
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

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Comprehensive Mandated Benefit Review (October 2025)

Highlight Summary

Every four years, the Center for Health Information and Analysis (CHIA), is required to review the impacts of currently mandated benefits to health insurance premiums and public health, pursuant to Massachusetts General Law (M.G.L.) Chapter 3, §38. This comprehensive review of health benefit mandates focuses primarily on the financial impact of mandated benefits and summarizes their medical efficacy based on available applicable literature.

Key Findings

- This report includes a review of 59 mandates. Since the 2021 report, 18 new mandates have been enacted, 16 of which are included in this report.ⁱ
- The total marginal cost of the mandates, representing the additional expenditures directly attributable to the mandates, is estimated at \$159 million with a total estimated impact on premiums of 0.93%.
- The required direct costs (RDCs) are the sum of the costs of providing mandated benefits. RDCs include both the base costs (costs that would be incurred even in the absence of the mandate due to voluntary coverage or other state and federal requirements) and marginal costs (additional expenditures directly attributable to the mandate itself). The RDC of the mandates is estimated at \$4.147 billion with a total estimated impact on premiums of 24.16%.

ⁱ An Act Promoting Access to Midwifery Care and Out-of-Hospital Birth Options was excluded, as the provisions of Chapter 186 of the Acts of 2024 apply only to the MassHealth population and Chapter 260 of the Acts of 2020 § 70 COVID-19 Tests, Vaccines, and Treatment was excluded due to the evolving landscape of COVID-related medical services. The mandate Long-Term Antibiotic Therapy for the Treatment of Lyme Disease has been repealed since the prior report and thus is excluded from this report.

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

Executive Summary

Statutory Basis and Scope

The Center for Health Information and Analysis (CHIA) is required to produce a report every 4 years analyzing the health insurance cost and public health impact of currently mandated benefits, per Massachusetts General Law (M.G.L.) Chapter 3 Section 38. CHIA engaged BerryDunn to prepare this analysis.ⁱⁱ

A health benefit mandate requires certain insurers to provide “health insurance coverage for specific health services, specific diseases or certain providers of health care services.”¹ This report addresses mandated benefits in effect through 2025.ⁱⁱⁱ

Most Massachusetts mandates require carriers to cover specific services or to provide benefits to members with specific conditions. A subset of mandates requires carriers to cover services delivered by specific provider types, to pay the specified provider type when the practitioner provides a covered service and is licensed to do so, or to reimburse providers at a certain rate. This review only includes medical insurance policies and does not address non-medical services.

Massachusetts statutes place various other requirements on health insurance carriers^{iv}; however, review of these other types of requirements is outside of the scope of the statute charging CHIA with producing this report.

ⁱⁱ This is the fifth comprehensive review of health benefit mandates and the fourth under 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.

ⁱⁱⁱ Appendix A lists all mandates included in this report, encompassing those from prior reviews as well as new mandates enacted after the analysis period (i.e., the timeframe for which data were available) for the 2025 report. Actuarial analysis of An Act Relative to Pharmaceutical Access, Costs, and Transparency was excluded because at the time of this analysis carriers had not yet finalized their preferred drug lists. Actuarial analysis of An Act Promoting Access to Midwifery Care and Out-of-Hospital Birth Options was also excluded, as the provisions of Chapter 186 of the Acts of 2024 apply only to the MassHealth population. Actuarial analysis of PANDAS (Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections)/Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) was excluded because it was immeasurable due to several limitations explained in Section 4.0. Chapter 260 of the Acts of 2020 § 70 COVID-19 Tests, Vaccines, and Treatment was also excluded from analysis due to the evolving landscape of COVID-related medical services.

^{iv} Examples of other requirements for carriers include, but are not limited to, confidentiality, coverage practices (continuity of coverage, dependent coverage, coordination of benefits, etc.), and limitations on carriers' ability to deny coverage in general to individuals with specified conditions (people who are blind, victims of domestic abuse, etc.).

Approach to Reviewing Mandate Efficacy

This report aims to objectively review the available evidence^v to assess the efficacy of each mandated benefit.^{vi} For provider-centered mandates, this report describes whether the services from these providers are widely covered and/or whether standard-setting entities, such as Medicare, pay for them. A complete assessment of the clinical effectiveness of an entire profession is beyond the scope of this review. Some mandates have a potentially significant public health impact.^{vii} This report attempts to describe the potential impact but does not attempt to quantify it.^{viii}

The COVID-19 pandemic impacted health care utilization trends with varying effects depending on the service. These impacts are reflected in the mandate's effect on health and noted in the estimated mandate costs, as applicable. Actuarial analysis of Chapter 260 of the Acts of 2020 § 70 COVID Tests, Vaccines and Treatment was excluded from this report due to the fluid and evolving nature of COVID-related medical services.

The language in this report endeavors to be respectful of individual identity expression and the diverse gender spectrum. Recognition is given to individuals who may identify differently from the sex they were assigned at birth.²

During report preparation, several federally supported data sources were discontinued or became unavailable. Alternative sources were identified where feasible to support ongoing analysis.

Approach to Analyzing Mandate Costs

This section summarizes the methodology for measuring the costs associated with mandated health benefits for certain Massachusetts premium payers.

Applicable Population

This study estimates the effect of state mandates on health care costs for individuals covered under Massachusetts-issued health insurance plans that are subject to Massachusetts health benefit mandate laws; those plans fall into two main groups:

1. All mandates in the study apply to fully insured commercial plans^{ix} regulated by the Division of Insurance (DOI).
2. A subset of the mandates in this study explicitly require coverage for public employees provided under the Massachusetts Group Insurance Commission (GIC), as specified in the statute.

^v Examples of evidence include, but are not limited to, available literature, professional guidelines, federal and state law, and state comparisons (as applicable).

^{vi} If the efficacy of a mandated service is controversial, this report describes but does not attempt to resolve the controversy.

^{vii} "Public health impact" means an effect on the health of individuals other than those covered by the mandated benefit.

^{viii} This approach is consistent with the treatment of indirect costs in this report's analysis of mandated benefit costs and, furthermore, it is consistent with the treatment of indirect costs in previous comprehensive reviews of mandated benefits.

^{ix} Fully insured plans are health plans that employers can purchase from insurance companies whereby the insurance company assumes financial risk for medical claims for the organization's employees.

While the majority of GIC coverage is provided on a self-insured^x basis and self-insured plans are not legally required to follow state benefit mandates, the GIC has historically aligned its coverage offerings with all mandates. Accordingly, this report assumes the GIC covers all Massachusetts mandates.

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

- Self-insured policies (except the GIC population, as previously noted); these policies are governed by federal Employee Retirement Income Security Act of 1974 (ERISA) statutes and are 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; Transformed Resources, Integrated Care, Affordable Reimbursement for Employees (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 does not address potential effects of the mandated benefits 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.

Overall Population Subject to the Mandates

The sum of the employer-sponsored state residents, nonresidents, and individually insured produces a total estimate of 1.8 million fully insured members in Massachusetts. Because self-insured GIC plans follow the mandates voluntarily, an additional 315,000 members were added to the covered population (based on membership figures provided directly to BerryDunn by the GIC) for a total of 2.2 million individuals included in this review.

This study includes 59 mandates. Since the 2021 Comprehensive Report, updated January 2022, mandated coverage of long-term antibiotic therapy for Lyme disease was repealed by Chapter 29, Section 21 of the Acts of 2021, and accordingly this mandate is not in this report.³ Sixteen new mandates were added to the mandate list for the 2025 study:^{xi}

- Applied Behavior Analysis (ABA) for Down Syndrome
- Abortion
- Annual Mental Health Wellness Examinations

^x Self-insured plans are health plans that employers can offer where the organization assumes some or all risk for medical claims for its employees.

^{xi} 16 mandates total are included in the bulleted list (fifteen plus one as referenced in the text).

- Collaborative Care
- Contraceptive Services
- Emergency Services Programs (ESPs)
- Fertility Preservation Services
- Human Donor Milk (DHM)^{xii}
- Medically Necessary Breast Screenings and Exams for Equity and Early Detection
- Mental Health Acute Treatment, Community-Based Acute Treatment, and Intensive Community-Based Acute Treatment
- Pharmaceutical Access, Costs, and Transparency: excluded from the cost impact analysis because at the time of this analysis carriers had not yet finalized their preferred drug lists
- Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections/Pediatric Acute-onset Neuropsychiatric Syndrome (PANDAS/PANS): excluded from the cost impact analysis because it was immeasurable due to several limitations explained in Section 4.0
- Postpartum Depression (PPD) Screenings
- Telehealth
- Tobacco Cessation
- Universal Postpartum Home Visiting Services

This study estimates that health benefits mandated by the Commonwealth had a marginal cost impact of \$142.73 million on 2023 paid claims. Adjusting this amount for carrier administrative costs (including profits) results in an estimated \$158.99 million marginal impact on Commonwealth fully insured (and self-insured GIC) health insurance premiums, or 0.93% of total Commonwealth fully insured health insurance premiums. **Table 1** summarizes the estimated costs of Massachusetts mandated benefits, shown in 2023 dollars (millions).

^{xii} While this report refers to this mandate as “human donor milk”, reviewed studies often describe this service as “donor human milk”, which is the source of the DHM acronym. This report uses the DHM acronym to reference this mandate, as this is the more widely used acronym for this service.

Table 1. Summary of Estimated Costs for Massachusetts Mandated Benefits as of 2023 Dollars in Millions
(000,000s)^{xiii}

MANDATE	MARGINAL CLAIMS ESTIMATE	MARGINAL PREMIUM IMPACT	PERCENT OF PREMIUM
Unduplicated Total All Mandates	\$ 142.73	\$ 158.99	0.93%
Massachusetts State Mandates With Potential Direct Marginal Cost			
Infertility Services	\$ 113.04	\$ 125.43	0.73%
Acute Treatment and Clinical Stabilization Services	\$ 9.98	\$ 11.31	0.07%
Medically Necessary Breast Cancer Screenings and Exams	\$ 5.02	\$ 5.67	0.03%
Annual Mental Health Wellness Examinations	\$ 4.47	\$ 5.05	0.03%
Oral Cancer Therapy	\$ 1.85	\$ 2.10	0.01%
Hearing Aids for Children	\$ 1.85	\$ 2.10	0.01%
Abortion	\$ 1.04	\$ 1.17	0.01%
Telehealth	\$ 0.99	\$ 1.11	0.01%
Contraceptive Services	\$ 0.88	\$ 1.00	0.01%
Low Protein Food Products	\$ 0.78	\$ 0.87	0.01%
Emergency Services Programs	\$ 0.73	\$ 0.82	0.00%
Nonprescription Enteral Formulas	\$ 0.61	\$ 0.68	0.00%
Fertility Preservation Services	\$ 0.52	\$ 0.59	0.00%
Universal Postpartum Home Visiting Services	\$ 0.48	\$ 0.54	0.00%
Cleft Palate and Cleft Lip	\$ 0.32	\$ 0.36	0.00%
ABA Services for Down Syndrome	\$ 0.16	\$ 0.18	0.00%
Mandates Judged to Have Zero or Unmeasurable Marginal Cost			

xiii

Table 1 excludes 1) Midwifery Care and Out-of-Hospital Birth Options as it applies only to MassHealth, not commercial plans; 2) PANDAS/PANS lacks specific diagnosis and procedure codes, making attribution of services and costs infeasible with existing claims data; 3) Pharmaceutical Access, Costs, and Transparency because at the time of this analysis carriers had not yet finalized their preferred drug lists as required under the mandate; 4) COVID Tests, Vaccines and Treatment because of the evolving landscape of COVID-related medical services.

MANDATE	MARGINAL CLAIMS ESTIMATE	MARGINAL PREMIUM IMPACT	PERCENT OF PREMIUM
Abuse-Deterrent Opioids	\$ -	\$ -	0.00%
Autism Spectrum Disorders	\$ -	\$ -	0.00%
Behavioral Health Care	\$ -	\$ -	0.00%
Bone Marrow Transplants for Treatment of Breast Cancer	\$ -	\$ -	0.00%
Cardiac Rehabilitation	\$ -	\$ -	0.00%
Certified Nurse Midwives	\$ -	\$ -	0.00%
Certified Registered Nurse Anesthetists	\$ -	\$ -	0.00%
Chiropractic Services	\$ -	\$ -	0.00%
Chiropractors	\$ -	\$ -	0.00%
Clinical Trials (to Treat Cancer)	\$ -	\$ -	0.00%
Collaborative Care	\$ -	\$ -	0.00%
Cytologic Screening	\$ -	\$ -	0.00%
Dentists	\$ -	\$ -	0.00%
Diabetes-Related Services and Supplies	\$ -	\$ -	0.00%
Early Intervention Services	\$ -	\$ -	0.00%
Hearing Screening for Newborns	\$ -	\$ -	0.00%
HIV-Associated Lipodystrophy Treatment	\$ -	\$ -	0.00%
Home Health Care	\$ -	\$ -	0.00%
Hormone Replacement Therapy (HRT)	\$ -	\$ -	0.00%
Hospice Care	\$ -	\$ -	0.00%
Human Donor Milk (DHM)	\$ -	\$ -	0.00%
Human Leukocyte Antigen (HLA) Testing	\$ -	\$ -	0.00%
Hypodermic Syringes or Needles	\$ -	\$ -	0.00%
Lead Poisoning Screening	\$ -	\$ -	0.00%
Mammography	\$ -	\$ -	0.00%
Maternity Health Care (Including Minimum Maternity Stay)	\$ -	\$ -	0.00%
Mental Health Acute Treatment, CBAT, ICBAT	\$ -	\$ -	0.00%

MANDATE	MARGINAL CLAIMS ESTIMATE	MARGINAL PREMIUM IMPACT	PERCENT OF PREMIUM
Nurse Practitioners	\$ -	\$ -	0.00%
Off-Label Uses of Prescription Drugs to Treat Cancer	\$ -	\$ -	0.00%
Off-Label Uses of Prescription Drugs to Treat HIV/AIDS	\$ -	\$ -	0.00%
Optometrists	\$ -	\$ -	0.00%
Physician Assistants	\$ -	\$ -	0.00%
Podiatrists	\$ -	\$ -	0.00%
Postpartum Depression Screening	\$ -	\$ -	0.00%
Prescription Eye Drops	\$ -	\$ -	0.00%
Preventive Care for Children Up to Age 6	\$ -	\$ -	0.00%
Prosthetic Devices	\$ -	\$ -	0.00%
Scalp Hair Protheses for Cancer Patients	\$ -	\$ -	0.00%
Speech, Hearing, and Language Disorders	\$ -	\$ -	0.00%
Substance Abuse Treatment Prior Authorization	\$ -	\$ -	0.00%
Tobacco Cessation	\$ -	\$ -	0.00%

Table 2 depicts the mandated benefits along with their respective affected insurance carrier license types and populations. Most mandates apply to plans under all types of insurance carrier licenses (indemnity, hospital/medical service corporation, health maintenance organization [HMO]); some, however, apply only to subsets of insurance licenses. Other mandates apply only to the large group market because they were enacted prior to December 31, 2011 and incorporated into Massachusetts's first Affordable Care Act (ACA) EHB benchmark plan.^{xiv,4} The statute membership, as shown in Table 2, refers to the cohort of members who are legally subject to the mandate and not superseded by ACA.^{xv} Also shown is the applicable population including the Massachusetts GIC which voluntarily follows all state mandated benefits. BerryDunn used CHIA's 2025 Annual Report on the Performance of the

^{xiv} Massachusetts selected the HMO Blue New England \$2000 Deductible Plan, supplemented with the Commonwealth Children's Health Insurance Program (CHIP) plan for pediatric dental and the Federal Employees Dental and Vision Insurance Program (FEDVIP) plan for pediatric vision, as its EHB Benchmark Plan for 2017 and subsequent years, pursuant to Section 1302 of the ACA and 45 CFR 156.100.

