows patients to refill eye drop medication prescriptions early under certain conditions.[1268] Since a certain amount of medication often goes unused due to spills or other factors when patients self-administer eye drops, the AAO's formal position is that patients should have the right to refill their eye drop prescriptions early when they run out of medicines.[1269]

This analysis uncovered no specific research outlining the impact on patient outcomes of insurance coverage for early refills of eye drops. The main treatment for glaucoma and other diseases of the eye is the consistent and correct use of eye drops. Treatment outcomes are dependent on the correct and consistent use of eye drops. Eye drops are more difficult to administer consistently than other medication types, such as pills. There is evidence some patients have difficulty instilling eye drops as directed, often using more drops than intended and exhausting their supply before the prescribed expected days of use. This treatment gap can negatively impact patient outcomes, and in the case of glaucoma, increases the patient's risk of vision loss and/or blindness.

Estimated Marginal Cost of the Mandate

Responses to the carrier survey consistently indicated these services would be covered in the absence of the mandate. In addition, CHIA's prospective mandated benefit review study of the bill resulting in this mandate found that the cost of enacting the mandate would be minimal.[1270] This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Preventive Care for Children to Age Six

The preventive care mandate requires coverage for preventive and primary care services for children through the attainment of age 6, including physical exams, sensory screening, neuropsychiatric evaluation and developmental screening, and assessment at the following intervals: six times during the child's first year after birth, three times during the next year, and annually until age 6. Such services shall also include hereditary and metabolic screening at birth; appropriate immunizations; tuberculin tests; hematocrit, hemoglobin, or other appropriate blood tests; and urinalysis as recommended by the physician.[1271]

Effect of the Mandate on Health

In 2004, the Institute of Medicine report defined child health 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."[1272] Supporting this broad definition, pediatric clinical practice in the United States has shifted its predominant focus from disease and infection to one of risk reduction and health promotion.[1273] As a result, healthcare interventions are focused on changing the physical, social, or emotional environments in which children live and learn, rather than on medical treatment, to maximize a child's physical, cognitive, social, and emotional development[1274] as well as optimal functioning at home.[1275]

As healthcare changed, criticism arose in the early 2000s regarding the inconsistency of the content and quality of well-child care and the lack of research proving the effectiveness of each of its elements, which highlighted the need for major revisions to well-child care.[1276,1277] In addition, researchers analyzing medical expenditure panel surveys identified disparities in the well-child preventive healthcare provided to minority children,[1278] children receiving Medicaid,[1279] and children with and without special healthcare needs.[1280] A review of evidence for preventive interventions targeting tobacco exposure, unintentional injury, obesity, and mental health problems, which are health concerns that are prevalent in childhood and can have a substantial lifelong impact, found variations in the effectiveness of preventive interventions for each condition, as well as gaps in the availability of evidence.[1281]

Unlike evidence-based medical care, which evaluates the effect of treatments on individual patients (e.g., antibiotics for common infections), child health promotion within pediatric medicine is considered to be evidence-informed rather than fully evidence-driven, identifying the need for a new framework to evaluate healthcare interventions and determine which kind and level of evidence is sufficient to recommend preventive interventions to promote children's overall health and well-being.[1282,1283] Although the currently available research justifies the implementation of healthcare interventions in the prenatal to preschool period—especially to reduce tobacco exposure and prevent injuries—there is an urgent need for carefully targeted, rigorous research to examine the longitudinal causal relationships and provide stronger economic data to help policymakers make the case that the entire society would benefit from wise investment in improving the health of preschool-age children and their families.[1284] Increasingly, the first three years of a child's life have been recognized as an important time for brain growth and a window of opportunity to optimize children's development in many ways, and the literature suggests that many primary care activities promoting the optimal development of children are efficacious.[1285]

As a result of this recognition of the importance of early brain development, the provision of appropriate services to young children has become the focus of many state and national policy initiatives promoting improving pediatric care.[1286] In 1990, the Maternal and Child Health Bureau (MCHB) of the U.S. Department of Health and Human Services Health Resources and Services Administration (HRSA) launched the Bright Futures initiative to improve the quality of health services for children through health promotion and disease prevention, and in 2002, the MCHB selected the American Academy of Pediatrics (AAP) to lead the Bright Futures initiative.[1287] Bright Futures has developed a robust set of recommendations for providing well-child care, including a periodicity schedule, which is the standard for preventive care for infants, children, and adolescents and is used by professional organizations, federal programs, and third-party payers.[1288,1289] Bright Futures is a set of principles, strategies, and tools that are theory based, evidence driven, and systems oriented that can be used to improve the health and well-being of all children through culturally appropriate healthcare interventions that address their current and emerging health promotion needs at the family, clinical practice, community, health system, and policy levels.[1290]

Recognizing the importance of preventive care for children, the AAP/Bright Futures-recommended services and its periodicity schedule of preventive services were formally incorporated into the federal Affordable Care Act (ACA) in 2010.[1291] The law requires that all children enrolled in individual and group non-grandfathered healthcare plans are covered, without cost-sharing, for all routine immunizations recommended by the United States Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP)[1292] and all evidence-informed preventive care screening and services recommended in the comprehensive guidelines supported by HRSA.[1293,1294] This latter category includes a schedule of services outlined in the Bright Futures Guidelines for Health Supervision

of Infants, Children, and Adolescents[1295,1296] and the recommendations of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, including its Uniform Screening Panel.[1297] The rationale and evidence for the various elements of the AAP/Bright Futures Guidelines are summarized in the Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents, Fourth Edition publication.[1298] Because the health status of infants and children has been shown to significantly influence the quality of life in adulthood, support of pediatric healthcare and promoting preventive activities will certainly have long-term advantages.[1299]

Estimated Marginal 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 evidence-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 EHBs that apply only to individual and small group plans.[1300] In the carrier survey, the health plans noted this overlap in addition to indicating these services are clinically and cost-effective care that would be offered in the absence of the mandate (one major carrier also noted the coverage was standard prior to enactment of the mandate). This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Limb Prostheses

The prosthetic device[xxxi] mandate requires coverage for prosthetic devices and repairs under the same terms and conditions that apply to other durable medical equipment covered under a policy, and restricts carriers' use of cost-sharing and coverage limits for prosthetic devices.[1301]