^{xv} For example, if a mandate applies to the entire fully insured market but is embedded in the EHB benchmark plan, only large group fully insured members would be included in statute membership, since small group and individual market members already receive the benefit through EHB.

Massachusetts Health Care System to estimate the statute membership and the applicable population by carrier license type and market segment.⁵

Table 2. 2023 Estimates of Populations to Which Mandates Apply^{xvi}

MANDATE	STATUTE MEMBERSHIP	Enacted prior to December 31, 2011? ^{xvii} (i.e., large group only)	ESTIMATED STATUTE MEMBERSHIP	ESTIMATED APPLICABLE POPULATION (incl. SI GIC)
Abuse-Deterrent Opioids	Fully insured, and all fully and self-insured GIC members	No	2,150,129	2,150,129
ABA Services for Down Syndrome		No		
Acute Treatment and Clinical Stabilization Services		No		
Annual Mental Health Wellness Examinations		No		
Collaborative Care		No		
Contraceptive Services (Access) [Chapter 120 of the Acts of 2017]		No		
Emergency Services Programs		No		
Fertility Preservation Services		No		
HIV-Associated Lipodystrophy Treatment		No		
Human Donor Milk		No		
Medically Necessary Breast Screenings and Exams for Equity and Early Detection		No		
Mental Health Acute Treatment, Community-Based Acute Treatment, and Intensive Community-Based Acute Treatment		No		
Oral Cancer Therapy		No		
Physician Assistants		No		
Postpartum Depression Screenings		No		
Prescription Eye Drops		No		
Substance Abuse Treatment Prior Authorization		No		

^{xvi} Table 2 excludes 1) Midwifery Care and Out-of-Hospital Birth Options, 2) PANDAS/PANS, 3) Pharmaceutical Access, Costs, and Transparency, and 4) COVID Tests, Vaccines and Treatment.

^{xvii} This report uses December 31, 2011 as the reference point for cost analysis, recognizing that mandates enacted before that date were embedded in the EHB benchmark plan for small group and individual markets, and their costs were considered part of baseline coverage.

MANDATE	STATUTE MEMBERSHIP	Enacted prior to December 31, 2011? ^{xvii} (i.e., large group only)	ESTIMATED STATUTE MEMBERSHIP	ESTIMATED APPLICABLE POPULATION (incl. SI GIC)
Telehealth [Chapter 260 of the Acts of 2020]		No		
Tobacco Cessation		No		
Universal Postpartum Home Visiting Services		No		
Autism Spectrum Disorders	Large group fully insured and, all fully and self-insured GIC members	Yes	1,530,411	1,530,411
Behavioral Health Care		Yes		
Bone Marrow Transplants for Treatment of Breast Cancer		Yes		
Cleft Palate and Cleft Lip		Yes		
Diabetes-Related Services and Supplies		Yes		
Hearing Aids for Children		Yes		
Hearing Screening for Newborns		Yes		
Hospice Care		Yes		
Human Leukocyte Antigen Testing		Yes		
Low Protein Food Products		Yes		
Maternity Health Care (Including Minimum Maternity Stay)		Yes		
Nonprescription Enteral Formulas		Yes		
Prosthetic Devices		Yes		
Scalp Hair Protheses for Cancer Patients		Yes		
Speech, Hearing, and Language Disorders		Yes		
Cardiac Rehabilitation	Large group fully insured members	Yes	1,215,317	1,530,411
Certified Registered Nurse Anesthetists		Yes		
Clinical Trials (to Treat Cancer)		Yes		
Cytologic Screening		Yes		
Early Intervention Services		Yes		
Home Health Care		Yes		
Hormone Replacement Therapy		Yes		

MANDATE	STATUTE MEMBERSHIP	Enacted prior to December 31, 2011? ^{xvii} (i.e., large group only)	ESTIMATED STATUTE MEMBERSHIP	ESTIMATED APPLICABLE POPULATION (incl. SI GIC)
Hypodermic Syringes or Needles		Yes		
Lead Poisoning Screening		Yes		
Mammography		Yes		
Nurse Practitioners		Yes		
Off-Label Uses of Prescription Drugs to Treat Cancer		Yes		
Off-Label Uses of Prescription Drugs to Treat HIV/AIDS		Yes		
Podiatrists		Yes		
Preventive Care for Children Up to Age Six		Yes		
Infertility Treatment	Massachusetts -resident large group fully insured members	Yes	928,345	1,243,438
Abortion	Massachusetts -resident fully insured and GIC members	No	1,786,680	1,786,680
Chiropractic Services	Non-HMO Blue Cross/Blue Shield fully insured members	No	117,963	433,057
Certified Nurse Midwives	Non-HMO fully insured members	No	465,885	780,978
Chiropractors		No		
Dentists		No		
Optometrists		No		

Data Sources

CHIA collects and manages data from commercial carriers, third-party administrators, and public programs, working with each carrier to conduct a quality control process on the Massachusetts All-Payer Claims Database (APCD)

data.⁶ The Massachusetts APCD is the most extensive source of health claims data in the Commonwealth,^{xviii} capturing medical and pharmacy claims from most major public and private payers for residents under age 65. BerryDunn primarily used claims from 2023 paid through June 2024.

The 2023 Massachusetts APCD and CHIA's enrollment data formed the foundation for this study's insured member population projections. CHIA publishes biannual enrollment trend reports and a supporting databook⁷ that provides resident enrollment by carrier, supplemented with additional sources beyond the APCD. BerryDunn used the Massachusetts APCD along with CHIA's published enrollment report and Division of Insurance (DOI)^{8,9} membership data to adjust for smaller carriers not fully represented in the CHIA reports.

In addition to data from CHIA, several Massachusetts insurance carriers^{xix} were surveyed about the potential cost of the mandates in this study. Carriers were asked to review and update prior study specifications, confirm cost and coverage findings, provide policy documents, and respond to mandate-specific questions. Carriers were also asked whether they would cover required services in the absence of the mandate. The Massachusetts Association of Health Plans (MAHP) aided with coordination and communication with its participating members.

Sample Population

To estimate the cost of each mandate, a sample per member per month (PMPM)^{xx} cost estimate was developed from available data sources and multiplied by the statute membership defined in the preceding section.

Average Fully Insured and Self-Insured Membership Subject to the Mandates

BerryDunn relied on this data sample^{xxi} and then joined claims to de-duplicated eligibility data to review match rates and average paid and allowed claims PMPM by carrier. The average fully insured and self-insured GIC medical membership subject to the mandates represented in the sample for 2023 was 1.6 million or 73% of the estimated 2.2 million total average membership for the fully insured and self-insured GIC population in Massachusetts. Cost estimates in this report assume the PMPM costs obtained from the Massachusetts APCD sample data are representative of the overall fully insured under-65 population.

^{xviii} The U.S. Supreme Court in *Gobeille v. Liberty Mutual* ruled that self-insured plans are not required to submit their data claims to state APCDs because the plans are governed by federal law (ERISA). The Massachusetts APCD includes some voluntary data from self-insured plans but is mostly composed of data from fully insured plans, the GIC, Medicare, and Medicaid.

^{xix} Blue Cross/Blue Shield of Massachusetts, Fallon Community Health Plan, Health New England, Point32Health (Tufts and Harvard Pilgrim Health Care), and WellSense provided input on the mandates.

^{xx} PMPM estimates help standardize costs across different groups (e.g., carriers, ages, demographics) by providing a monthly average per individual enrollee.

^{xxi} BerryDunn verified basic reasonableness checks on membership and expenses.

Definition of Mandate Costs

In practice, cost sub-categories are difficult to measure. No precise measurement of these cost breakouts can be achieved within the scope of this project, although conceptual definitions will help interpret the analysis results. 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 the applicable population, 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 costs that would be present even if the benefits were not mandated. 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 additional costs beyond the base direct costs that are imposed by the implementation of the mandate. This study estimates these costs.
- **Indirect costs.** These costs are incurred as a result of 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 [ED] visits for diabetics due to coverage for diabetes services and supplies).

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.¹⁰

Cost Estimation and Methodology

A main assumption of this report is that the PMPM costs obtained from the Massachusetts APCD sample data represent the overall fully insured commercial under-65 population. Generally, the entire APCD sample population was used for calculations, except for the mandates that do not cover all license types or market segments in the analysis.

BerryDunn’s cost estimation approach included:

- Reviewing, updating, and refining specifications for mandates previously reviewed, as well as for newly enacted mandates.^{xxii}

^{xxii} Participating carriers were asked to review the data specifications from the 2021 study, and BerryDunn incorporated their feedback on changes in clinical practice (e.g., new services, products, or diagnoses), coding updates, or other relevant factors.

- Incorporating lessons learned from prospective mandates to strengthen the analytic approach.
- Conducting quality control checks on coding specifications and analyses.^{xxiii}
- Extracting and reviewing Massachusetts APCD claims data using programming code to apply the specifications.
- Summarizing and adjusting results to produce aggregate values that meaningfully reflect the potential impact of each mandate.

Several mandates were deemed to have zero marginal direct cost, for one or a combination of the following reasons:

- Federal law or other state mandates superseded the state-mandated benefit, thus negating any incremental effect of the Massachusetts statute.
- Measuring their impact is not feasible.
- The mandated services had become clinically obsolete.

BerryDunn calculated the payer cost of each mandated benefit (i.e., paid PMPM) by first estimating medical and pharmacy PMPMs separately, using medical membership for medical claims and pharmacy membership for pharmaceutical claims, to account for the fact that some carriers use third-party pharmacy benefits managers (PBMs) and pharmacy data may be incomplete in the Massachusetts APCD. The two PMPMs were then combined and multiplied by the estimated Statute Population (Table 2) to calculate the total dollar impact. This method ensures that missing pharmacy claims do not bias the PMPM estimates downward.

Administrative loading (admin), the costs of administering a health plan beyond paying claims, was added to the claims expense measures to determine the paid PMPM with admin. BerryDunn estimated administrative loading based on CHIA's 2025 Annual Report¹¹ on the Performance of the Massachusetts Health Care System¹² and data provided to BerryDunn by the GIC. These administrative loading factors are shown in Table 3 below. The cost of each mandated benefit was divided by one minus the applicable administrative load to produce estimates of fully loaded health care premium costs. For example, this study estimates 2023 fully insured administrative loading across all market segments. Premium impacts applicable to this population are therefore calculated as paid claim expenses divided by $(1 - 0.118)$, or 0.882.

^{xxiii} For each mandate in the 2025 study, the data was compared either to the 2021 comprehensive report, updated January 2022, or to CHIA's prospective mandated benefit review studies, as applicable. BerryDunn reviewed any discrepancies and corrected code and/or results as necessary.

Table 3. 2023 Administrative Loading Factor Estimates

FUNDING TYPE/MARKET SEGMENT	2023 ADMIN FACTOR
All FI	11.8%
Large Group FI	12.9%
All FI + SI GIC	11.5%
Large Group FI + SI GIC	9.9%
Note: FI = Fully Insured; SI = Self Insured	

BerryDunn calculated the allowed PMPM by including member cost-sharing along with the payer cost of each mandated benefit.

To calculate the percentage of premium, the analysis uses the total number of member-months across all insurance license types as the denominator. 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 mandates that apply to less than the entire fully insured population, estimated claims were included in the numerator only for the subgroups indicated by the applicable population in **Table 2**, as these are the only claims related to benefits required by those 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.

Mandates With Limited Claims Data

To enhance the comprehensiveness and accuracy of total cost estimates, this report includes mandates that have taken effect more recently and on renewal. At the time of analysis, none of these mandates had a full year of claims data available, with the most recent year of data being 2023. This introduces a higher degree of uncertainty in the associated cost estimates. BerryDunn employed a methodology consistent with prospective mandated benefit reviews for these mandates.

Given the limited claims data available during the period these mandates were in effect, their cost estimates are inherently less certain. Accordingly, these mandates are presented in a separate section of the report (Section 4), where the methodology and its limitations are described in greater detail.

Results

1.0 Mandates With Estimated Marginal Direct Cost

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

The acute treatment services (ATS) and clinical stabilization services (CSS) mandate requires carriers to cover medically necessary ATS^{xxiv} and CSS^{xxv} for up to 14 days without preauthorization.¹³ The mandate places medical necessity determinations with providers in consultation with patients—requiring carriers to cover these services for 14 days without prior authorization. The mandate requires facilities to notify carriers of admission and the initial treatment plan within 48 hours of admission. Utilization review procedures may be initiated on Day 7. The mandate also requires a substance use disorder (SUD) evaluation to be covered without preauthorization.¹⁴

Effect of the Mandate on Health

SUD is a treatable and chronic mental health condition that affects a person's brain and behavior when an individual continues to use substances despite challenges that result from their use and/or the inability to control their use of substances.^{15,16} SUDs pertain to alcohol, cannabis, hallucinogens, inhalants, opioids, sedatives, hypnotics, anxiolytics, stimulants and psychostimulants, tobacco, and other substances.¹⁷ The most severe form of SUD is addiction,^{xxvi} which can involve functional changes to the brain, even for a long time after a person has stopped using substances.^{18,19} Many individuals with SUD may move between periods of remission and relapse throughout their life.²⁰ Additionally, nearly half of individuals diagnosed with SUDs also experience a mental health condition.²¹ Approximately 25% of individuals who experience serious mental illness (SMI)^{xxvii} have a comorbid,^{xxviii} or simultaneous, SUD diagnosis.²²

Nationally, substance use, and related deaths have increased, with a correlation to the COVID-19 pandemic. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), between 2022 and 2023, 48.5 million people aged 12 or older across the United States had a SUD,²³ and over 54 million people needed SUD treatment, of whom nearly 13 million people (about 24%) received needed SUD treatment.²⁴ In Massachusetts about 1.2 million people aged 12 or older had a SUD and over 1.3 million people needed SUD treatment, of whom about

^{xxiv} Acute treatment services refers to 24-hour medically supervised addiction treatment in an inpatient facility. The facility provides evaluation and withdrawal management including biopsychosocial assessment, counseling, groups, and discharge planning.

^{xxv} Clinical stabilization services refer to 24-hour clinically managed post-detoxification treatment, usually following acute treatment services, including education and counseling, relapse prevention, outreach to friends and families, and aftercare planning.

^{xxvi} Addiction is a “chronic, relapsing disorder characterized by compulsive drug seeking and use despite adverse consequences.”

^{xxvii} SMI includes major depressive disorder, schizophrenia, bipolar disorder, and other mental health conditions that cause serious impairment.

^{xxviii} Comorbidity also suggests that the two conditions interact and influence each other but does not suggest causality in either direction.

300,000 (about 23%) received needed SUD treatment.²⁵ From 2011 to 2021, Massachusetts had a greater number of drug overdose deaths (36.8 per 100,000) compared to the U.S. average (32.4 per 100,000)²⁶ and between 2013 and 2022, the opioid overdose death rate in Massachusetts more than doubled.^{xxix,27} In 2021, 88% of drug overdose deaths in Massachusetts were attributable to opioids, compared to 75% across the United States.²⁸ In Massachusetts, between 2013 and 2021 for every fatal opioid overdose, there was an average of nine non-fatal opioid overdoses (NFOs).²⁹ One out of every eleven NFOs resulted in a subsequent fatal NFO.³⁰

For individuals dealing with SUD, continued and repeated use of substances can alter the structure and function of the brain, leading to changes in a variety of mental faculties, such as personality, behavior, judgement, and memory.

An additional factor contributing to addiction and complicating recovery is the process of withdrawal. Withdrawal refers to the physical and mental symptoms that an individual has when they abruptly stop or reduce their use of an addictive substance.³¹ When an individual has developed a physiological dependence on a substance and suddenly stops using it, they may experience a range of symptoms, including tremors, nausea, vomiting, cramping, sneezing, yawning, hunger, excessive sleep, muscle and joint pain, psychomotor dysfunction, and autonomic dysfunction.³² Symptoms may be very uncomfortable, or so severe, that an individual may return to the use of the addictive substance in order to make the symptoms go away.³³ When experiencing withdrawal symptoms, an individual may look to alleviate symptoms as swiftly as possible, potentially causing them to engage in unsafe substance use, leading to an increased risk of adverse consequences including overdose.³⁴

Treatment for SUD varies based on the type, severity, and duration of the addiction, as well as on a variety of other factors unique to each individual situation.³⁵ Continuous monitoring and adjustment of treatment, simultaneously addressing other co-occurring mental illness, medication management, implementation of different behavioral therapies, and addressing the needs of the whole person are just a few of the many components of successful SUD treatment and recovery for youth and adults.³⁶ Like treatment for mental health conditions, treatment for SUD conditions should prioritize the use of the least restrictive environment. Use of the least restrictive environment means SUD treatment should balance the level of care an individual needs while preserving their individual autonomy. This allows an individual to stay engaged in educational, work, and social activities, as these activities are an important part of successful and long-term treatment.³⁷ The American Society of Addiction Medicine (ASAM) outlines a continuum of care for addiction treatment in adults:

- Level 1: Outpatient
 - 1.0: Long-Term Remission Monitoring
 - 1.5: Outpatient Therapy
 - 1.7: Medically Managed Outpatient
- Level 2: Intensive Outpatient (IOP)/ High-Intensity Outpatient (HIOP)
 - 2.1: IOP

^{xxix} The overdose rate grew from 14.2 – 30.7 deaths per 100,000 residents to 33.5 per 100,000 residents.

- 2.5: HIOP
- 2.7: Medically Managed Intensive Outpatient
- Level 3: Residential
 - 3.1: Clinically Managed Low-Intensity Residential
 - 3.5: Clinically Managed High-Intensity Residential
 - 3.7: Medically Managed Residential
- Level 4: Inpatient
 - 4: Medically Managed Inpatient
- Recovery Residence³⁸

Residential and inpatient treatment involves 24 hours a day, seven days a week support in a controlled environment, while outpatient treatment allows the individual to live at home while attending treatment sessions.³⁹ The treatment plan for an individual is determined based on the results of assessments of their medical, psychological, and social needs.⁴⁰

In Massachusetts, detoxification/withdrawal management services are known as acute treatment services or ATS, which are designed to address the initial assessment and detoxification phase of inpatient SUD treatment.⁴¹ ATS treats adults over the age of 18 who meet the criteria for ASAM Level 3.7 care, where an individual is experiencing withdrawal symptoms from alcohol and/or other drugs and requires nursing care and medical monitoring but does not require the level of care available in a hospital setting.^{42,43} Treatment takes place in licensed acute care settings that must accept and treat patients 24 hours a day, seven days a week.⁴⁴ Services provided through ATS programs include biopsychosocial evaluation, individual and group counseling, psycho-educational groups, and discharge planning.⁴⁵ Following detoxification through ATS, individuals are highly encouraged to continue receiving addiction treatment in other residential or outpatient settings.⁴⁶

CSS programs are designed to cover the phases of SUD treatment following detoxification. Often, individuals will begin a CSS program following the completion of ATS.⁴⁷ CSS programs provide intensive residential treatment for individuals who meet the criteria for ASAM Level 3.5 care. Individuals meeting these criteria are experiencing SUD, are at risk for relapse, and need a protected and structured environment, but outpatient, partial hospital, or inpatient treatment options would not be appropriate environments for the level of care they need.^{48,49} Through CSS programs, individuals have access to supportive milieu and clinical staff 24 hours a day, 7 days a week and can often complete treatment in 30 days or less, typically 10 – 14 days.⁵⁰ Services provided through CSS programs include nursing, intensive education and counseling, relapse prevention, and aftercare planning.⁵¹ In addition to services focusing on the individual, CSS programs may also involve the individual's family and/or group interventions. Treatment components, such as self-help groups like Alcoholics Anonymous (AA) and Narcotics Anonymous (NA), may be incorporated into an individual's treatment plan.⁵² Upon discharge from the program, the individual will have a current

crisis prevention plan, safety plan, and/or relapse prevention plan.⁵³ Following completion of CSS, individuals may continue treatment through transitional support services (TSS) or other appropriate service types.⁵⁴

Recovery can often not be achieved through the use of detoxification services in isolation. Detoxification does not necessarily address the psychological, social, and behavioral issues related to SUD, as the sole focus of detoxification is managing acute intoxication and withdrawal symptoms. To effectively achieve recovery, individuals need to continue with rehabilitative treatment after the detoxification phase. Although detoxification cannot be used alone to achieve optimal outcomes, it is an integral part of successful recovery from SUD. Research shows that when an individual continues with rehabilitation within a short window of time after finishing detoxification, through services like CSS, they are more likely to experience longer periods of abstinence, fewer numbers of arrests, and fewer days in jail in the year after discharge from detoxification. Continuation of care after detoxification was also found to be associated with a reduced likelihood of homelessness and an increased likelihood of being employed at three months following discharge.⁵⁵ Individuals who complete detoxification but do not continue with rehabilitation after are likely to experience relapse and require use of detoxification services again.^{56,57} There are several factors that, when present, may facilitate more successful treatment with detoxification. Individuals who gain immediate or very swift access to detoxification services are more likely to see success following completion of the detoxification phase.⁵⁸ Residential services following detoxification have been shown to have a positive impact for individuals maintaining abstinence and avoiding relapse. Specifically, full completion of detoxification followed by residential rehabilitation has been connected to lower mortality rates. Other factors, like the amount of additional support, social support, and positive therapeutic relationships an individual has, have been shown to support successful SUD treatment as well.⁵⁹

When considering the efficacy of programs like ATS and CSS, it is important to acknowledge that SUD treatment is unique to the needs of each individual and the type of substance they are using.⁶⁰ Additionally, it is common for individuals with SUD to require multiple courses of treatment throughout their lifetime.⁶¹ Programs like ATS and CSS are intensive treatment options that might not be appropriate for every situation or episode but are potentially useful treatment components for individuals with severe SUD, comorbidities, and other complicating factors.^{xxx, 62}

Alternatively, medications delivered through outpatient services have become a prominent standard of care for individuals with opioid use disorder (OUD) and may be an appropriate treatment option for many, therefore not requiring the use of ATS and CSS programs. For others, medication-assisted treatment (MAT) may be an ideal treatment option, but they might require a more supportive or structured treatment setting than what can be offered through outpatient services. For these individuals, they could be able to receive MAT in conjunction with services typically provided during ATS. Additionally, some individuals may be able to effectively treat their conditions without medications and through outpatient service options and might not need care at the level of acuity provided through ATS and/or CSS.⁶³

As a result of this mandate, insurance carriers cannot impose prior authorization requirements for up to 14 days for ATS and CSS programs.⁶⁴ The absence of prior authorization requirements supports individuals in being able to

^{xxx} Examples of complicating factors that an individual could have that would make them suitable for inpatient or residential treatment include unstable housing and/or lack of familial support.

initiate SUD treatment in a timely manner, potentially increasing their chances of success.^{65,66} Research shows that delays in accessing or initiating SUD treatment can worsen an individual's condition and require more extensive treatment.⁶⁷ There is little research on the effect of prior authorization requirements on access to residential treatment for SUD, but there is research supporting that the removal of prior authorization requirements for medications for OUD increases access to treatment and decreases the likelihood of relapse.⁶⁸ This evidence, along with research detailing the impact of the removal of prior authorization requirements on health care more generally, creates strong potential for the same effect to be observed for ATS and CSS.

Estimated Marginal Cost of the Mandate

Carrier survey responses indicated that ATS and CSS would generally be covered in the absence of the mandate and would be subject to prior authorization and utilization review. BerryDunn reviewed claims for ATS and CSS using the APCD for 2023 for the current costs, and the 2014 data extracts from a retrospective study, conducted prior to the effective date of the mandate, October 1, 2015. Overall admissions per 1,000 members increased by about 0.04 between 2014 and 2023. When the incremental increase in admissions per 1,000 is applied to the sample membership, there are an estimated 708 additional admissions, which is worth 3,441 additional bed days when accounting for the 4.4-day pre-implementation average length of stay (ALOS).

Table 4. Impact of Increased Admissions Due to the Mandate

[a] 2014 Admissions per 1,000	0.20
[b] 2023 Admissions per 1,000	0.24
[c] = [b] – [a] Change in Admissions per 1,000	0.04
[d] 2023 Sample Monthly Membership	1,576,663
[e] = [c] / 1000 x ([d] x 12) Increase in Admissions	708
[f] 2014 ALOS	4.4
[g] = [f] x [e] Additional Days Due to Increased Admissions	3,126

Next, BerryDunn considered the change to the ALOS before and after the introduction to the mandate. The pre-implementation 2014 ALOS was 4.4 days based on 2021 comprehensive analysis. For the post-implementation 2023 ALOS, BerryDunn excluded claims for ATS and CSS longer than 14 days. This mandate limits the carrier's ability to apply utilization management prior to 14 days; therefore, members who exceeded 14 days were approved by the carrier's utilization management policies regardless of the mandate. The 2014 ALOS from the 2021 comprehensive analysis did not remove claims where the stay was longer than 14 days and would have been unaffected by the mandate. It is possible, although unlikely, that the 2014 ALOS is overstated and thus, the marginal cost of the mandate could be understated without this adjustment. The overstatement of the 2014 ALOS was considered unlikely due to ALOS being well-below the 14-day threshold set by the mandate. The ALOS in 2023 for members who stayed less than or equal to 14 days was 5.4. Therefore, this mandate increased the ALOS by 1.0 days.

Table 5. Impact of Increased ALOS Due to the Mandate

[a] 2014 Average Length of Stay	4.4
[b] 2023 Average Length of Stay	5.4
[c] = [b] – [a] Change in Average Length of Stay	1.0
[d] 2023 Sample Admissions	3,176
[g] = [f] x [e] Additional Days Due to Increased ALOS	3,079

BerryDunn calculated 6,205 additional residential bed days, attributable to Chapter 258 based on combining the increase in admissions and ALOS. Next, using the APCD, BerryDunn calculated a 2023 average paid cost per day of \$1,179 for ATS and CSS for those with an LOS of 14 days or shorter. 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 \$0.39 PMPM. Adjusted for administrative loading, BerryDunn estimates this mandate has a \$0.44 PMPM, or 0.066%, impact on total Commonwealth premium. Table 7 displays the results.

Table 6. Acute Treatment and Clinical Stabilization Services Mandate Contribution to Premium

MEASURES	SAMPLE AMOUNT PLANS SUBJECT TO MANDATE
Sample Average Members	1,576,663
Paid PMPM	\$ 0.39
Paid PMPM With Admin	\$ 0.44
Allowed PMPM	\$ 0.44
UPPER BOUND IMPACT	
Insured Population	2,150,129
Contribution to Total Annual Claims	\$ 9,978,649
Contribution to Total Annual Premium	\$ 11,311,298
Percent of Total Premium	0.066%
*No significant overlaps were found between this and other mandates.	

Cleft Palate and Cleft Lip

This mandate requires coverage for medically necessary services for cleft palate and cleft lip for children under age 18. Medical, dental, speech therapy (ST), audiology, and nutrition services are required to be covered. Coverage

includes surgical management (treatment planning and execution) provided by a plastic or oral surgeon, preventive and restorative services, orthodontic treatment and management, as well as any oral and facial surgery needed to treat cleft lip and cleft palate.⁶⁹

Effect of the Mandate on Health

Orofacial clefts, encompassing cleft lip and cleft palate, are congenital conditions that occur during pregnancy when the tissues forming a baby's upper lip or the roof of the mouth (palate) do not fully develop or join as expected. Between the fourth to seventh weeks of pregnancy, the lips and mouth form as body tissue and cells from the sides of the head grow toward the center of the face. If the tissue around the upper lip does not join completely before birth, a cleft lip can result. This opening can range from a small notch to a larger gap extending through the lip and into the nose. Cleft lip can occur on one or both sides of the lip and may also be accompanied by cleft palate. The palate forms between the sixth to ninth weeks of pregnancy when tissue on the roof of the mouth joins together. Cleft palate occurs when these tissues do not join completely; in some instances, the front and back of the palate remain open while for others only part of the palate is open.⁷⁰

Orofacial clefts are among the most common congenital conditions,⁷¹ with their occurrence varying across different populations. They are more frequently observed in individuals of Native American and Asian ancestry and less commonly seen in those of African ancestry.⁷² In the United States, an estimated 3,560 babies are born each year with a cleft lip, with or without a cleft palate. This represents approximately 1 in every 1,032 births, or a rate of 9.7 per 10,000 births.⁷³ In comparison, the rate for babies born in Massachusetts with an orofacial cleft (a cleft lip with or without a cleft palate) is 6.0 per 10,000 births.⁷⁴ Without surgical repair, children with orofacial clefts may face challenges such as dental issues, difficulties with feeding and speech, recurrent ear infections, and hearing problems.⁷⁵ They are also more likely to experience hospitalizations during childhood compared to children without orofacial clefts.^{76,77}

The etiology of orofacial clefts is complex and not fully understood.⁷⁸ Orofacial clefts can occur in isolation or as part of a broad range of chromosomal, Mendelian,^{xxx} or teratogenic^{xxxii} syndromes, with the non-syndromic forms thought to be the result of a combination of genetic and environmental factors.^{79,80} Further, although the specific cause of orofacial clefts is unknown, several factors are known to increase the risk. These include a family history of orofacial clefts, smoking, alcohol consumption, and the use of certain anti-seizure medications during the first trimester of pregnancy. Other risk factors include having diabetes (Type 1 or Type 2), obesity, and taking certain medications during pregnancy.^{81,82} Additionally, an inadequate intake of essential nutrients, such as folic acid, before and during pregnancy can also increase the risk of orofacial clefts.^{83,84}

The treatment and services provided to children with orofacial clefts vary based on the cleft's severity, the child's age and specific needs, and the presence of other congenital conditions or associated syndromes.⁸⁵ Surgical repair is recommended within the first 12 months of life for cleft lip and within the first 18 months for cleft palate (earlier if

^{xxx} Mendelian refers to certain patterns of passing traits from parents to offspring.

^{xxxii} Teratogens are substances known to cause congenital disorders in a developing embryo or fetus.

possible).⁸⁶ Surgical repair of orofacial clefts can help restore function to the mouth and lips and may also help improve the child's facial appearance as well as breathing, hearing, and speech and language development.^{87,88} Additional procedures are often necessary as children age, and they may also require ST and special dental or orthodontic care.⁸⁹

The American Cleft Palate-Craniofacial Association recommends care by an interdisciplinary team of specialists who see sufficient numbers of patients per year to maintain their expertise in the diagnosis and treatment of these individuals.⁹⁰ These specialized teams can coordinate the variety of services needed throughout infancy, childhood, adolescence, and if necessary, adulthood⁹¹ and include health professionals from medical, dental, surgical, and allied health disciplines,⁹² such as "craniofacial surgeons, otolaryngologists, geneticists, anesthesiologists, speech-language pathologists (SLPs), nutritionists, orthodontists, prosthodontists, psychologists, neurosurgeons, and ophthalmologists."⁹³ According to the American Cleft Palate-Craniofacial Association, there are four such teams in Massachusetts: three in Boston and one in Worcester.⁹⁴ In addition to the treatment of the orofacial cleft, some children and families also benefit from peer and other emotional support resources, and these resources can be particularly beneficial during the birth hospitalization for parents.^{95,96} The treatment of orofacial clefts continues to advance, driven by ongoing innovations in surgical techniques and perioperative care.⁹⁷

Despite limited evidence-based randomized control studies related to orofacial cleft treatment, and the absence of standardized management practices or consensus on optimal techniques for lip repair across centers, most children with orofacial clefts achieve positive outcomes and go on to lead healthy lives.^{98,99}

Estimated Marginal Cost of the Mandate

In the 2009 prospective mandated benefit review, expert interviews and carrier survey responses confirmed that medical services (such as surgery) for these conditions were well covered prior to its implementation.¹⁰⁰ Therefore, costs of previously uncovered dental, orthodontic, and prosthodontic services provided to treat cleft palate and lip comprise the marginal impacts of the mandate. Due to limitations in the ability to identify these services in the Massachusetts APCD, BerryDunn calculated the estimated 2023 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 2023.