Effect of the Mandate on Health

A prosthetic device, also referred to as a prosthesis,[1302] is an artificial device that is built to replace a missing limb or part of a limb that assists with regaining independence.[1303,1304] A prosthesis should enable people with limb loss to perform daily activities (such as walking, eating, and dressing), with some artificial limbs enabling people to function nearly as well as before they lost their limb.[1305] Loss of all or part of a limb, often resulting from amputation, occurs for a number of reasons, such as circulation problems from atherosclerosis or diabetes; traumatic injuries; cancer; and birth defects.[1306] Among those living with limb loss, the main causes are vascular diseases (54%), trauma (45%), and

[xxxi] As set forth in the mandate, "prosthetic device" shall mean an artificial limb device to replace, in whole or in part, an arm or leg.

cancer (less than 2%).[1307,1308] An estimated 2 million or more Americans live with limb loss, and approximately 185,000 amputations occur annually in the United States.[1309]

To understand the prevalence of patients with limb loss and incidence rates of new amputations, considering patient age is important. For children, there are two main categories of limb loss: acquired amputations resulting from traumatic injury or disease, and congenital limb deficiency with the complete absence of a limb or part of a limb, presenting at birth.[1310] Although trauma accounts for only 16% of all amputation-related hospital discharges, an estimated 45% of the prevalent cases of limb loss are due to trauma, with over two thirds of the amputations due to trauma occurring among adolescents and adults below the age of 45 years.[1311] In contrast, approximately 64% of amputations resulting from peripheral vascular disease and diabetes (dysvascular disease)[1312] occur among adults 65 and older.[1313] By 2050, it is estimated that the prevalence of limb loss will more than double from 1.6 to 3.6 million people, and that the number of people with diabetes who are living with the loss of a limb will nearly triple.[1314]

In general, amputations are categorized as upper limb (arm and hand) and lower limb (leg and foot).[1315] Complications related to limb loss include: severe depression; wound infections; phantom limb pain and sensation; stump pain; stump osteomyelitis; stump overgrowth; soft tissue and muscle atrophy; skin problems; joint contracture; soft tissue and bone infections; overuse syndromes in remaining extremities and proximal joints; and heterotopic ossification, or an overgrowth of bone instead of scar tissue.[1316,1317] In the short term, prosthetic patients are more likely to experience depression and anxiety, as well as social discomfort and body-image anxiety.[1318] One study found that a well-adjusted lower limb prosthesis probably has a better cosmetic appearance compared to that of an upper limb prosthesis; this perception of cosmetic appearance might be the key factor that leads to increased levels of body-image anxiety and social discomfort for amputees.[1319]

Adjustment to prostheses and the coping strategy is individualized and influenced by many factors, such as age, sex, type of prosthesis, experience, rehabilitation program, type of work performed by the prosthesis, cause of amputation, site of limb loss, and the social situation.[1320,1321] Some studies have reported lower limb prostheses have a high rate of acceptance while upper limb prosthetics have a high rate of rejection.[1322] However, a recent study found similar rates of acceptance among those with upper and lower limb prostheses.[1323] Often, patients reject using a prosthesis because of discomfort or functionality.[1324,1325,1326] These characteristics are associated with the type of prostheses: cosmetic, body-powered, or electric-powered, with some prostheses being myoelectric and controlled by electromyographic signals in the residual musculature and others using pressure, a switch and a harness, a positional service device or a strain gauge.[1327,1328,1329] Myoelectric prostheses are more functional than the other types of artificial limbs, and as a result they might be more accepted by patients.[1330] Prostheses need to be customized to the individual needs of a patient by a prosthetist who develops a prosthetic socket, the piece that connects the prosthesis to the body.[1331] Depending on the level of limb loss, as well as the patient's physical abilities and needs, each prosthesis will be different; the goal of the artificial replacement for a missing limb or part of a limb is regaining independence.[1332] Passive prostheses are generally considered to be devices that are worn purely for cosmetic purposes, while functional prostheses are devices that enable an amputee to perform tasks; the latter might also serve a cosmetic purpose.[1333]

Beyond functionality, appearance-related beliefs are associated with distress and psychosocial adjustment difficulties for patients dealing with limb loss.[1334] One study found that for lower-limb amputations, assessment of a patient's

body image, self-esteem, and quality of life should be carried out as a routine procedure to monitor patients' post-amputation progress.[1335] In addition, psychological interventions focusing on increasing body image and self-esteem, especially for patients with phantom pain sensations, might reduce the impact of the loss of a body part and improve the patients' overall quality of life.[1336] Another study found that patients identified an ongoing awareness of differences in their appearance and ability resulting from upper limb loss, as well as a recognition that psychosocial and functional adjustments are needed to minimize this sense of difference.[1337] A patient's prosthesis and their positive coping style facilitates these psychosocial and functional adjustments, with patients often identifying the personal meaning of their prosthesis and highlighting the terms of its use, resulting in the minimization of their sense of difference and patients regaining a sense of worth.[1338] In a study looking at the impact of bone-anchored prostheses, patients described a revolutionary change in their lives as amputees using their prosthesis; and that change went beyond the functional improvements to include implications in their concept of quality of life.[1339]

As summarized by one study, prostheses have a number of deep personal meanings for patients, centering on what they can practically achieve with their prosthesis, as well as the management of personal information and identity.[1340] In fact, most amputees with a prosthetic use them extensively and expressed satisfaction with the device's overall performance and quality. [1341] However, a large number were dissatisfied with their own ability to interact with the prosthetic, and almost 33% were dissatisfied with their comfort; satisfaction was significantly higher among patients with a shorter wait to their first prosthesis fitting.[1342] Although prosthetic technology has made great progress in recent decades, acceptance rates and user satisfaction are not only dependent on the technical aspects of a prosthesis, but also on social and psychological factors.[1343] Current research suggests that ease of prosthesis use, and the ability to conceal limb loss/absence and ward off social stigmatization, enables social integration and reduces emotional problems surrounding these disabilities.[1344] To the extent changes in coverage required under this mandate improve the quality of devices and treatment available to the patients—and consequently the patients' recovery experience, including adjusting to limb loss and to a device—they are likely to lead to better outcomes, such as greater ongoing functionality and emotional stability for patients.