To estimate a case rate for these services, BerryDunn reviewed 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 and a nonprofit advocacy organization focused on cleft and craniofacial conditions. BerryDunn reviewed the estimates of the 2009 case rate of \$18,500 utilized in the 2009 prospective mandate review of this mandate and the 2018 case rate of \$24,000 utilized in the 2021 Comprehensive Report, updated January 2022.¹⁰¹ The 2009 case rate was then adjusted to 2023 dollars using monthly dental care inflation rates published by the U.S. Department of Labor Bureau of Labor Statistics (BLS).¹⁰² This calculation resulted in a 2023 case rate estimate of \$27,805. BerryDunn utilized \$28,000, or \$1,556 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 – 2015 from the Massachusetts Executive Office of Health and Human Services (EOHHS)¹⁰³ 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 2023. Dividing BerryDunn's estimate of 2023 fully insured and GIC self-insured Massachusetts commercial health insurance membership for this age range by a U.S. Census Bureau estimate of 2023 Massachusetts population in the same age range resulted in an estimated proportion of children in the age range covered by fully insured commercial insurance or self-insured GIC policies of 26%. BerryDunn then reduced this percentage to remove carriers that said they would cover these services absent the mandate. This resulted in an adjusted proportion of children of 17%. Applying this percentage to the estimate of Massachusetts children with craniofacial clefts resulted in an estimate of 478 children with fully insured commercial or self-insured GIC health coverage in 2023.

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 2025 annual report¹⁰⁴ on the performance of the Massachusetts health care system, 67% of the combined fully insured and self-insured GIC members are in large group plans.¹⁰⁵ Applying this percentage to the estimate of 478 fully insured and self-insured GIC member children with a craniofacial cleft resulted in an estimate of 319 children in the mandate population. Multiplying \$1,556 per year by 319 children yielded an estimate of approximately \$325,000 in paid claim costs, or \$360,000 with administrative loading. Dividing this impact estimate by the total 2023 Massachusetts large group fully insured membership estimate resulted in a 2023 PMPM marginal impact estimate for this mandate of \$0.02 in claims cost and \$0.02 with administrative loading. The estimated impact on total 2023 Massachusetts fully insured market premium is 0.002%. These results are summarized below in **Table 7**.

Table 7. Cleft Palate and Cleft Lip Mandate Contribution to Premium

2023 MEASURES	ESTIMATED IMPACT
[a] Per Case Cost, 0-17	\$ 28,000
[b] Cost per Case per Year	\$ 1,556
[c] Estimated Massachusetts Cases	1,818
[d] Percent of Cases FI + GIC-SI	17%
[e] Percent of FI + GIC-SI in LG	67%
Contribution to Total Annual Claims	\$ 324,517
= [b] x [c] x [d] x [e]	\$ 360,088
Contribution to Total Annual Premium	
Insured Population	1,530,411
Paid PMPM	\$ 0.02
Paid PMPM With Admin	\$ 0.02
Percent of Total Premium	0.002%

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

Hearing Aids for Children

The children's hearing aid mandate requires coverage for any child, age 21 years or younger, for one hearing aid^{xxxiii} per hearing-impaired ear, up to \$2,000 for each hearing aid, every 36 months. Coverage must be provided when accompanied by a written statement from the child's treating physician that the hearing aids are necessary, regardless of etiology. Coverage is required for all related services prescribed by an audiologist or hearing instrument specialist,^{xxxiv} including the initial hearing aid evaluation, fitting and adjustments, and supplies, including ear molds.¹⁰⁶

Effect of the Mandate on Health

Hearing loss impacts the development of speech, language, and social skills. Without timely or adequate support for language access, children often experience delays in development and permanent deficits.^{107,108,109} The first three years of life is the most important time to learn language; consequently, the earlier that hearing loss is detected and

^{xxxiii} As defined in M.G.L. Chapter 112, section 196 (c.112 §196), A hearing aid is "...a wearable aid or device, not including surgical implants, which is inserted directly into the ear or worn with an ear mold and air conduction receiver or bone oscillator attachment and any part, attachment or accessory but excluding batteries, cords and accessories thereto, designed for or offered for the purpose of aiding or compensating for hearing loss."

^{xxxiv} As defined in M.G.L. c.112 §196, an audiologist is "...a person licensed as an audiologist in the commonwealth;" and a hearing instrument specialist is "...a person licensed as a hearing instrument specialist in the commonwealth."

services are provided to children, the more likely children are to overcome related challenges.^{110,111,112} Hearing loss can occur any time in life when any part of the ear is not functioning properly, including the acoustic nerve and auditory system as well as the inner, middle, or outer ear.¹¹³ In children, hearing loss can be broadly categorized as either congenital^{xxxv,114} or acquired.

Congenital hearing loss in infants frequently has a genetic cause (approximately 50% of cases). Non-genetic causes include maternal infections during pregnancy, complications after birth, or head trauma.^{115,116} Approximately 30% of infants' hearing loss due to genetic causes involves a syndrome or condition in addition to the hearing loss, such as Down syndrome or Usher syndrome.^{117,118} Acquired hearing loss is primarily caused by otitis media^{xxxvi,119} with effusion.¹²⁰ Other acquired causes include cholesteatoma,^{xxxvii,121} impacted wax, otosclerosis,^{xxxviii,122} and trauma.¹²³

Once identified, hearing loss is categorized as one of four types:¹²⁴

- Conductive: Sound is obstructed from reaching the outer or middle ear.
- Sensorineural: Resulting from inner ear or nerve impairments
- Mixed: Caused by a combination of conductive and sensorineural issues
- Auditory neuropathy spectrum disorder: Inner ear or nerve damage disrupts the brain's processing of sound

Hearing loss is also categorized based on the degree of hearing loss, which can range from mild to profound; it is also based on other characterizations/descriptions as follows:¹²⁵

- Degree:
 - Mild: Able to perceive some speech; soft sounds may be challenging to hear
 - Moderate: Unable to hear most speech at normal level
 - Severe: Unable to hear speech at normal levels; only some loud sounds are audible
 - Profound: Unable to hear speech and only perceives very loud sounds
- Unilateral or bilateral: Impacts one or both ears
- Pre-lingual or post-lingual: Occurs before or after the individual has acquired language skills

^{xxxv} Congenital means existing at or dating from birth.

^{xxxvi} Otitis media is an ear infection of the middle ear, an air-filled space between the eardrum and inner ear that houses the delicate bones that transmit sound vibrations from the eardrum to the inner ear.

^{xxxvii} A cholesteatoma is an abnormal growth behind the ear drum in the middle ear.

^{xxxviii} Otosclerosis is an irregular bone remodeling/growth that occurs in the middle ear or, more rarely, in the inner ear, and interferes with sound's ability to travel through the ear.

- Symmetrical or asymmetrical: Impacts both ears equally or differently
- Progressive or sudden: Hearing loss that worsens gradually over time or occurs suddenly
- Fluctuating or stable: Hearing loss that fluctuates in its severity over time or remains consistent
- Congenital or acquired/delayed onset: Hearing loss that presents at birth or develops later in life

Although the exact number of children with hearing loss is unknown, the CDC estimates that approximately 1 – 3 per 1,000 children has hearing loss.¹²⁶ The most recent data available estimates that 9.2% of infants who do not pass screening are found to have hearing loss or 2.0 per 1,000 newborns in Massachusetts; these numbers are similar to the national figures of 9.6% and 1.7 per 1,000.¹²⁷

Treatment and intervention depend on the type of hearing loss. Different options available include special education, early intervention (EI) to assist in language and other important skills, medications, and surgery, as well as technology such as hearing aids, cochlear or brain stem implants, and other assistive devices.¹²⁸ Medications and surgery are most frequently used to correct conductive hearing loss,^{xxxix} which can be caused by infection or malformation of the outer and/or middle ear. Children with severe to profound hearing loss might benefit from a cochlear implant, a device surgically implanted into the ear that conducts sound directly to the auditory nerve. Although technology, such as hearing aids, cannot cure hearing loss, it can significantly enhance a child's use of their remaining hearing capacity.

Designed to amplify sounds, hearing aids can maximize residual hearing and can be used by people of any age, including infants.¹²⁹ Hearing aids are small electronic devices that are composed of three basic parts—microphone, amplifier, and speaker—and are available as in-the-ear, behind-the-ear, or in-the-canal varieties. Hearing aids increase the volume of sounds that are received through a microphone and convert the sound waves to electronic signals and send them to the amplifier. The amplifier manipulates the power of the signals and sends them to the ear through the speaker. There are two newer types of hearing aids that require surgical implantation: middle ear implants, which are attached to one of the bones in the middle ear, and bone-anchored hearing aids, which are attached to the bone behind the ear. These devices work differently than traditional hearing aids and are designed to help increase the transmission of sound vibrations entering the inner ear rather than making sounds louder.¹³⁰

Studies have found that the early provision and consistent use of hearing aids for children who have mild to severe hearing loss results in improved speech and language development, as well as increased participation in social activities.^{131,132,133} Beyond the beneficial impacts on speech and language, quality of life indicators improve with hearing aid use for children with hearing impairments and their parents.^{134,135} Many studies have demonstrated that speech and language development in the preschool years significantly impacts the success of children in school;

^{xxxix} Conductive hearing loss results when sound cannot travel through the outer or middle ear due to infections, blockages, or structural abnormalities.

therefore, early hearing aid fitting is a significant factor in achieving better speech and language development as well as better communication outcomes.^{136,137}

Estimated Marginal Cost of the Mandate

In previous comprehensive mandate studies CHIA has included routine childhood hearing screenings in the RDC of this mandate since the statute language requires 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 (i.e., the mandates for 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 2023. Therefore, any incremental impact of the state mandate is limited to the large group population, as shown in Table 8 below.

To calculate the incremental effect of the mandate, BerryDunn first summarized 2023 Massachusetts 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, and thus, self-insured GIC costs for these benefits are not incremental to the state mandate.¹³⁸ 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. BerryDunn also explored the change in the cost from 2018, and found that it was driven by spend on hearing fitting across all carriers.

Table 4. Hearing Aids for Children Contribution to Premium

MEASURES	SAMPLE AMOUNT
	PLANS SUBJ. TO MANDATE
Sample Average Members	1,095,604
Paid PMPM	\$ 0.10
Paid PMPM With Admin	\$ 0.11
Allowed PMPM	\$ 0.11
UPPER BOUND IMPACT	
Insured Population	1,530,411
Contribution to Total Annual Claims	\$ 1,851,397
Contribution to Total Annual Premium	\$ 2,098,652
Percent of Total Premium	0.012%

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

As summarized in Table 8 above, these steps resulted in an estimated incremental PMPM paid claim impact of \$0.10, with a total PMPM cost, after administrative loading, of \$0.11 (or 0.012% of the Commonwealth total premium).

Infertility Treatment

The infertility mandate requires coverage for both the diagnosis and treatment of infertility to the same extent as benefits provided for other pregnancy-related procedures for members enrolled in plans with pregnancy-related benefits.¹³⁹ Pursuant to 211 CMR 37.00, “infertility” is defined as the condition of an individual who is unable to conceive or produce conception during a period of one year if the (biological) female is age 35 or younger or during a period of six months if the (biological) female is over the age of 35. Massachusetts’ existing infertility mandate became part of the State’s EHB benchmark plan as a result of the ACA, because the selected benchmark plan already included coverage for infertility services.

Effect of the Mandate on Health

The Centers for Disease Control and Prevention (CDC) defines infertility as the inability to conceive after one year or more of unprotected sexual intercourse. Due to the age-related decline in fertility among (biological) females, some providers may consider infertility after six months of unprotected sex among (biological) females aged 35 years or older. These definitions of infertility do not dictate recommendations regarding the delivery of fertility treatments, and providers make treatment recommendations based on individuals’ circumstances.¹⁴⁰

The prevalence of infertility is relatively high; in the United States, almost one fifth (approximately 19%) of married (biological) females aged 15 – 49 years who have never given birth experience infertility, and about one fourth (26%) encounter challenges becoming pregnant or experience impaired fecundity, i.e., difficulty maintaining a pregnancy. Among (biological) females who have previously given birth, infertility and difficulty carrying a pregnancy to term are less prevalent—approximately 6% of married (biological) females face infertility, and 14% experience difficulties conceiving or maintaining a pregnancy.¹⁴¹ Among heterosexual couples who are experiencing infertility, for (biological) males, infertility can be a factor in 30% – 40% of infertility cases, and 20% of infertility cases are solely due to the (biological) male partner.¹⁴² In 2021, Massachusetts had a fertility rate of 49.0 per 1,000 (biological) females aged 15 – 44, with a total of 69,137 births.¹⁴³

The causes of infertility in (biological) females can include endometriosis, structural abnormalities, autoimmune conditions, kidney disease, thyroid disease, pelvic inflammatory disease, genetic or chromosomal disorders, polycystic ovary syndrome, and infrequent or absent menstrual periods.¹⁴⁴ The causes of infertility in (biological) males can include genetic disorders, chromosomal disorders, urogenital abnormalities or infections, low testosterone, sexual dysfunction, prior chemotherapy or radiation therapy, and environmental toxins.^{145,146}

Infertility treatment varies depending on the cause, how long an individual has been infertile, the age of the individual (and their partner if applicable), and individual preferences.¹⁴⁷ Medication, surgery, or assisted reproductive

technology (ART) are common treatments that can address infertility. Lifestyle modifications can supplement these treatments and, in some cases, might be able to address the infertility without further intervention.¹⁴⁸ For (biological) females, pharmacological interventions, such as fertility medicines, can facilitate ovulation. Intrauterine insemination (IUI) is also an option and involves the direct placement of healthy sperm into the uterus. Surgical procedures, such as hysteroscopy or laparoscopic surgery, can address conditions affecting fertility, including polyps or endometriosis. ART, such as in vitro fertilization (IVF) as the most common form of ART, entails multiple steps from oocyte retrieval, oocyte fertilization, and embryo implantation.^{149,150} Additional techniques such as intracytoplasmic sperm injection (ICSI) and assisted hatching may supplement IVF cycles. Donor eggs or sperm, along with gestational carriers for those unable to carry a pregnancy, offer alternative pathways but are not covered under this mandate.¹⁵¹ For (biological) males, prescription medications may be utilized to enhance sperm count and improve the likelihood of successful pregnancy. Surgical interventions may also be considered in certain cases to address sperm blockages or repair varicoceles, with the aim of restoring fertility and increasing the chances of conception. Sperm retrieval procedures may be employed to collect sperm when ejaculation is problematic or when sperm is absent from semen and are particularly beneficial in cases of low or irregular sperm counts and when assisted reproductive techniques are being pursued.^{152,153}

IVF has emerged as the most effective method for achieving pregnancy and live birth in cases of infertility.^{154,155} However, it is more invasive and costly compared to alternative treatments like IUI. A 2022 study found that out of 1,437 IUI cycles in 758 couples, the per-cycle pregnancy rate was 10.9%.¹⁵⁶ In 2020 in Massachusetts, 5.6% of all infants born resulted from ART procedures, compared to 2.0% of all infants born in the United States from ART procedures.¹⁵⁷ The CDC National ART Summary reported that in 2020 approximately 82% of pregnancies originating from ART procedures resulted in a live birth delivery.¹⁵⁸ Pregnancies that originate from ART procedures can result in multiple births due to the potential for multiple embryos to be transferred during the process. In 2020 in Massachusetts, 41.3% of all ART procedures resulted in pregnancy; of these births, 94.0% were single births, and 6% were multiple births.¹⁵⁹ The decision-making process surrounding infertility treatment is multifaceted and involves careful consideration of various factors. By assessing the probability of conception without intervention, the intricacy of treatment options, the duration of infertility, and the age of the individual, health care providers and patients can collaboratively determine the most suitable course of action. This holistic approach ensures that treatment plans are tailored to the specific needs and circumstances of each individual or couple, maximizing the chances of achieving the desired outcome.¹⁶⁰

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 and accordingly, 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 Massachusetts 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 residing in Massachusetts; it does not extend to nonresidents covered by Massachusetts employers) in large group products in the state in 2023.