Estimated Marginal 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. Responses to the carrier survey consistently indicated these services would be covered in the absence of the mandate. In addition, one major carrier indicated some overlap of this mandate with EHB requirements of the ACA. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Scalp Hair Prostheses

The scalp hair prosthesis, an artificial substitute for scalp hair, mandate requires policies providing coverage for any other prosthesis to provide coverage for expenses for scalp hair prostheses worn for hair loss suffered as a result of the treatment of any form of cancer or leukemia, in an amount not to exceed $350 per year.[1345] However, since this mandate was enacted prior to January 1, 2012, coverage for a scalp hair prosthesis is considered an Essential

Health Benefit (EHB) and may not have any annual or lifetime dollar limit.[1346] As a result, a carrier may substitute an actuarially equivalent limit that is not a dollar limit (for example, one designated wig).[1347]

Effect of the Mandate on Health

Hair loss, also called alopecia, may be a side effect of some cancer treatments, including chemotherapy, radiation therapy, hormonal therapy, or bone marrow/stem cell transplants.[1348,1349] Chemotherapy-induced alopecia (CIA) results from chemotherapy drugs damaging hair follicles, making hair fall out.[1350] CIA typically begins after several weeks or cycles of treatment, with the amount of hair loss being dependent on both the drug and dose administered and varying from person to person.[1351] CIA is often the most traumatic side effect of chemotherapy, causing depression, loss of self-confidence, and humiliation in men and women of all ages.[1352,1353] Many women cite CIA as the most disturbing anticipated side effect of chemotherapy.[1354] For children, a common array of emotions when they being losing their hair include anger, sadness, and embarrassment;[1355] and the resulting perceived changes in physical appearance have both direct and indirect effects on depressive symptoms and social anxiety.[1356]

CIA can have profound psychosocial consequences, resulting in anxiety, depression, a negative body image, lowered self-esteem, and a reduced sense of well-being.[1357] Likewise, CIA can negatively impact overall quality of life by affecting body image,[1358] sexuality, self-esteem, and social functioning while also being a visible reminder of having cancer.[1359] One study found that patients who fear CIA may sometimes select regimens with less favorable outcomes or may refuse treatment.[1360] While research continues into the management of CIA, methods to prevent the hair loss have not yet proven effective,[1361, 1362] and no standard of care for treatment exists yet.[1363]

Given the significant impact CIA has on patients, providers should emphasize the need for psychological support of the patient experiencing CIA and the use of creative measures to preserve self-image, while ensuring patients and their families understand the timing, extent, and duration of the hair loss.[1364] Scalp hair prostheses offer some patients the possibility of mitigating the emotional side effects of hair loss, and obtaining the scalp hair prosthesis before it is necessary often reduces anxiety.[1365] Patients perceive a scalp hair prosthesis, frequently referred to as a wig, as very helpful, since it camouflages baldness and reduces the cancer stigma related to CIA.[1366]

Estimated Marginal Cost of the Mandate

Carrier survey responses generally indicated these services would be covered in the absence of the state mandate. In addition, a review of MA APCD data indicated that, with one exception, carriers allow coverage greater than the $350 per year cap required by the mandate. The carrier that did not cover the benefit in excess of the cap indicated it would provide the mandated coverage absent the state mandate. In addition, that carrier is small, and their corresponding impact to the Commonwealth fully insured premium is effectively zero. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Speech, Hearing, and Language Disorders

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; however, such coverage shall not extend to the diagnosis or treatment of speech, hearing, and language disorders in a school-based setting.[1367]

Effect of the Mandate on Health

Communication disorders can affect or impair how a person receives, sends, processes, and understands concepts, and might be evident in the processes of hearing, language, speech, and/or cognition.[1368,1369,1370] Developmental or acquired, communication disorders range in severity from mild to profound, and might be primary or secondary to disorders associated with speech, hearing, and language.[1371,1372] Communication disorders and delays are associated with a wide variety of conditions, ranging from chronic illnesses such as cerebral palsy to acute events such as brain injuries and strokes; known causes of communication disorders include: [1373]

- Neurological abnormalities
- Craniofacial malformations
- Laryngeal abnormalities
- Chromosomal abnormalities
- Neuromuscular disorders
- Neurodevelopmental disorders
- Reduced hearing levels

Most patients with communication disorders benefit from speech-language therapy, and treatment depends on the type and severity of the disorder, as well as an understanding of the underlying causes.[1374] A speech disorder is an impairment of the articulation of speech sounds, fluency, and/or voice; a hearing disorder is the result of impaired auditory sensitivity of the physiological auditory system, and a language disorder is impaired comprehension and/or use of spoken, written, and/or other symbol systems.[1375] Language and communication disorder assessments include audiological evaluations to rule out significant hearing loss as a contributing factor and to verify that hearing is adequate for other assessment procedures.[1376] Nearly 1 in 12 children, ages 3 – 17, in the United States have been impacted by a disorder related to voice, speech, language, or swallowing.[1377] Aphasia, a loss of the ability to use or understand language, can be acquired by anyone, but most patients experience aphasia in their middle to late years.[1378]

The specific problems and disorders vary widely, as do treatment methods and modalities; consequently, speech-language treatment programs employ a variety of approaches dependent on the particular needs and circumstances of the patient.[1379] For children, primary speech and language disorders and delays represent common developmental difficulties that, if left unresolved, can cause difficulties with learning and socialization lasting into adolescence and beyond.[1380] In general, speech-language therapy aims to maximize the ability to communicate through speech, gesture, and/or supplementary means, such as communication aids, enabling patients to become independent communicators.[1381]

Most studies reviewed suggest the effectiveness of treatment for speech, hearing, and language disorders in general. However, one large systematic review of speech pathology interventions for patients with motor neuron disease found that most of the evidence supporting treatment effectiveness was based on “clinical opinion” rather than on controlled clinical trials.[1382] Another review concluded that there is an overall positive effect of speech and language therapy interventions for children with expressive phonological and expressive vocabulary difficulties, while the evidence for expressive syntax difficulties is more mixed.[1383] A study reviewing children up to 16 years of age with

primary speech and/or language impairment in the absence of any learning, physical, or sensory difficulty found that an average of six hours of speech and language therapy in a six-month period can produce significant improvement in performance, and has been shown to be more effective than no treatment over the same six-month period.[1384]