Carrier survey responses indicated that these services would not be covered, or that coverage would have been limited, in the absence of the mandate. BerryDunn assumed the marginal cost of the mandate is the PMPM paid claim expenses from the Massachusetts APCD CY 2023 for the year 2023. The marginal cost of the mandate may be overstated due to services that would have been approved prior to the mandate. Such data is unavailable currently.

BerryDunn calculated the PMPM claim paid expenses to be \$7.58 PMPM. With administrative loading, the cost of the mandate increased to \$8.59 PMPM. This represents a 0.731% impact on the Commonwealth premium. These results and related statistics are displayed in Table 4 below.

Table 9. Infertility Treatment Mandate Contribution to Premium

MEASURES	SAMPLE ESTIMATE
Sample Average Members	531,931
Paid PMPM	\$ 7.58
Paid PMPM With Admin*	\$ 8.59
Allowed PMPM	\$ 7.75
PREMIUM IMPACT ESTIMATE	
Insured Population	1,243,438
Contribution to Total Annual Claims	\$ 113,039,567
Contributions to Total Annual Premium	\$ 125,430,225
Percent of Total Premium	0.731%

*\$8.59 PMPM represents large group FI premium. The equivalent amount is \$8.41 when including SI GIC, as is the case in the premium impact estimate section of the exhibit.

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

Low Protein Food Products

The low protein food products mandate requires coverage for low protein food products for individuals who have inherited diseases of amino acids and organic acids in an amount not to exceed \$5,000 annually.¹⁶¹

Effect of the Mandate on Health

Hereditary metabolic disorders are caused by abnormalities in genes children inherit from their parents^{xl,162} that affect metabolism.¹⁶³ The specific gene changes cause distinct types of metabolic disorders, which include amino acid and organic acid diseases. Most commonly, hereditary metabolic disorders, also called inborn errors or metabolism and inherited metabolic disorders, result from gene changes that are passed down from both parents, but they are sometimes inherited from only one parent or occur because of spontaneous mutation.^{164,165,166}

Amino and organic acid disorders impact metabolism. Metabolism is a complex process involving chemical reactions within the body that convert food into energy.^{167,168,169} Chemicals in the digestive system convert food, which is made up of proteins, carbohydrates, and fats, into sugars and acids, which are fuel for the body that can be used right away or stored in the body's tissues.¹⁷⁰

^{xl} Heredity is the passing of genes from one generation to the next. Children inherit their parents' genes.

Metabolic disorders arise from malfunctions in biochemical processes, often due to enzyme insufficiency^{xli,171} or other underlying issues.¹⁷² Such disorders typically stem from one or both of the following:

- Failure to metabolize a substance as required, leading to the accumulation of toxic intermediates
- Inability to synthesize essential substances necessary for bodily functions¹⁷³

Metabolic disorders are classified by the substance affected and whether it builds up too much because it cannot be broken down, is too low, or is missing.¹⁷⁴ Consequently, even though they are both metabolic disorders, amino acid and organic acid disorders impact metabolism in different ways. In amino acid disorders, key enzymes are either not produced or do not work properly, which results in the body being unable to metabolize proteins from food properly.¹⁷⁵ Organic acid disorders arise from an enzyme not functioning properly, resulting in an excessive buildup of certain organic acids in the body.¹⁷⁶ There are hundreds of inherited metabolic disorders,¹⁷⁷ many of which are amino acid and organic acid metabolic disorders, including, but not limited to, the following conditions newborns are screened for in Massachusetts:¹⁷⁸

AMINO ACID DISORDERS	ORGANIC ACID DISORDERS
Argininemia	2-Methyl-3-Hydroxybutyric Aciduria
Arginosuccinic Aciduria	2-Methylbutyrylglycinuria
Benign Hyperphenylalaninemia	3-Hydroxy-3-Methylglutaric Aciduria
Biopterin Defect in Cofactor Biosynthesis	3-Methylcrotonyl-CoA Carboxylase Deficiency
Biopterin Defect in Cofactor Regeneration	3-Methylglutaconic Aciduria
Carbamoyl Phosphate Synthetase I Deficiency	β-Ketothiolase Deficiency
Citrullinemia, Type I	Glutaric Acidemia Type I
Citrullinemia, Type II	Holocarboxylase Synthase Deficiency
Classic Phenylketonuria (PKU)	Isobutyrylglycinuria
Gyrate Atrophy of the Choroid and Retina	Isovaleric Acidemia
Homocystinuria	Malonic Acidemia
Hypermethioninemia	Methylmalonic Acidemia (Cobalamin Disorders)
Hyperornithine with Gyrate Deficiency	Methylmalonic Acidemia (Methylmalonyl-CoA Mutase)

^{xli} Enzymes are proteins that help speed up metabolism, or the chemical reactions in our bodies. Essential for digestion, too much or too little of a certain enzyme can cause health problems.

AMINO ACID DISORDERS	ORGANIC ACID DISORDERS
Maple Syrup Urine Disease	Methylmalonic Acidemia with Homocystinuria
Ornithine Transcarbamylase Deficiency	Propionic Acidemia
Tyrosinemia Type I	
Tyrosinemia Type II	
Tyrosinemia Type III	

Each of these disorders results from a different single enzyme deficiency, causing a block within the corresponding metabolic pathway.¹⁷⁹ While hereditary metabolic disorders are individually rare, the total number of identified disorders likely equals the multitude of symptoms indicative of metabolic disturbances.¹⁸⁰ An inborn error of metabolism is estimated to occur in 1 out of every 2,500 births worldwide.¹⁸¹ Collectively, these disorders contribute to both infant and childhood mortality and morbidity.^{182,183}

Preconception screening and counseling of asymptomatic parents represents the first opportunity to address inborn errors of metabolism and has been shown to decrease prevalence.¹⁸⁴ Although some hereditary metabolic disorders, such as PKU,^{xlii,185} can first be found and diagnosed during pregnancy with ultrasound followed by amniocentesis^{xliii,186} or chorionic villus sampling,^{xliv,187} most are detected after birth with newborn screening tests.^{188,189}

For many inborn errors of metabolism, medical foods^{xlv,190} are the cornerstone of therapy and the only effective interventions that have been identified to prevent disability and death.¹⁹¹ As a result, once diagnosed, beginning treatment as soon as possible is essential. While some inborn errors of metabolism, like organic acid disorders, require other modalities in addition to dietary modifications, for many of these disorders, such as PKU, maple syrup

^{xlii} PKU causes an amino acid called phenylalanine to build up in the body, which can lead to serious health problems.

^{xliii} Amniocentesis is a prenatal test that can diagnose genetic and other health issues in a fetus by analyzing a small amount of amniotic fluid obtained from within the uterus between 15 and 20 weeks of pregnancy.

^{xliv} Performed around 10 – 12 weeks of pregnancy, chorionic villus sampling is a test that takes a small sample of cells, called chorionic villi, from the placenta that can be used to diagnose certain genetic problems.

^{xlv} A medical food “is formulated for a special dietary use by the requirement that it be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision, and intended for the specific dietary management of a disease or condition.”

urine disease, homocystinuria,^{xlvi,192} galactosemia^{xlvi,193} and glycogen storage disease (GSD) (Type I/III),^{xlvi,194} dietary therapy is the mainstay of treatment.¹⁹⁵ These dietary interventions are not only a central component to disease stabilization but are also essential for an individual's adequate mental development and survival.¹⁹⁶

While amino and organic disorders both disrupt the normal breakdown of proteins through metabolism, each disorder is caused by problems with different enzymes. This leads to varying treatments and symptoms across the different disorders, as well as differences from person to person who have the same disorder.^{197,198} For example, individuals with beta-ketothiolase deficiency (BKD) and maple syrup urine disease are unable to properly process certain protein building blocks (amino acids), but BKD is caused by problems with the mitochondrial acetoacetyl-CoA thiolase enzyme, while maple syrup urine disease is caused by absence of a group of enzymes called branched-chain ketoacid dehydrogenase.^{199,200} Beginning in infancy, these conditions have varied symptoms, which can include poor appetite, vomiting, sluggishness, and seizures, and without treatment, long-term effects can include intellectual disabilities and poor growth.^{201,202,203,204} Both maple syrup urine disease and BKD are managed through diet with severe protein restriction as well as through other interventions specific to the respective disorder.^{205,206}

Although traditional management of inborn errors of metabolism has consisted of dietary therapy, other treatment options have emerged, such as pharmacological interventions, removal of harmful substances, organ and cell transplantation, and gene therapy.^{207,208,209,210} One such advancement is the use of Pegvaliase as an enzyme substitution for the treatment of PKU, potentially limiting the need for medical food.^{211,212,213} For individuals with PKU, a defect in the gene that helps create the liver enzyme required to break down the amino acid phenylalanine (Phe) results in a buildup of Phe in the blood and other tissues.^{214,215} Like other inborn errors of metabolism, if left untreated, PKU can lead to serious medical complications, including microcephaly, growth failure, seizures, intellectual impairment, and behavioral abnormalities caused by the accumulation of toxic byproducts of Phe.^{216,217} Traditional treatment of PKU, like other amino acid and organic disorders, includes medical food and formulas, minimal animal products, and a diet consisting mostly of fruits and vegetables that are high in carbohydrates and low in saturated and polyunsaturated fat and cholesterol.²¹⁸ For individuals with PKU and uncontrolled Phe concentrations, pegvaliase provides an enzyme substitution therapy that has been found to reduce Phe to clinically significant levels²¹⁹ and allows for the possibility of an unrestricted diet.²²⁰

^{xlvi} Homocystinuria is a rare inherited condition that prevents the body from being able to use certain needed proteins. As a result, affected individuals can experience vision problems, a higher risk of blood clots, developmental delays, cognitive impairment, learning difficulties, seizures, and/or blood disorders.

^{xlvi} Galactosemia is a rare inherited metabolic condition that prevents the body from breaking down a sugar (galactose) found in foods (mainly dairy), the body, breast milk, and baby formula. Galactosemia can lead to cataracts, developmental delays, cognitive impairment, hormone deficiencies and infertility, tremors, kidney disease, liver failure, or sepsis. If untreated, the sugar build up can be life threatening, especially for newborns.

^{xlvi} GSD is a rare inherited disease that prevents the body from breaking down carbohydrates (energy), leading to a buildup in the liver and muscles. Depending on the type, GSD can lead to developmental and growth delays, inability to exercise, muscle cramps, weakness, fatigue, heart disease, liver disease (a build up of scar tissue called cirrhosis), enlarged liver, low blood sugar, and high cholesterol.

Optimal long-term outcomes for amino and organic acid disorders depend on prompt diagnosis and early treatment to reduce disease severity and delay or prevent metabolic multisystemic consequences.^{221,222,223} Given the rarity of these genetic conditions, there have been very few randomized, double-blinded clinical trials.^{224,225,226}

Estimated Marginal Cost of the Mandate

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 responses did not indicate that these products would be consistently covered in the absence of the mandate, and accordingly the marginal cost estimate was based on data from those carriers that indicated they would not or were unsure if they would 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 \$0.04, with a total PMPM cost, after administrative loading, of \$0.05 (or 0.005% 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. These overlap amounts have been deducted from the impact estimate for the nonprescription enteral formula mandate, below. Table 10 displays a summary of these results and related statistics.

Table 5. Low Protein Food Products Mandate Contribution to Premium

MEASURES	SAMPLE AMOUNT*
Sample Average Members	1,095,604
Paid PMPM	\$ 0.04
Paid PMPM With Admin	\$ 0.05
Allowed PMPM	\$ 0.04
UPPER BOUND IMPACT*	
Insured Population	1,530,411
Contribution to Total Annual Claims	\$ 780,089
Contribution to Total Annual Premium	\$ 865,597
Percent of Total Premium	0.005%

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

Nonprescription Enteral Formulas

The nonprescription enteral formula mandate requires coverage of medically necessary nonprescription enteral formulas for home use when prescribed by a physician to treat malabsorption caused by conditions such as

ulcerative colitis, Crohn's disease, gastro-esophageal reflux, gastrointestinal (GI) motility disorders, and chronic intestinal pseudo-obstruction, as well as inherited amino acid and organic acid disorders.²²⁷

Effect of the Mandate on Health

Enteral nutrition (EN), which can also be referred to as tube feeding, is a method of delivering nutrition directly to the stomach or small intestine.²²⁸ EN can be utilized as a supplement or as a main source of nutrition for an individual. For individuals who are experiencing difficulty eating but whose GI tracts are functioning normally, EN is preferable to parenteral^{xlix} nutrition, or IV feeding, as it is more similar to normal digestion and can aid immune system functioning.²²⁹ EN that is provided in a home setting is referred to as home enteral nutrition (HEN). For short-term EN, a nasogastric tube, in which a tube goes through the nose and into the stomach, is utilized. Another option is a nasojejunal tube,^l in which the tube goes through the nose and into the small intestine. For individuals who need a feeding tube for longer durations, a gastrostomy may be used, in which a tube goes through the skin on the abdomen and into the stomach, with another option being a jejunostomy, in which the tube goes into the small intestine instead.²³⁰

EN provides essential nutrients for individuals who are unable to consume enough orally.²³¹ Enteral formulas differ in caloric content and can include different sources and amounts of carbohydrates, proteins, fats, and micronutrients.²³² There are standard formulations of EN, as well as disease-specific formulations.²³³

EN can be needed for individuals with neurological conditions that impact swallowing, such as stroke, multiple sclerosis, and Parkinson's disease, as well as for individuals who are unable to swallow due to mechanical ventilation or altered mental status.²³⁴ Additional indications for EN include severe anorexia due to chemotherapy, HIV, sepsis, cystic fibrosis, severe burns, and dementia.²³⁵ For children, EN is indicated when the standard dietary intake alone is insufficient to fulfill energy and nutritional requirements of those who are experiencing growth delays, weight faltering, or weight deficit. EN may also be beneficial for children who have Crohn's disease, food allergies, and intolerances.²³⁶ EN is contraindicated for people with bowel ischemia or necrosis, active GI bleeding, small or large bowel obstruction, and peritonitis. It may also be contraindicated for those with severe malabsorption, diverticular disease, fistulas in the small bowel, and early-stage short bowel disease.^{237,238} Studies have demonstrated the effectiveness of EN on improving clinical outcomes, including reducing mortality for individuals who are critically ill in intensive care units.^{239,240} However, EN is associated with a range of complications, including complications due to tube placement, such as obstruction, leakage, breakage, and bleeding, as well as complications due to infections, such as infection at the tube insertion site, peritonitis, aspiration pneumonia, and infective gastroenteritis. GI complications can also occur with EN, such as nausea and vomiting, diarrhea, constipation, cramps, and bloating, as well as regurgitation and aspiration. The incidence of these complications can vary depending on the individual and the setting. For complications related to tube placement, studies have found a range of 0.5% – 16% of mispositioned

^{xlix} Parenteral refers to nutrition that is delivered intravenously.

^l A nasojejunal tube is a thin, flexible tube that is inserted through the nose to through the stomach, into the jejunum, a segment of the small intestine.

tubes. For GI complications, diarrhea is the most common and has been seen in 30% of patients, with nausea noted in 20% – 30% of patients after the initiation of enteral feeding.²⁴¹

Responding to recent consumer demands for more natural, health-conscious food sources, some manufacturers of EN have introduced commercially prepared food-based blenderized (food that has been blended until it becomes liquid) enteral formulations. This expansion has resulted in a wider array of enteral formula options available on the market, including standard (polymericⁱⁱ), semi-elementalⁱⁱⁱ, disease-specific, and specialty formulations with phytonutrients^{liii} and proposed pharmacological properties. However, disease-specific and specialty formulas can lack evidence from high-quality clinical trials to substantiate their claims. EN is classified by the U.S. Food and Drug Administration (FDA) as "medical food" that is designed for consumption or administration under physician supervision and is specifically tailored for managing certain diseases or conditions with distinct nutritional needs. Yet because the medical foods are not considered drugs by the FDA, companies who manufacture EN formulas are exempt from drug regulations, including labeling and clinical trial requirements.²⁴²

The American Gastroenterological Association recommends EN for patients who are unable or unwilling to consume food orally, who have a functioning GI tract, and who possess a safe and accessible method of access. HEN can serve as a vital life-sustaining therapy for individuals with a functional GI tract who cannot fulfill their nutritional requirements through oral intake but can reside in their own home.²⁴³

Estimated Marginal Cost of the Mandate

Carrier survey responses indicated a divide on whether non-prescription enteral formulas would be covered in the absence of the mandate because the formulas are considered food products, which are generally not covered by health insurance. The marginal cost was based on data from the carriers that indicated they would not or were unsure if they would cover nonprescription enteral formulas absent the mandate.

The mandate requires "coverage for nonprescription enteral formulas for home use...which are medically necessary for the treatment of mal-absorption caused by Crohn's disease, ulcerative colitis, gastro-esophageal reflux, GI 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 along with 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, and it is therefore considered an EHB under the ACA. The state mandate therefore impacts only large group plans.

ⁱⁱ Polymeric refers to a type of enteral formula composed of intact proteins, carbohydrates, and fats that is suitable for individuals with normal digestive function.

ⁱⁱⁱ Semi-elemental describes an enteral formula containing partially hydrolyzed proteins and simpler nutrients, often used for individuals with compromised GI function.

^{liii} Phytonutrients are bioactive compounds found in plants that are believed to have health-promoting properties and beneficial effects on physiology.

The estimated PMPM paid claim amount was \$0.03, with a total PMPM cost, after administrative loading, of \$0.04 (or 0.004% 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. These overlap amounts have been deducted from the impact estimate for the nonprescription enteral formula mandate, below. Table 11 displays a summary of these results and related statistics.

Table 6. Nonprescription Enteral Formulas Mandate Contribution to Premium

MEASURES	SAMPLE AMOUNT*
Sample Average Members	1,095,604
Paid PMPM	\$ 0.03
Paid PMPM With Admin	\$ 0.04
Allowed PMPM	\$ 0.03
UPPER BOUND IMPACT*	
Insured Population	1,530,411
Contribution to Total Annual Claims	\$ 612,092
Contribution to Total Annual Premium	\$ 679,185
Percent of Total Premium	0.004%

*Net amounts exclude overlap between the services mandated under the nonprescription enteral formula mandate and the low protein foods mandate.

Oral Cancer Therapy

The oral cancer therapy mandate requires coverage for cancer chemotherapy treatment for prescribed, orally administered anticancer medications used to kill or slow the growth of cancerous cells on a basis not less favorable than intravenously administered or injected cancer medications covered as medical benefits.²⁴⁴

Effect of the Mandate on Health

As one of the most common treatments for cancer, chemotherapy is a drug treatment that uses powerful chemicals to kill fast-growing cells, such as cancer cells that grow and multiply rapidly in the body.^{245,246} Chemotherapy drugs can be used alone or in combination to treat many forms of cancer.²⁴⁷ Chemotherapy drugs are cytotoxic, meaning the drugs can kill tumor cells.²⁴⁸ Unlike surgery and radiation, which can only treat one part of the body, chemotherapy is considered a systemic treatment and is intended to stop the rapid growth and reproduction of cancer cells by traveling throughout the bloodstream to reach all parts of the body. As a systemic treatment, chemotherapy can kill cancer cells that have spread (metastasized) away from the original (primary) tumor.^{249,250} The use of chemotherapy has three possible cancer treatment goals: to cure by destroying the cancer cells completely so

they do not come back; to control the cancer by slowing the growth of cancer cells or by shrinking tumors to help the individual feel better and live longer; and to ease symptoms, improving comfort and quality of life when cancer has spread and cannot be controlled, referred to as palliative chemotherapy.²⁵¹

Metastatic cancer was first cured by chemotherapy in 1956, and over the ensuing years, chemotherapy drugs have been used to successfully treat cancer, leading to long-term remissions and even cures.²⁵² Many types of chemotherapy are administered intravenously, through a catheter typically in the forearm or hand.²⁵³ For people with a longer chemotherapy regimen, a central venous catheter (CVC),^{liv} also called a port, is often used to minimize vein damage.²⁵⁴ Chemotherapy can include a single drug, but often several drugs are used together, referred to as combination therapy;²⁵⁵ treatments most often happen at a clinic, doctor's office, or hospital.²⁵⁶ Chemotherapy can be administered daily, weekly, or monthly but is typically given in on-and-off cycles; for example, in a three-week cycle a patient might get chemotherapy the first two weeks and then have a week off to let the body build new healthy cells and regain strength.²⁵⁷ A course of chemotherapy encompasses several cycles and varies based on the stage and type of cancer being treated.²⁵⁸

Although intravenous (IV) chemotherapy is commonly used to treat many types of cancer,²⁵⁹ alternative chemotherapy treatment regimens with new routes of administration are also available. These include oral chemotherapy, taken by mouth in the form of capsules, pills, or liquids, and topical chemotherapy, which is applied directly to the skin.^{260,261} Many patients prefer oral chemotherapy because it gives them a sense of control over their care, provides the convenience of a home-based therapy, and helps avoid multiple office visits.^{262,263} As with IV chemotherapy, physicians often prescribe oral chemotherapy drugs in combination, and they are sometimes given in rounds or cycles at varying doses. Although not all chemotherapy drugs are available in oral form, there are many that can be used to treat a variety of cancers, including ovarian, breast, colorectal, leukemia, lymphoma, multiple myeloma, and small-cell lung cancer.^{264,265} Side effects occur with both oral and IV chemotherapy, such as hair loss, skin changes, mouth sores, fatigue, bruising easily, infection or flu-like symptoms, and nausea, vomiting, or diarrhea.²⁶⁶

The success of oral chemotherapy depends on patients to strictly adhere to instructions, such as taking the right dose at the right time, reporting any missed doses, monitoring for complications, and knowing how to appropriately handle and store the medications.²⁶⁷ In order to decrease adverse events and maximize treatment effectiveness, patients need to have comprehensive medication therapy management services available that include education on oral chemotherapy medications, symptom management, and information related to food and drug interactions.^{268,269} Because patients are required to take a more active role in their treatment when undergoing oral chemotherapy, research has highlighted the significance of communication with clinicians and found that clinicians need to provide

^{liv} A CVC or port is a catheter that is placed in a large chest or arm vein via a minor procedure. The CVC/port can remain in place for a long period of time and be used to administer chemotherapy, antibiotics, and other treatments and medicines, as well as blood tests.

patients with information and support throughout their course of treatment to ensure their oral chemotherapy drugs are taken correctly.^{270,271,272,273,274}

Survival rates and chance of remission vary based on the type and stage of cancer. Research comparing the efficacy of oral chemotherapy drugs compared to their IV forms is limited. Studies that have compared the use of IV 5-fluorouracil (5-FU)^{lv,275,276} with oral 5-FU have demonstrated that the use of oral therapy has not compromised efficacy, safety, and quality of life.²⁷⁷ In some cases, oral chemotherapy may be more effective than the IV form as demonstrated in a study where oral paclitaxel^{lvi,278,279} and encequidar,^{lvii,280} were shown to be superior to the IV paclitaxel for progression-free survival as well as overall survival in metastatic breast cancer.^{281,282} By allowing patients to take their medication at home, oral chemotherapy offers a greater sense of control over treatment, minimizes disruptions to work and social life, and reduces the use of health care resources.^{283,284}

Estimated Marginal Cost of the Mandate

The marginal impact of this mandate was calculated as the decrease in PMPM patient cost sharing expenses (defined as the difference between PMPM allowed expenses and PMPM carrier-paid 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 2023 (after implementation of the law). The decrease in PMPM patient cost sharing was calculated by developing an estimate of the 2023 carrier-paid expenses in the absence of the mandate, by applying the ratio of carrier-paid expenses to allowed expenses in 2012 to the 2023 PMPM allowed expenses and then subtracting it from the 2023 PMPM carrier-paid expenses. BerryDunn used the 2012 estimate obtained from Massachusetts APCD Release 4.0 as the “before” period in the analysis of this mandate in CHIA’s 2016 comprehensive mandate review.^{lviii,285} 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 2023 than 2012 in the absence of the mandate, the effect of the mandate is understated by this methodology.^{lix}

^{lv} 5-FU is a drug commonly used for the treatment of certain forms of cancer by targeting rapidly dividing cells and can be delivered intravenously, orally, and topically.

^{lvi} Paclitaxel is a highly effective cancer treatment that works by disrupting cell division. Paclitaxel can be administered intravenously, or orally with the help of a P-glycoprotein inhibitor (a cell pump that regulates what enters and exits cells, including toxic substances like chemotherapy), such as encequidar.

^{lvii} Encequidar is a drug that helps the body absorb oral chemotherapy by bypassing toxicity receptors in the intestines to allow for chemotherapy absorption.

^{lviii} Massachusetts APCD Release 8.0 includes data for the years 2019 – 2023.

^{lix} That is, if patient cost sharing is measured at \$0.06 PMPM in 2012 and \$0.01 PMPM in 2023, but in the absence of the mandate patient cost sharing in 2023 would have been \$0.08, $\$0.06 \text{ PMPM} - \$0.01 \text{ PMPM} = \$0.05 \text{ PMPM}$ understates the effect of the mandate, which was actually $\$0.08 \text{ PMPM} - \$0.01 \text{ PMPM} = \$0.07$. Conversely, if for some reason 2023 cost sharing PMPM would have been lower than 2012 for these products even in the absence of the mandate, $\$0.05 \text{ PMPM}$ would overstate the effect of the mandate.

The estimated PMPM paid claim amount was \$0.07, with a total PMPM cost, after administrative loading, of \$0.08 (or 0.012 percent of the Commonwealth total premium). Table 9 below displays a summary of these results and related statistics.

Table 12. Oral Cancer Therapy Mandate Contribution to Premium

MEASURES	SAMPLE AMOUNT*
Sample Average Members	1,576,663
Decrease in Cost Sharing PMPM, 2012 – 2018	\$ 0.07
Decreased Cost Sharing With Admin	\$ 0.08
UPPER BOUND IMPACT	
Insured Population	2,150,129
Contribution to Total Annual Claims	\$ 1,854,850
Contribution to Total Annual Premium	\$ 2,095,168
Percent of Total Premium	0.012%

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

2.0 Aggregated Results of Mandates With 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 8. 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. Newer mandates deemed to have potential marginal direct cost will be covered in Section 4.0. The resulting marginal premium cost estimate of the statute membership is \$6.16 PMPM when spread over the entire fully insured and self-insured GIC commercial population, or 0.93% of premium. Table 7 below displays a summary of these results.

Table 7. All Benefit Mandates Total Contribution to Premium

MEASURES	PREMIUM IMPACT ESTIMATE
Insured Population	2,150,129
Paid PMPM	\$ 5.53
Paid PMPM with Admin	\$ 6.16
Contribution to Total Annual Claims	\$ 142,731,365
Contribution to Total Annual Premium	\$ 158,985,680
Percent of Total Premium	0.93%

Table 8 below shows these results at the mandate level.

Table 8. Summary of Estimated Costs for Massachusetts Mandated Benefits as of 2023 Dollars in Millions (000,000s)

MANDATE	MARGINAL CLAIMS ESTIMATE	MARGINAL PREMIUM IMPACT	PERCENT OF PREMIUM
Unduplicated Total All Mandates	\$ 142.73	\$ 158.99	0.93%
Massachusetts State Mandates with Potential Direct Marginal Cost			
Infertility Services	\$ 113.04	\$ 125.43	0.73%
Acute Treatment and Clinical Stabilization Services	\$ 9.98	\$ 11.31	0.07%
Medically Necessary Breast Cancer Screenings and Exams	\$ 5.02	\$ 5.67	0.03%
Annual Mental Health Wellness Examinations	\$ 4.47	\$ 5.05	0.03%
Oral Cancer Therapy	\$ 1.85	\$ 2.10	0.01%
Hearing Aids for Children	\$ 1.85	\$ 2.10	0.01%
Abortion	\$ 1.04	\$ 1.17	0.01%
Telehealth	\$ 0.99	\$ 1.11	0.01%
Contraceptive Services	\$ 0.88	\$ 1.00	0.01%
Low Protein Food Products	\$ 0.78	\$ 0.87	0.01%
Emergency Services Programs	\$ 0.73	\$ 0.82	0.00%
Nonprescription Enteral Formulas	\$ 0.61	\$ 0.68	0.00%

MANDATE	MARGINAL CLAIMS ESTIMATE	MARGINAL PREMIUM IMPACT	PERCENT OF PREMIUM
Fertility Preservation Services	\$ 0.52	\$ 0.59	0.00%
Universal Postpartum Home Visiting Services	\$ 0.48	\$ 0.54	0.00%
Cleft Palate and Cleft Lip	\$ 0.32	\$ 0.36	0.00%
ABA Services for Down Syndrome	\$ 0.16	\$ 0.18	0.00%

The first result column in Table 14 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. 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

Abuse-Deterrent Opioids

This mandate requires coverage for abuse-deterrent opioid (ADO) drug products on a basis not less favorable than non-abuse deterrent drug (NADO) drug products without an increase in patient cost sharing.²⁸⁶ For carriers with tiered copay structures based on a drug's benefit tier, carriers must apply the same cost sharing for an ADO as they do for the NADO that the Drug Formulary Commission (DFC) has identified as its chemically equivalent counterpart.²⁸⁷ If the DFC has not identified a chemically equivalent NADO for a particular ADO, carriers are not restricted in how they assign the drug to a benefit tier.²⁸⁸

Effect of the Mandate on Health

Opioids^{lx} are a class of drugs that can relax the body and reduce pain.²⁸⁹ Prescription opioids are mainly used to treat pain^{lxi,290} but are also used to treat some GI conditions or to treat a cough.²⁹¹ Opioids are sometimes taken for nonmedical reasons, which can be dangerous as opioids can be highly addictive.²⁹² Over time, individuals can develop a tolerance to opioids, requiring a higher dose to achieve either a therapeutic or otherwise desired effect and

^{lx} Opioids can be natural, semi-synthetic, or synthetic.