Many investigators and systematic reviews cited the need for additional research to be conducted to evaluate the effectiveness of treatment based on the causes of specific disorders.[1385, 1386, 1387, 1388, 1389,1390,1391,1392,1393,1394] They also recommended 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.[1395, 1396, 1397, 1398, 1399,1400,1401,1402,1403,1404]

Estimated Marginal Cost of the Mandate

Responses to the carrier survey consistently indicated these services would be covered in the absence of the mandate. In addition, one large carrier indicated this coverage is required by the ACA. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

Substance Abuse Treatment Prior Authorization

Among the provisions of Chapter 258 of the Massachusetts Acts of 2014, one broadly places restrictions on the ability of health insurance carriers to require authorization for substance use disorder (SUD) services. Carriers generally require providers to obtain prior authorization for substance use disorder services or the carrier will deny payment. Chapter 258 eliminates preauthorization across the spectrum of substance use disorder services, Specifically, for substance use disorder, the law requires:

> "Any [health insurance] coverage…shall not require a member to obtain preauthorization for substance abuse treatment if the provider is certified or licensed by the department of public health." The law further defines substance abuse treatment to include "early intervention services for substance use disorder treatment; outpatient services including medically assisted therapies; intensive outpatient and partial hospitalization services; residential or inpatient services, not covered [elsewhere in the law]; and medically managed intensive inpatient services, not covered [elsewhere in the law]."[1405]

Effect of the Mandate on Health

Substance use disorder, its prevalence, and the efficacy of treatment and this mandate's requirements are reviewed under the "Acute Treatment Services (ATS) and Clinical Stabilization Services (CSS)" mandate.

Estimated Marginal Cost of the Mandate

Given capacity constraints in the supply of substance use disorder treatment and the interaction of various requirements of Chapter 258, CHIA's prospective mandated benefit review report of the provision of Chapter 258 prohibiting prior authorization requirements for SUD treatment estimated the effect of this provision at zero.[1406] BerryDunn tested this assumption by analyzing utilization and cost trends for 2015 and 2016 (the relevant sections of Chapter 258 became effective on October 1, 2015). The analysis found a small, 0.4% decrease, in PMPM paid expenses for the affected population, and a larger, 8.1%, utilization decrease, as measured by claims per member, across the full continuum of SUD care. Over the same time period, the sample data show a nearly 10% increase in cost per claim across the continuum. These trends suggest the ATS/CSS provisions of the law, as anticipated, have

increased utilization of high-intensity, high-cost residential services (see Section 1.1), but constrained supply of less-intensive services has neutralized the upward utilization pressures of the prior authorization provision. This study therefore estimates the 2018 marginal, direct cost impact of this mandate as $0 and 0% of Commonwealth fully insured premium.

4.0 Discussion and Conclusions

The marginal cost of those benefits that carriers say they would not provide without the mandate laws, or actuarial analysis suggests is non-zero, is estimated as $103 million. Table 26 displays this impact in percentage of premium, PMPM, and total implied spending in the fully insured market.

In addition to the direct cost impacts, there are indirect cost effects of benefit mandates that BerryDunn is not able to address in this study. Some of these indirect costs might 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. Finally, there are individual and socially beneficial impacts aside from health care spending that these mandates might, 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.[1407]

Table 26

Summary of Estimated Costs for Massachusetts Mandated Benefits as of 2018

Dollars in Millions (000,000s)

Mandate	Marginal Claims Estimate	Marginal Premium Impact	Percent of Premium
Unduplicated Total All Mandates	$ 90.41	$ 103.48	0.72%
Massachusetts State Mandates with Potential Direct Marginal Cost			
Infertility Services	$ 76.38	$ 87.23	0.61%
Chiropractors	$ 4.82	$ 5.64	0.04%
Acute Treatment and Clinical Stabilization Services	$ 3.61	$ 4.16	0.03%
Child Hearing Aids	$ 1.84	$ 2.15	0.02%
Oral Cancer Drugs	$ 1.57	$ 1.80	0.01%
Low Protein Foods	$ 0.60	$ 0.69	0.00%
Chiropractic Services	$ 0.53	$ 0.62	0.00%
Nonprescription Enteral Formulas	$ 0.44	$ 0.50	0.00%
Cleft Palate and Lip	$ 0.44	$ 0.50	0.00%
HIV-Associated Lipodystrophy Treatment	$ 0.18	$ 0.21	0.00%
Mandates Judged to Have Zero or Unmeasurable Marginal Cost			
Abuse-deterrent Opioids	$ -	$ -	0.00%
Autism Services	$ -	$ -	0.00%
Bone Marrow Transplants for Breast Cancer	$ -	$ -	0.00%
Cardiac Rehab	$ -	$ -	0.00%
Certified Nurse Midwives	$ -	$ -	0.00%
Certified Registered Nurse Anesthetists	$ -	$ -	0.00%
Clinical Trials for Cancer	$ -	$ -	0.00%
Contraception	$ -	$ -	0.00%
Cytologic Screening	$ -	$ -	0.00%
Dentists	$ -	$ -	0.00%
Diabetes	$ -	$ -	0.00%
Early Intervention	$ -	$ -	0.00%
Hearing Screening for Newborns	$ -	$ -	0.00%
HLA Testing	$ -	$ -	0.00%
Home Health Care	$ -	$ -	0.00%
Hospice Care	$ -	$ -	0.00%
HRT	$ -	$ -	0.00%
Lead Screening	$ -	$ -	0.00%
Limb Prosthesis	$ -	$ -	0.00%
Long term antibiotic therapy for the treatment of Lyme disease	$ -	$ -	0.00%
Mammography	$ -	$ -	0.00%
Maternity Care	$ -	$ -	0.00%
Mental Health	$ -	$ -	0.00%
Nurse Practitioner	$ -	$ -	0.00%
Off-label Uses of Prescription Drugs - Cancer	$ -	$ -	0.00%
Off-label Uses of Prescription Drugs - HIV/AIDS	$ -	$ -	0.00%
Optometrists	$ -	$ -	0.00%
Physician Assistants	$ -	$ -	0.00%
Podiatrist	$ -	$ -	0.00%
Prescription Eye Drops	$ -	$ -	0.00%
Preventive Care to Age 6	$ -	$ -	0.00%
Scalp Hair Prosthesis	$ -	$ -	0.00%
Speech & Hearing	$ -	$ -	0.00%
Substance Abuse Treatment Prior Authorization.	$ -	$ -	0.00%
Syringe	$ -	$ -	0.00%