^{lxi} Opioids are used to treat chronic pain (pain lasting more than three months) and acute pain, cancer-related pain, post-surgical pain, and vascular pain.

causing withdrawal symptoms if they do not raise their doses or if they run out of their prescription. This can lead to individuals finding illegal sources of the opioid or using heroin.²⁹³

Any person who takes opioids is at risk of developing addiction,²⁹⁴ and all opioids carry a high risk of addiction.²⁹⁵ OUD is a pervasive condition that results from the “chronic use of opioids that causes clinically significant distress or impairment,” ranging from dependence on opioids to addiction.²⁹⁶ OUD affects about 2.1 million people in the United States of all educational and socioeconomic backgrounds. OUD signs and symptoms can be severe, and treatment can be difficult due to biological, environmental, genetic, and psychosocial factors.²⁹⁷

Opioid use is the major driver of the U.S. drug overdose crisis, with most recent overdose deaths linked to illegally manufactured fentanyl^{lxii,298} and other synthetic opioids.^{lxiii,299} In 2022, nearly 82,000 people in the United States died from opioid overdoses, including overdoses due to prescription opioids.³⁰⁰ Nationally, while opioid-involved deaths have increased from 2019 to 2022, commonly prescribed opioids are no longer driving the overdose epidemic.³⁰¹

In Massachusetts, between 2013 and 2022, the opioid overdose death rate more than doubled.^{lxiv,302} Between 2013 and 2021, for every fatal opioid overdose, there were an average of nine NFOs.³⁰³ In 2023, the Massachusetts Department of Public Health (DPH) reported a 10% decline in opioid-related deaths, with the rate dropping from 33.5 to 30.2 deaths per 100,000 residents.³⁰⁴ This decrease corresponds to a reduction in fatalities from 2,357 in 2022 to 2,125 in 2023. From January to March 2024, DPH estimates 507 people had an opioid-related death.^{lxv,305}

Abuse-Deterrent Formulations and Technology

Both types of pharmacologically formulated opioids, immediate-release (IR)³⁰⁶ and extended-release (ER)^{lxvi} opioid formulations, are subject to abuse, misuse, and diversion;^{307,308} however, ER formulations have a greater risk of overdose compared to IR formulations.³⁰⁹ ADOs were developed as part of a multifaceted strategy to address the opioid epidemic.³¹⁰ Abuse-deterrent IR and ER formulations have qualities that make manipulation such as chewing or crushing and nonoral routes (i.e., inhalation or IV injection) more difficult and/or less rewarding.³¹¹ Misuse of prescription opioids via tampering^{lxvii,312} is associated with greater medical costs than misuse without tampering.

^{lxii} Illegally or illicitly manufactured fentanyl is usually sold as a powder and/or made into pills that look like other prescription opioids.

^{lxiii} These synthetic opioids are often mixed with other illicit drugs (e.g., heroin, cocaine, methamphetamine, MDMA) without the buyer's knowledge, significantly increasing the risk of overdose.

^{lxiv} From 14.2 to 30.7 deaths per 100,000 residents to 33.5 per 100,000 residents.

^{lxv} DPH confirmed 85 opioid-related overdose deaths and estimated an additional 382 – 463 deaths from January to March 2024.

^{lxvi} ER opioids are intended for the treatment of chronic pain conditions, have higher amounts of the active agent, and are designed to release the active agent over a longer period. IR formulations provide pain relief for 3 – 6 hours, and ER formulations provide pain relief for 6 – 24 hours, depending on the formulation. ER formulations have a greater risk of overdose compared to IR formulations.

^{lxvii} Tampering “refers to the manipulation of prescription opioid tablets, capsules or patches to achieve a more rapid psychoactive effect or “high” through chewing, inhalation, nasal insufflation or injection.”

Both the abuse-deterrent formulation technologies and the analytical, clinical, and statistical methods for determining the efficacy of these technologies are relatively new and rapidly evolving.³¹³ The “abuse-deterrent” label does 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.^{314,315} The FDA encourages the development of abuse-deterrent formulations of prescription opioids, while also recognizing that ADOs are not abuse- or addiction-proof.³¹⁶ There are currently four opioids with FDA-approved abuse-deterrent properties, including one generic opioid (See Table 9).³¹⁷

Table 9. ADO Attributes

ADO	ADO ATTRIBUTES ³¹⁸
OxyContin (oxycodone ER)	Physical and chemical properties that make it difficult to crush, break, or dissolve for intranasal or IV abuse
Hysingla ER (Hydrocodone bitartrate)	Physical and chemical properties that make it difficult to crush, break, or dissolve for intranasal or IV abuse
Xtampza ER	Physical and chemical properties that allow it to maintain its ER properties even after chewing and crushing; becomes viscous when crushed and heated for IV abuse; waxy formulation causes drug to smear rather than breaking apart
RoxyBond	Only IR ADO currently available; contains inactive ingredients that make it difficult to extract opioid for intranasal or IV abuse
Hydrocodone Bitartrate (generic)	Physical and chemical properties that make it difficult to crush, break, or dissolve for intranasal or IV abuse

Utilization of ADOs remains low in part because cost is a significant barrier³¹⁹ for patients to receive an ADO due to inadequate insurance coverage, prior authorization requirements,^{320,321} and limited generic options.³²² One recent study reports that ADOs would be effective at preventing 2,300 new cases of opioid misuse with a cost of \$535 million (i.e., \$232,000 to prevent one new case of misuse), assuming 100% effectiveness of the technology.³²³ In a similar study that modelled Massachusetts’ ADO health policy, researchers found that converting all NADOs to ADOs over one year would prevent 850 new cases of opioid misuse with a cost of \$599,000 per case.³²⁴ Some patients would also not be able to use ADOs, including patients who cannot take medications orally, such as hospice patients.³²⁵

The United States is experiencing a drug overdose epidemic, with opioids as a main driver. ADOs were developed as part of a mitigation strategy to reduce opioid misuse. Research on the safety and efficacy of ADOs is both limited and ongoing.³²⁶ ADOs are associated with a decrease in the number of opioids prescribed and dispensed, and formulary coverage for ADOs is associated with decreased rates of opioid abuse and overdose.³²⁷ Some ADOs are better than others at deterring opioid diversion and manipulation.³²⁸ ADO formulations do not alter the potential for dependence, an individual’s physical adaptation to prescribed opioids, or the potential for addiction. ADO formulations can deter or reduce certain methods of misuse but not all instances.³²⁹ Cost is a significant consideration for prescribing ADOs, both for individuals and for the health care system overall.

Estimated Marginal Cost of the Mandate

The majority of responses to the carrier survey indicated that these products would be covered in the absence of the state mandate and have zero cost. One respondent to the carrier survey indicated that the cost associated with the mandate was unclear, and another respondent to the carrier survey indicated there was a slight cost. In the prior comprehensive study, the three-year average cost trends for abuse-deterrent and non-abuse-deterrent opioids were negative. This has remained true based on the three-year average trend of -11% for ADOs from 2021 to 2023. This study therefore estimates the 2023 marginal, direct cost of this mandate as \$0 and 0% of Commonwealth fully insured premium.

Autism Spectrum Disorders

The autism spectrum disorder (ASD) mandate requires coverage for the diagnosis and treatment of ASDs^{lxviii} in individuals on a nondiscriminatory basis, equivalent to the terms applied to medical and surgical conditions. As defined in the mandate, treatment of ASDs includes habilitative or rehabilitative care,^{lix} pharmacy care, psychiatric care, psychological care, and therapeutic care as prescribed by a licensed physician or a licensed psychologist who determines the care to be necessary.³³⁰

Effect of the Mandate on Health

ASD is a complex neurological and developmental disorder that typically emerges early in life, impacting how individuals interact with others, communicate, behave, and learn.³³¹ In order to be diagnosed with ASD pursuant to Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria, symptoms must be present in the early development period. While these symptoms might not become fully apparent until social demands surpass the individual's capabilities, they must cause clinically significant impairments in social, occupational, or other critical areas of functioning.³³² These disturbances, which cannot be better explained by intellectual disability or global developmental delay, are defined by two key characteristics: persistent deficits in social communication and interaction, and restricted, repetitive patterns of behavior, interests, or activities.^{333,334,335} Further, as set forth in the DSM-5, individuals with a well-established DSM-IV diagnosis of autistic disorder, Asperger's disorder, or pervasive developmental disorder not otherwise specified should be given an ASD diagnosis.³³⁶

The symptoms of ASD are further influenced by challenges such as deficits in imitation and difficulties processing information across sensory modalities, including vision (e.g., gestures) and hearing (e.g., language).³³⁷ Additionally,

^{lxviii} Pursuant to M.G.L. c.175 §47AA, 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."

^{lix} 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."

approximately one quarter of children with ASD experience regression in language or social skills, most commonly between 18 and 24 months of age.³³⁸

Co-occurring conditions are also prevalent in individuals with ASD, including sleep disorders, seizures, other developmental and behavioral diagnoses, GI disorders, and obesity. These conditions significantly impact health and quality of life, requiring appropriate medical management.³³⁹ For autistic adults, living with ASD can present additional challenges, such as difficulties in social interactions, heightened sensitivities to light or sound, and strong reliance on routines.³⁴⁰ These factors can make independent living more difficult for some adults with ASD.³⁴¹

Diagnosing ASD can be challenging because there is no single medical test, such as a blood test, to confirm the condition. The diagnostic process involves multiple steps, which may lead to some individuals being diagnosed only in adolescence or adulthood.³⁴² In order to diagnose ASD, doctors observe a child's behavior and review their developmental history.³⁴³ Although the initial signs and symptoms are usually apparent early in a child's development, and ASDs can be identified by age one in certain cases, 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.³⁴⁴ The American Academy of Pediatrics (AAP) recommends that developmental and behavioral screening be conducted for all children during regular well-child visits at 9, 18, and 30 months of age; it further recommends children be screened specially for ASD during well-child visits at 18 and 24 months of age.^{345,346,347} The U.S. Preventive Services Task Force (USPSTF) is updating its 2016 screening recommendations for ASDs in young children; its final recommendation is still in development.³⁴⁸

From 2000 to 2020, the prevalence of ASDs has risen dramatically based on estimates from the Autism and Developmental Disabilities Monitoring (ADDM) Network as reported by the CDC,^{lxx,349,350} set forth in [Table 10](#) below:

Table 10. ADDM Network 2000 – 2020: Prevalence of ASDs Among Children Aged 8 Years³⁵¹

SURVEILLANCE YEAR	2000	2006	2012	2018	2020
Prevalence	1 in 50	1 in 110	1 in 69	1 in 44	1 in 36
Per 1000 children	6.7	9.0	14.5	23.0	27.6

The median age of earliest ASD diagnosis varies, ranging from 36 months in California to 59 months in Minnesota, with a median age of 49 months across ADDM sites.³⁵² The CDC attributes the rising prevalence of ASD largely to increased awareness, resulting in more children being identified with the condition.³⁵³

^{lxx} The ADDM Network is an active surveillance program that estimates the prevalence of ASDs among children aged eight years. To determine ASD among children aged eight years, ADDM Network staff review and abstract developmental evaluations and records from community medical and educational service providers to determine if a child meets the ASD case definition. In 2020, there were 11 ADDM sites in the United States (Arizona, Arkansas, California, Georgia, Maryland, Minnesota, Missouri, New Jersey, Tennessee, Utah, and Wisconsin).

Each child with ASD has different needs³⁵⁴ and there is no one standard treatment for ASD; however, there are many therapies and interventions to help minimize symptoms and maximize abilities.³⁵⁵ ASD treatment should be based on sound theoretical constructs, objective scientific evidence of effectiveness, and rigorous methods.³⁵⁶ As set forth in a 2020 AAP clinical report, the goals of treatment, which should be individualized, developmentally appropriate, and intensive, for children with ASDs are to:³⁵⁷

- 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

Although there is no cure for ASDs, research has shown that EI can improve learning, communication, and social interaction, making early identification and diagnosis of ASDs important to treatment outcomes.^{358,359,360,361} A recent meta-analysis concluded that while EI may not always result in positive outcomes for cognitive ability, language, communication, and socialization in children with ASDs, these findings should be interpreted cautiously due to the significant variability in participants and the characteristics of the interventions.³⁶² However, despite these findings, the same study found that EI had significant positive effects on daily living and motor skills, which are important for everyday life and social communication. The study emphasized the need for future research focused on more specific intervention groups with comparative cognitive ability at baseline.³⁶³ As categorized by the CDC, the types of ASD treatments and interventions available can generally be broken down into the following categories: behavioral, developmental, educational, social-relational, pharmacological, psychological, and complementary and alternative.³⁶⁴

Behavioral treatments have the most evidence for treating symptoms of ASD, focusing on changing behaviors by understanding what happens before and after a behavior, and are widely accepted by educators and health care professionals and used in many schools and treatment clinics. ABA is a notable behavioral treatment that encourages desired behaviors and discourages undesired behaviors to improve a variety of skills and track progress. Some examples of the different types of ABA are Discrete Trial Training (DTT); Early Intensive Behavioral Intervention (EIBI); Pivotal Response Training (PRT); and Verbal Behavior Intervention (VBI).^{365,366} As a discipline focused on applying behavioral science in real-world environments aiming to improve behavior problems and learning,³⁶⁷ 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).³⁶⁸ Comprehensive ABA interventions are aimed at producing changes in specific skills that impact 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.³⁶⁹

ABA has been studied for decades as an intervention used in children with ASDs and its effectiveness has been well documented.³⁷⁰ This research shows that intensive ABA therapy was associated with achieving optimal developmental outcomes³⁷¹ and that long-term comprehensive ABA is suggested to result in (positive) medium-to-large effects regarding intellectual functioning, language development, acquisition of daily living skills, and social

functioning.³⁷² Considered as an evidence-based^{lxxi} treatment by the U.S. Surgeon General,³⁷³ ABA interventions have been shown to be effective for improving social skills, adaptive behaviors, language abilities, and cognitive skills as well as helpful for reducing anxiety in children and adolescents.³⁷⁴

Developmental treatment approaches for ASD focus on enhancing essential skills such as language and physical abilities. These approaches include speech and language therapy, occupational therapy (OT), sensory integration therapy, and physical therapy (PT), all aimed at fostering overall development. Educational approaches to ASD treatment are provided in the classroom setting. Treatment and Education of Autistic and Related Communication Handicapped Children (TEACCH) provided teachers with ways to adjust classroom structure and improve outcomes and is based on the concept that people with autism thrive on consistency and visual learning. Based on the principles of ABA, Early Start Denver Model (ESDM) is another developmental approach where 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. Social-relational treatment approaches can involve parent or peer mentors and focus on improving social skills and building emotional bonds, such as the Developmental, Individual Differences, Relationship-Based Approach (also called “Floortime”).³⁷⁵ EIBI is an immersive behavioral therapy recommended for preschool to early school-aged children with ASDs.³⁷⁶ Psychological approaches to ASD treatment focus on helping people with ASD cope with anxiety, depression, and other mental health conditions.³⁷⁷

There are no medications to specifically treat ASD itself; however, pharmacological treatments target co-occurring symptoms or conditions, helping individuals with ASD to function more effectively. These treatments can be a valuable complement to behavioral and environmental interventions.^{378,379,380} Relatedly, the FDA has approved aripiprazole and risperidone for the treatment of ASD-associated irritability.^{381, 382} Pharmacologic interventions might also be used to treat other maladaptive behaviors such as aggression, self-injurious behavior, repetitive behaviors, sleep disturbance, mood lability, anxiety, hyperactivity, inattention, destructive behavior, or other disruptive behaviors after careful consideration of the potential benefits and risks on a case-by-case basis.³⁸³

With an unknown etiology and no cure, ASDs continue to remain challenging conditions for patients and families. However, significant advances have been made in diagnosing and managing ASD and there are many interventions that may help individuals with ASD by alleviating some symptoms and improving skills;³⁸⁴ with EI, there are some children who make such significant progress that they are no longer on the autism spectrum when they are older.³⁸⁵ To ensure appropriate care for all children and families affected by ASD, collaboration among health care, education, and public health systems is essential.³⁸⁶ Further, as research advances, genetic testing may play a key role in identifying effective interventions related to specific etiologies.³⁸⁷

Estimated Marginal Cost of the Mandate

The majority of responses to the carrier survey indicated that these services would be covered in the absence of the state mandate and have zero cost. While some carriers did note a potential cost to the mandate, responses indicated

^{lxxi} Evidence-based means that ABA has passed scientific tests of its usefulness, quality, and effectiveness.

that the cost is minor and difficult to measure. This study therefore estimates the 2023 marginal direct cost of this mandate as \$0 and 0% of Commonwealth fully insured premium.