Appendix A: Summary of Health Insurance Benefit Mandates

Mandate	Statute	Summary	In 2016 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. 176B § 4EE 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, 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.	Yes
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. Added: 12 month supply, no cost sharing, emergency contraception, voluntary female sterilization patient education and counseling, follow-up services related to covered contraceptive drugs. (effective 7/1/2018)	Yes
Cytologic screening	c. 175 §§ 47G and 110(L); c. 176A § 8J; c. 176G § 4	Mandates coverage for cytologic 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,	Yes

Mandate	Statute	Summary	In 2016 Report
		lancets, insulin, syringes, lab tests, urine & lipid profiles, special shoes, etc.	
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. 32A § 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 regardless of etiology. Coverage under this section shall include all related services prescribed by a licensed audiologist or hearing instrument specialist, including the initial hearing aid evaluation, fitting and adjustments and supplies, including ear molds.	Yes
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
HIV Associated Lipodystrophy Treatment	c. 175 § 47II; c. 176A § 8KK; c. 176B § 4KK; c. 176G § 4CC	Mandates coverage for medical or drug treatments to correct or repair disturbances of body composition caused by HIV associated lipodystrophy syndrome including, but not limited to, reconstructive surgery, such as suction assisted lipectomy, other restorative procedures and dermal injections or fillers for reversal of facial lipoatrophy syndrome:	No
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
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

Mandate	Statute	Summary	In 2016 Report
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
Long term antibiotic therapy for the treatment of Lyme disease	c. 175 § 47HH; c. 176A § 8JJ; c. 176B § 4JJ; c. 176G § 4BB	Mandates coverage for long-term antibiotic therapy for a patient with Lyme disease when determined to be medically necessary and ordered by a licensed physician after making a thorough evaluation of the patient's symptoms, diagnostic test results or response to treatment. An experimental drug shall be covered as a long-term antibiotic therapy if it is approved for an indication by the United States Food and Drug Administration; provided, however, that a drug, including an experimental drug, shall be covered for an off-label use in the treatment of Lyme disease if the drug has been approved by the United States Food and Drug Administration.	No
Low protein food products	c. 175 § 47I; c. 176A § 8L; c. 176B § 4K; c. 176G § 4D	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
Acute Treatment and Clinical Stabilization Services	c. 175 § 47GG; c. 176A § 8II; c. 176B § 4II; c. 176G § 4AA; c. 32A § 17N	Mandated coverage for medically necessary acute treatment services and medically necessary clinical stabilization services for up to a total of 14 days and shall not require preauthorization prior to obtaining acute treatment services or clinical stabilization services; provided that the facility shall provide the carrier both notification of admission and the initial treatment plan within 48 hours of admission; provided further, that the utilization review procedures may be initiated on day 7; provided further, any policy, contract, agreement, plan or certificate of insurance issued, delivered or renewed within the commonwealth, which is considered creditable coverage pursuant to section 1 of chapter 111M, shall cover, without preauthorization, a substance use disorder evaluation ordered pursuant to section 511/2 of chapter 111. Medical necessity shall be determined by the treating clinician in consultation with the patient and noted in the patient's medical record.	No

Mandate	Statute	Summary	In 2016 Report
Substance Abuse Treatment Prior Authorization.	c. 175 § 47FF; c. 176A § 8HH; c. 176B § 4HH; c. 176G § 4Z; c. 32A § 17M	Any policy…shall not require a member to obtain a preauthorization for substance abuse treatment if the provider is certified or licensed by the department of public health.	No
Abuse-deterrent Opioids	c. 175 § 47EE; c. 176A § 8GG; c. 176B § 4GG; c. 176G § 4Y; c. 32A § 17L	Mandates coverage for abuse deterrent opioid products listed on the formulary, compiled pursuant to subsection (b) of section 13 of chapter 17, on a basis not less favorable than non-abuse deterrent opioid drug products that are covered by such policy, contract, agreement, plan or certificate of insurance. An increase in patient cost sharing shall not be allowed to achieve compliance with this section.	No
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, substance abuse disorders, 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 $5,000 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
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
Orally administered anticancer medications	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.	Yes
Prescription Eye Drops	c. 175 § 47HH; c. 176A § 8JJ; c. 176B § 4JJ; c. 176G § 4BB	Mandates coverage for refills of prescription eye drops in accordance with the Medicare Part D guidelines on early refills of topical ophthalmic products when: (i) the prescribing health care practitioner indicates on the original prescription that additional quantities of the prescription eye drops are needed; (ii) the refill requested by the insured does not exceed the number of additional quantities indicated on the original prescription by the prescribing health care practitioner; and (iii) the prescription eye drops prescribed by the	No

Mandate	Statute	Summary	In 2016 Report
		health care practitioner are a covered benefit under the policy or contract of the insured.	
Preventive care for children up 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, hearing and language disorders	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
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
Physician Assistants	c. 176S; c. 176S, c. 176S	We may not have included because PAs need to bill under a supervising physician. Statute sections affecting various forms of insurance, plus c. 176S, require all forms of insurance (and GIC under c. 176R) to cover services of physician assistants (PAs) when services are reimbursed when performed by any other practitioner and are within the lawful scope of practice of PAs. c. 176S allows PAs to serve as PCPs.	Yes

Mandate	Statute	Summary	In 2016 Report
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

Appendix B: Methodology of Cost Estimation

Definition of Population and Costs Measured

This study estimates the calendar year 2018 costs to the Massachusetts health care system of state mandates in force throughout 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 DOI. 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. 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 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 (RDCs).** 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. RDCs are the sum of *base direct costs* and *marginal direct costs.*
    - ***Base direct costs*** 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*** are those additional costs beyond the base direct costs that the imposition of the mandate impels. This study estimates these costs.
- **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 direct costs reasonably, measuring their breakdown into base and marginal direct costs is far more difficult, and measuring indirect costs even more challenging. 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 RDCs because 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.

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 multivariate statistical analysis using multistate 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.[1408]

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 eight carriers provided input on the mandates:

- Blue Cross/Blue Shield of Massachusetts
- Boston Medical Center Health Plan
- Fallon Community Health Plan
- Harvard Pilgrim Health Care
- Health New England
- Allways Health Partners (formerly Neighborhood Health Plan)
- Tufts Health Plan
- 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 and analysis staff. In addition, the

Massachusetts Association of Health Plans (MAHP) provided assistance with coordination and communication with its participating member plans.

Each carrier participating in the current study was asked to review the data specifications used for the 2016 study to update them for any changes in clinical practice, coding, or other relevant factors. Six mandates were added to the mandate list for the present study:

- HIV-associated lipodystrophy treatment
- Long-term antibiotic treatment for Lyme disease
- Prescription eye drops
- Prohibition of prior authorization requirements for substance abuse treatment (Chapter 258 of the Acts of 2014)
- Abuse-deterrent opioids (Chapter 258 of the Acts of 2014)
- ATS and CSS for substance use disorder (Chapter 258 of the Acts of 2014)

BerryDunn (or its predecessor firm, Compass Health Analytics) prepared the prospective actuarial assessment of each of the new mandates, and developed draft 2020 retrospective review specifications for review by the carriers based on the specifications and findings of the prospective studies.

Data sources

The allowed amount and paid claims PMPM estimates developed from claim data for the present study drew upon calendar year 2018 data from CHIA's MA APCD,[1409] Release 8.0.[xxxii] CHIA collects and manages data from commercial carriers, third-party administrators, and public programs.[1410] 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. BerryDunn relied on data from those carriers in the quality-controlled sample that passed additional basic reasonableness checks on membership and expenses. This quality-controlled sample of carriers comprises approximately 90% of 2018 total commercial fully insured and GIC primary medical membership under age 65 in the Commonwealth. The analogous figure for pharmacy membership is 87%.

BerryDunn used the MA APCD claims, eligibility, product, and provider data to extract claims and estimate per member costs for services required by the mandates.

Applicable population

U.S. Census Bureau data on the Massachusetts population and percent covered by employer-sponsored plans and MA APCD eligibility data[1411] lead to an estimate of 3.7 million Massachusetts residents under age 65 covered by employer-sponsored plans in 2018, approximately 1.4 million of whom are fully insured. BerryDunn used MA APCD state of residence data to develop an estimate of approximately 293,600 additional individuals under age 65 residing in other states that are covered by Massachusetts-issued fully insured employer-sponsored insurance subject to the mandates. Finally, the CHIA enrollment trends report through March 2020[1412] yielded an estimate of approximately 306,000 persons under age 65 who purchased insurance in the non-group market in 2018. The sum of the employer-sponsored state residents, nonresidents, and individually insured produces a total estimate of 2 million fully insured

[xxxii] Service year 2018 (paid through June 30, 2019) is the most recent full year available in Release 8.0.

members. Because self-insured GIC plans follow the mandates voluntarily, an additional 320,000 members are added to the covered population (based on membership figures provided directly to BerryDunn by the GIC) for a total of 2.3 million individuals. Appendix C contains more details about these population calculations.

For calculating the percentage of premium, the analysis uses as a member-months denominator the sum of member-months for all license types. The percent of premium estimates presented, therefore, represent the costs of the benefits spread over the entire fully insured and self-insured GIC population covered by health insurance plans regulated by the Commonwealth of Massachusetts. 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 subgroups indicated in Table B-3, as these are the only claims related to benefits required by those mandates. Estimates of the insured population by carrier license type and market segment were derived from CHIA's December 2019 report on the performance of the health care market in Massachusetts in 2018.[1413] Except as noted in the individual mandate results sections above, 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 subgroup(s) to which the mandate applies.

Sample population

To develop the dollar estimates in the study, PMPM claim expense estimates were developed from the MA APCD. Paid claim expenses PMPM from representative samples were developed, and then multiplied by the applicable populations discussed in the preceding section. The PMPM claim expense estimates developed from claim data drew upon CHIA's MA APCD Release 8.0. BerryDunn joined claims for the quality-controlled medical carriers to de-duplicated eligibility data to review average PMPM allowed amount expenses by carrier. Seven large carriers with a reasonable resulting "matched" 2018 average PMPM allowed expenditure comprised the analytical sample. Combined fully insured, self-insured, and GIC matched 2018 average PMPM allowed expenditures by payer in the medical sample ranged from $235 for one individual-market carrier to $426 for a carrier with a large presence in the GIC market.

The average monthly fully insured and self-insured GIC medical membership subject to the mandates represented in the seven carrier sample passing this additional quality-control step for 2018 is 1.7 million, or 74% of the estimated 2.3 million total average monthly membership for the fully insured, self-insured GIC, non-Medigap population under age 65 in Massachusetts.

The average monthly fully insured and self-insured GIC medical membership subject to the mandates represented in the seven carrier sample passing this additional quality-control step for 2018 is 1.6 million, or 70% of the estimated 2.3 million total average monthly membership for the fully insured, self-insured GIC, non-Medigap population under age 65 in Massachusetts. Combined fully insured, self-insured, and GIC-matched 2018 average PMPM allowed expenditures by payer in the pharmacy sample ranged from $75.81 to $120.48. 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 for the mandates that do not cover all license types or market segments in the analysis.

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 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 may not be included in the MA APCD sample. As a result, the sample pharmacy membership and its 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 medical and pharmaceutical PMPMs were then added together, and were multiplied by the population membership to calculate the estimated total dollar impact. This prevented a downward bias to the PMPM estimates that would otherwise have been caused by missing pharmacy claims.[xxxiii]

Cost estimation methodology

The mandates, except for those deemed *a priori* to have zero marginal, direct cost based on carrier input or overlap with federal statute, were analyzed using detailed clinical data specifications applied to detailed claim data. CHIA provided an extract from the Massachusetts MA APCD Release 8.0 as the data source for these estimates. BerryDunn studied calendar year 2018 paid through June 30, 2019 claims and membership from the extract for this review. 2018 was the most recent full year of data available in this extract.

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 update specifications of previous comprehensive mandate review study, and develop new specifications for more recently enacted mandates
- Assess quality control of specifications and follow-up by BerryDunn
- Extract and quality check data using programming language to implement the specifications
- Summarize and adjust 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 2016 study, and BerryDunn-drafted initial specifications for the mandates new to the present study, to provide feedback on any changes in clinical practice, coding, or other relevant factors.
- *Review and refinement of the specifications.* BerryDunn reviewed the feedback for each specification and translated each of the specifications into programming code to extract and summarize the data. In general,

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

carrier-recommended additions of services, products, or diagnoses were incorporated into the specifications.

- *Quality checking the data.* The data extracted for each mandate included in the 2020 study were summarized and compared to the 2016 results. Results for newly enacted mandates were compared to CHIA's prospective mandated benefit review studies. Where mandate results diverged significantly from the previous study or other benchmarks, BerryDunn reviewed the specifications and programming code for errors and corrected results as necessary. Where these results continued to diverge from expected results, BerryDunn drilled into the results (by carrier, code, etc.) and performed further research to validate or further refine the results.

After completing the quality control process, 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. BerryDunn estimated administrative loading for the populations to which the mandates apply based on CHIA's December 2019 report on the performance of the Massachusetts health care system[1414] and data provided to BerryDunn by the GIC. These administrative loading factors are shown in Table B1 below. To arrive at estimates of fully loaded healthcare premium costs, claims costs were divided by one minus the applicable administrative load. For example, this study estimates the 2018 fully insured administrative loading across all market segments. Premium impacts applicable to this population are therefore calculated as paid claim expenses divided by (1 – 0.145), or 0.855.

Table B1

2018 Administrative Loading Factor Estimates

Funding Type/Market Segment	2018 Admin Factor
All Fully Insured (FI)	14.5%
Large Group FI	14.5%
All FI + self-insured (SI) GIC	13.1%
Large Group FI + SI GIC	12.4%

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 1.

These estimated premium amounts were calculated as an approximate percentage of healthcare premiums in Massachusetts by dividing them by the estimated average commercial fully insured and self-insured GIC 2018 premium of $512 from CHIA's October 2019 report multiplied by the number of persons in these markets.[1415]

Appendix C: Estimation of Population Subsets

Membership potentially affected by proposed mandated change criteria includes Commonwealth residents with fully insured, employer-sponsored health insurance issued by a Commonwealth-licensed company (including through the GIC); nonresidents with fully insured, employer-sponsored insurance issued in the Commonwealth; Commonwealth residents with individual (direct) health insurance coverage; and lives covered by GIC self-insured coverage.

Please note these are unprecedented economic circumstances due to the COVID-19 outbreak, which makes estimating membership extremely challenging. Membership projections are used to determine the total dollar impact of the proposed mandate in question; however, variations in the membership forecast will not affect the general magnitude of the dollar estimates. As such, given the uncertainty, BerryDunn took a simplified approach to the membership projections as described below. These membership projections are not intended to be used for any other purpose than producing the total dollar range in this study. Further, to assess how recent volatility in commercial enrollment levels might affect these cost estimates, please note that the PMPM and percentage of premium estimates are unaffected because they are per-person estimates, and the total dollar estimates will vary by the same percentage as any percentage change in enrollment levels.

The 2018 Massachusetts APCD formed the base for the projections. The Massachusetts APCD provided fully insured membership by insurance carrier. The Massachusetts APCD was also used to estimate the number of nonresidents covered by a Commonwealth policy. These are typically cases in which a nonresident works for a Commonwealth employer that offers employer-sponsored coverage. Adjustments were made to the data for membership not in the Massachusetts APCD, based on published membership reports available from CHIA and the DOI.

CHIA publishes monthly enrollment summaries in addition to its biannual enrollment trends report and supporting databook (enrollment-trends-March-2020-databook[1416] and Monthly Enrollment Summary – August 2020[1417]), which provides enrollment data for Commonwealth residents by insurance carrier for most carriers (some small carriers are excluded). CHIA uses supplemental information beyond the data in the Massachusetts APCD to develop its enrollment trends report. The supplemental data was used to adjust the resident totals from the Massachusetts APCD. The impact of the COVID-19 outbreak on fully insured employers over the five-year projected period is uncertain. BerryDunn conservatively assumed that membership would revert to 2019 levels by January 1, 2022, thereby increasing our cost estimates. Given this approach, the 2021 assumption is dependent upon emerging 2020 fully insured membership levels.

The DOI published reports titled Quarterly Report of HMO Membership in Closed Network Health Plans as of December 31, 2018,[1418] and Massachusetts DOI Annual Report Membership in MEDICAL Insured Preferred Provider Plans by County as of December 31, 2018.[1419] These reports provide fully insured covered membership numbers for licensed Commonwealth insurers where the member's primary residence is in the Commonwealth. The DOI reporting includes all insurance carriers and was used to supplement the Massachusetts APCD membership for small carriers not in the Massachusetts APCD.

The distribution of members by age and gender was estimated using Massachusetts APCD population distribution

ratios and was checked for reasonableness and validated against U.S. Census Bureau data.[1420] Membership was projected from 2020 – 2025 using Massachusetts Department of Transportation population growth rate estimates by age and gender.[1421]

Projections for the GIC self-insured lives were developed using the GIC base data for 2018 and 2019, received directly from the GIC, as well as the same projected growth rates from the Census Bureau that were used for the Commonwealth population. Breakdowns of the GIC self-insured lives by gender and age were based on the Census Bureau distributions.

Appendix D: List of Study Acronyms

AAO	American Academy of Ophthalmology
AAP	American Academy of Pediatrics
ABA	Applied Behavioral Analysis
ACA	Affordable Care Act
ACCF	American College of Cardiology Foundation
ACIP	Advisory Committee on Immunization Practices
ACOG	American College of Obstetricians and Gynecologists
ACS	American Cancer Society
ADDM	Autism and Developmental Disabilities Monitoring
ADO	Abuse-Deterrent Opioid
AGS	American Glaucoma Society
AHA	American Heart Association
AHFS-DI	American Hospital Formulary Service-Drug Information
AHRQ	Agency for Healthcare Research and Quality
AIDS	Acquired Immunodeficiency Syndrome
AMA	American Medical Association
AMI	Any Mental Illness
APA	American Psychiatric Association
APRN	Advanced Practice Registered Nurse
ART	Assisted Reproduction Technology
ARV	Antiretroviral
ASAM	American Society of Addiction Medicine
ASDs	Autism Spectrum Disorders
ATS	Acute Treatment Services
BCBSMA	Blue Cross/Blue Shield of Massachusetts
BLL	Blood Lead Level
BMT	Bone Marrow Transplant
BSN	Bachelor of Science in Nursing
CAM	Complementary and Alternative Medicine

CBTs	Cord Blood Transplants
CDC	Centers for Disease Control and Prevention
CHIA	Center for Health Information and Analysis
CHT	Combined Hormone Therapy
CIA	Chemotherapy-Induced Alopecia
CLD	Chronic Lyme Disease
CMS	Centers for Medicare and Medicaid Services
CNM	Certified Nurse-Midwife
COH	Controlled Ovarian Hyperstimulation
COPD	Chronic Obstructive Pulmonary Disease
CR	Collaborative Reanalysis
CR	Cardiac Rehabilitation
CRNA	Certified Registered Nurse Anesthetist
CSS	Clinical Stabilization Services
CVD	Cardiovascular Disease
DBT	Digital Breast Tomosynthesis
DIR	Developmental, Individual Differences, Relationship-Based Approach
DMEPOS	Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
DOI	Massachusetts Division of Insurance
DPA	Diagnostic Pharmaceutical Agents
DPM	Doctor of Podiatric Medicine
DSM	Diagnostic and Statistical Manual of Mental Disorders
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, 5th edition
DSM-V	Diagnostic and Statistical Manual of Mental Disorders, 5th edition
DTT	Discrete Trial Training
DVT	Deep Vein Thrombosis
EHDI	Early Hearing Detection and Intervention
EIBI	Early Intensive Behavioral Intervention
ED	Emergency Department
EHB	Essential Health Benefit
EM	Erythema Migrans

EN	Enteral Nutrition
EOHHS	Massachusetts Executive Office of Health and Human Services
ERISA	Employee Retirement Income Security Act
ESDM	Early Start Denver Model
FDA	United States Food & Drug Administration
FDAAA	FDA Amendments Act
FDAMA	Food and Drug Administration Modernization Act
FEHB	Federal Employees Health Benefit Plan
FI	Fully Insured
GAO	United States General Accounting Office
GI	Gastrointestinal
GIC	Group Insurance Commission
HDC-ABMT	High-dose Chemotherapy plus Autologous Bone Marrow Transplant
HEN	Home Enteral Nutrition
HIV	Human Immunodeficiency Virus
HHA	Home Health Agency
HHC	Home Health Care
HLA	Human Leukocyte Antigen
HMO	Health Maintenance Organization
HPV	Human Papillomavirus
HRSA	Health Resources and Services Administration
HRT	Hormone Replacement Therapy
HSCTs	Hematopoietic Stem Cell Transplants
HT	Hormone Therapy
IDSA	Infectious Diseases Society of America
ILADS	International Lyme and Associated Diseases Society
IPV	Intimate Partner Violence
IUD	Intrauterine Device
IVF	In Vitro Fertilization
JCIH	Joint Commission on Infant Hearing
LARC	Long-Acting Reversible Contraception

LDHIV	HIV-Associated Lipodystrophy
LPF	Low Protein Food
MA APCD	Massachusetts All Payer Claims Database
MCHB	Maternal Child Health Bureau
MD	Medical Doctor
MDD	Major Depressive Disorder
MDPH	Massachusetts Department of Public Health
M.G.L.	Massachusetts General Law
MHPAEA	Mental Health Parity and Addiction Equity Act of 2008
MWS	Million Women Study
NBEO	National Board of Examiners in Optometry
NCCIH	National Center for Complementary and Integrative Health
NCSBN	National Council of State Boards of Nursing
NDC	National Drug Code
NIDA	National Institute of Drug Abuse
NIH	National Institutes of Health
NMDP	National Marrow Donor Program
NP	Nurse Practitioner
NPI	National Provider Identifier
NPPES	National Plan and Provider Enumeration System
NRTI	Nucleoside Reverse Inhibitors
NSDUH	National Survey on Drug Use and Health
N-SSATS	National Survey of Substance Abuse Treatment Services
ORP	Ordering, Referring and Prescribing
PA	Physician Assistants
PAM	Pain Assessment and Management
Phe	Phenylalanine
PI	Protease Inhibitors
PKU	Phenylketonuria
PMPM	Per-Member Per-Month
PRT	Pivotal Response Training

PLDS	Post-Lyme Disease Syndrome
PTLDS	Post-Treatment Lyme Disease Syndrome
PTSD	Post Traumatic Stress Disorder
RDC	Required Direct Cost
RN	Registered Nurse
SAMHSA	Substance Abuse and Mental Health Services Administration
SI	Self-insured
SMI	Serious Mental Illness
SNF	Skilled Nursing Facility
SNRIs	Serotonin/Norepinephrine Reuptake Inhibitors
SSRIs	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
USPSTF	U.S. Preventive Services Task Force
VBI	Verbal Behavior Intervention
WHI	Women's Health Initiative
WHI Study	WHI Clinical Trial and Observation Study
5-FU	5-fluorouraci

Endnotes

Endnotes

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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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Revision EH-8.1: **https://www.healthypeople.gov/node/4356/data_details#revision_history_header**.

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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.

2) Reduce the mean blood lead levels in children: Baseline 1.8 mcg/dL was the average blood lead level in children aged 1 to 5 years in 2003–04. Target 1.6 mcg/dL average blood lead level in children aged 1 to 5 years.

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