Behavioral Health Care^{lxxii}

This mandate requires coverage for the diagnosis and medically necessary treatment of any mental disorder described by the most recent edition of the DSM and approved by the Commissioner of Mental Health. Diagnosis and treatment must be provided by a licensed mental health professional^{lxxiii} and can include inpatient treatment,^{lxxiv} outpatient visits,^{lxxv} and intermediate services.^{lxxvi} Carriers must also provide coverage for the diagnosis and treatment of biologically based mental disorders as outlined in the most recent edition of the DSM, including:

- Schizophrenia
- Schizoaffective disorder
- Major depressive disorder (MDD)
- Bipolar disorder
- Paranoia and other psychotic disorders
- Obsessive-compulsive disorder
- Panic disorder
- Delirium and dementia
- Affective disorders
- Eating disorders
- Post-traumatic stress disorder (PTSD)
- SUD
- ASD

The mandate also requires carriers to cover mental health benefits 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.³⁸⁸

Effect of the Mandate on Health

Mental health includes emotional, psychological, and social well-being, and it affects how people think, feel, and act.³⁸⁹ Mental health conditions, also known as mental illnesses, are disorders ranging from mild to severe that affect a person's thinking, mood, and/or behavior.³⁹⁰ Mental illnesses are among the most common health conditions in the United States, with more than one in five adults currently living with a mental illness.³⁹¹ Moreover, suicide, which is

^{lxxii} The behavioral health care statute describes coverage for mental and behavioral health conditions. References to this mandate use the terms 'mental health care' and 'behavioral health care' synonymously.

^{lxxiii} Licensed mental health professional means a licensed psychiatrist, psychologist, independent clinical social worker, mental health counselor, nurse mental health clinical specialist, a clinician practicing under the supervision of a licensed professional and working toward licensure in a licensed clinic, alcohol and drug counselor, or a licensed marriage and family therapist within the lawful scope of practice for such therapist.

^{lxxiv} For each 12-month period, the mandate requires at least 60 days coverage for inpatient treatment.

^{lxxv} For each 12-month period, the mandate requires coverage for a minimum of 24 outpatient visits.

^{lxxvi} Intermediate services include Level III community-based detoxification, acute residential treatment, partial hospitalization, and/or day treatment and crisis stabilization.

most often attributable to mental illness, is the 11th leading cause of death in America, with over 48,000 cases each year.³⁹²

There are two broad categories that define mental illnesses: any mental illness (AMI) and serious mental illness (SMI).³⁹³ AMI is defined as a mental, behavioral, or emotional disorder, with varying impact for an individual.³⁹⁴ SMI is a smaller and more severe subset of AMI that results in serious functional impairment for an individual.³⁹⁵ As of 2022, 23.1% of U.S. adults live with a mental illness, and the prevalence of SMI in adults is 6%.³⁹⁶ As of 2024, in Massachusetts, an estimated 1,300,000 people over 18 have AMI, and an estimated 330,000 people over 18 have SMI.³⁹⁷

There is no single cause for developing a mental health condition, but many factors can contribute to the development and/or presentation of mental illness, such as biological factors, life experiences, trauma, and family history of mental health conditions.³⁹⁸ A person may experience multiple mental health conditions simultaneously.³⁹⁹ Mental health and physical health are closely linked and are both important components of overall health.⁴⁰⁰ Research suggests that social determinants of health (SDOH) such as income, employment, socioeconomic status, education, food security, housing, and access to care can affect the likelihood of development of mental health conditions or protect against the development and/or severity of certain conditions.^{401,402}

The ACA⁴⁰³ requires all non-legacy plans to cover screenings with an “A” or “B”^{lxxvii,404} grade from the USPSTF and treatment without cost sharing.⁴⁰⁵ For mental health preventive services, the USPSTF currently gives a grade “A” or “B” rating to:⁴⁰⁶

- Screening adults, including pregnant and postpartum women, for depression. Adequate systems should be in place for accurate diagnosis, effective treatment, and appropriate follow-up.
- Screening adolescents (12 – 18 years of age) for MDD. Adequate systems should be in place for accurate diagnosis, effective treatment, and appropriate follow-up.
- Screening for intimate partner violence (IPV) in women of reproductive age. Provide or refer women who screen positive to ongoing support services.
- Screening in primary care settings of adults 18 years or older, including pregnant women, for unhealthy alcohol use and providing people engaged in risky or hazardous drinking with brief behavioral counseling interventions to reduce unhealthy alcohol misuse.
- Screening adults 18 years or older for unhealthy drug use. This should be implemented when services for accurate diagnosis, effective treatment, and appropriate care can be offered or referred.

^{lxxvii} The USPSTF assigns letter grades to recommendations to describe the strength of recommendations. A “B” grade means the USPSTF recommends the service be offered or provided and there is a high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial.

- Screening all adults about tobacco use, advising them to stop using tobacco, providing behavioral interventions, and providing FDA-approved pharmacotherapy for cessation to nonpregnant adults who use tobacco.
- Screening all pregnant people about tobacco use, advising them to stop using tobacco, and providing behavioral interventions for cessation to pregnant people who use tobacco.
- Providing interventions by primary care clinicians, including education or brief counseling, to prevent initiation of tobacco use among school-age children and adults.
- For pregnant and postpartum people at risk of perinatal depression (PND), providing or referring to counseling interventions.

A positive screen can help identify if a person needs further evaluation for a mental health condition. A person must be evaluated by a qualified mental health professional^{lxxviii} to be diagnosed with a mental illness.⁴⁰⁷ Currently, the DSM-V-TR is the most up-to-date manual used to diagnose mental health disorders in the United States.

Treatments for mental health conditions vary by individual, illness, and other factors that also influence outcomes. Research on effectiveness includes these factors and other variables. The most common mental health treatment is psychotherapy,^{lxxix,408} medication, or both.⁴⁰⁹ Psychotherapy is used to help patients understand their illnesses, and it provides tools to manage symptoms and improve function. Medications can be an important part in treating mental disorders and conditions.⁴¹⁰ Medications can affect people in different ways, and several options may be attempted before an individual finds the medication that works best with the fewest side effects.⁴¹¹ Common medications used to treat mental health conditions include antidepressants, anti-anxiety medications, stimulants, antipsychotics, mood stabilizers,⁴¹² and medications for OUD (a type of SUD).⁴¹³

The United States is currently experiencing a mental health crisis in addition to an opioid epidemic, both contributing to increased mental and behavioral health needs.⁴¹⁴ Although the prevalence of mental health disorders is high and continues to grow, the majority of individuals who meet diagnostic criteria for a mental disorder are unable to access evidence-based psychological treatments and mental health professionals needed to facilitate such treatment.⁴¹⁵ The Health Resources and Services Administration (HRSA) projects significant shortages for mental and behavioral

^{lxxviii} The list includes psychiatrists, psychologists, psychiatric nurses, social workers, and mental health counselors. Family doctors, internists, and pediatricians can diagnose more common disorders such as depression, anxiety disorders, and ADHD.

^{lxxix} Psychotherapy, or talk therapy, involves a variety of treatments that aim to help a person identify and change troubling emotions, thoughts, and behaviors. The goals of psychotherapy are to have individuals gain relief from symptoms, maintain or enhance daily functioning, and improve quality of life. There are many types of therapy, and psychotherapy treatment is tailored to specific disorders.

health providers, due to low reimbursement rates, restrictive and inconsistent scopes of practice and policies across states, large workloads, large caseloads, workplace violence, a lack of organizational support, and burnout.^{lxxx,416}

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/SUD benefits and medical/surgical benefits.⁴¹⁷ In 2024, the U.S. Department of Health and Human Services (HHS), Labor, and the Treasury released new final rules implementing MHPAEA with content requirements and time frames for responding to requests for nonquantitative treatment limitations (NQTLs) comparative analysis. These final rules aim to protect plan members from facing greater restrictions on access to mental health treatment benefits as compared to medical/surgical benefits.⁴¹⁸ Some final rules apply to group health plans and group health insurance coverage on January 1, 2025, and some final rules apply on January 1, 2026.⁴¹⁹

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 2023 marginal, direct impact of the state mandate is therefore \$0 and 0% of Commonwealth fully insured premium.

^{lxxx} Burnout often occurs because of emotionally taxing positions, high-stress environments, lack of career advancement, low salaries, and high caseloads.

Bone Marrow Transplants (BMT) for Treatment of Breast Cancer

The bone marrow transplant (BMT) mandate requires coverage for BMTs for patients with metastatic^{lxxxix,420} breast cancer if they meet criteria set by the DPH.^{lxxxii,421,422}

Effect of the Mandate on Health

In the 1990s, despite limited clinical evidence of its efficacy, more than 41,000 patients underwent high-dose chemotherapy^{lxxxiii,423} combined with autologous^{lxxxiv} BMT^{lxxxv,424} (HDC-ABMT) as a treatment for breast cancer.⁴²⁵ Although most often considered experimental,^{426,427} HDC-ABMT was used as a treatment for advanced breast cancer or breast cancer with a high probability of recurrence, as there were no other treatment options believed to reduce the probability of cancer recurrence.^{428,429} A few studies supported the use of HDC-ABMT as a valid treatment option with the potential to increase the disease-free survival rate for certain breast cancer patients.^{430,431,432}

However, during the time of HDC-ABMT's use, treatment for high-risk breast cancer was rapidly evolving with the development of new interventions and additional research findings discrediting HDC-ABMT as a treatment regimen for this patient population. These studies found that HDC-ABMT had serious side effects, including an increased treatment-related mortality, with little or no increase in survival for patients with early poor prognosis breast cancer⁴³³ when compared to standard dose chemotherapy.^{434,435,436,437,438,439,440,441} As a result of these findings, HDC-ABMT was removed from the National Comprehensive Cancer Network clinical practice guidelines in 1996.⁴⁴²

Recent advancements in tumor biology and prognostic biomarkers, such as progesterone and estrogen receptors and HER2/neu,^{lxxxvi,443} have resulted in cancer staging and typing to target treatment instead of determining treatment by tumor size.⁴⁴⁴ Along with changes in breast cancer staging impacting treatment options, newer agents have been developed, such as taxanes^{lxxxvii} and immunotherapy drugs. These agents have shown benefits in both the adjuvant^{lxxxviii} and metastatic settings without large increases in toxicity for the treatment of breast cancer.^{445,446} As a

^{lxxxix} Pursuant to 105 CMR 240.004, metastatic disease refers to "Stage III and Stage IV breast cancer, as well as Stage II breast cancer...which has spread to ten or more lymph nodes, as defined by the American College of Surgeons."

^{lxxxii} 105 CMR 240.005 stipulates that carriers provide coverage for BMT if the individual meets the eligibility requirements for a clinical trial that meets the requirements set forth in 105 CMR 240.006. Pursuant to these requirements, the clinical trial shall be conducted: 1) "in accordance with a protocol approved by an institutional review board meeting the requirements for the protection of human subjects specified in 45 CFR Part 46"; and 2) "at a licensed health care facility which is located at the principal site of an academic medical center which participates in NCI sponsored or approved research in any cancer specialty area" or "which has a formal affiliation agreement with an academic medical center to provide bone marrow transplantation as part of an NCI sponsored or approved research protocol."

^{lxxxiii} HDC is an intensive drug treatment that kills cancer cells and destroys bone marrow. HDC is usually followed by a bone marrow or stem cell transplantation to rebuild the bone marrow.

^{lxxxiv} Autologous means that the individual is both the donor and the recipient.

^{lxxxv} Autologous BMT is "a procedure in which a patient's healthy stem cells (blood-forming cells) are collected from the bone marrow before treatment, stored, and then given back to the patient after treatment. An autologous bone marrow transplant replaces a patient's stem cells that were destroyed by treatment with radiation or high doses of chemotherapy."

^{lxxxvi} HER2/neu, also called HER2, is a type of tumor marker and stands for human epidermal growth factor receptor.

^{lxxxvii} Taxanes are a class of chemotherapy drugs that inhibit cell division and destroy cancer cells.

^{lxxxviii} Adjuvant refers to an additional treatment administered after the primary treatment to enhance its effectiveness.

result, current treatments for breast cancer no longer include the use of HDC-ABMT and are focused on the use of less toxic and targeted agents.⁴⁴⁷

Estimated Marginal Cost of the Mandate

BMT as a breast cancer treatment is no longer considered medically necessary as newer treatments perform better and cause less toxicity. Therefore, this mandate requires coverage of services that are generally no longer performed. Additionally, respondents to the carrier survey universally agreed that this mandate will not result in additional expenditures. This study therefore estimates the 2023 marginal direct cost of this mandate as \$0 and 0% of Commonwealth fully insured premium.

Cardiac Rehabilitation

The cardiac rehabilitation (CR) mandate requires insurance coverage of CR services. For the purposes of this review, CR shall mean the multidisciplinary, medically necessary treatment of individuals with documented cardiovascular disease (CVD) that is provided in either a hospital or other setting and meets standards promulgated by the Commissioner of Public Health. These standards include, but are not limited to, outpatient treatment that is initiated within 26 weeks after the diagnosis of a cardiovascular condition or disease.^{448,449}

Effect of the Mandate on Health

CVD is the leading cause of death for people in the United States and has been the leading cause for over 100 years.^{450,451} Coronary artery disease caused by atherosclerosis^{lxxxix,452} is the most common CVD and often leads to a heart attack.⁴⁵³ In the United States in 2021, there were 931,578 cardiovascular-related deaths, and 40.3% of these were attributed to coronary artery disease, 17.5% to smoking, 13.4% to high blood pressure, 9.1% to heart failure, 2.6% to diseases of the arteries, and 17.1% to all other minor CVD causes.⁴⁵⁴ In Massachusetts in 2022, there were 12,427 heart disease-related deaths and 8.1% of adults report being told by a doctor they have CVD.^{455,456} It is estimated that 48.6% of people in the United States currently have some type of CVD or risk factor for developing CVD such as coronary heart disease, heart failure, or high blood pressure.⁴⁵⁷ High blood pressure (also referred to as hypertension) is the most common risk factor for developing CVD affecting 46.7% of U.S. adults, of whom 38% are unaware of their condition.⁴⁵⁸ In addition to hypertension, there are many other risk factors for developing CVD, including high cholesterol, smoking, diabetes, obesity, unhealthy diet, lack of physical activity, and excessive alcohol use.⁴⁵⁹

CR is a medical program designed to help individuals improve their cardiovascular health to address a cardiovascular-related condition or following a serious cardiac event such as heart attack (myocardial infarction) or sudden cardiac arrest.⁴⁶⁰ Conditions for which CR can be beneficial include atherosclerosis, cardiac arrest, congenital heart defects, heart attack, coronary artery disease, heart valve disease, peripheral artery disease, stable angina, stable chronic heart failure, cardiac arrhythmias, and severe arterial hypertension. In addition, CR is

^{lxxxix} Atherosclerosis is a condition where plaque formed by cholesterol, fat, blood cells, and other substances builds up in the arteries, which causes narrowing of the arteries and leads to reduced blood flow throughout the body.

beneficial after coronary artery bypass surgery, percutaneous coronary interventions, heart transplantation, and heart valve repair.^{461,462,463} There are three phases of CR: clinical, outpatient CR, and post-CR.⁴⁶⁴

Table 11. Phases of CR

Clinical
<ul style="list-style-type: none"> ▪ Follows stabilization after a cardiac event ▪ Takes place in the hospital, typically at the bedside with therapists and nurses ▪ Involves: <ul style="list-style-type: none"> ○ Working on range of motion ○ Limiting deconditioning ○ Addressing activities of daily living (ADLs) ○ Learning to use assistive devices ○ Individual and family education ○ Developing strategies for avoiding excessive stress ○ Post-discharge planning
Outpatient CR ^{465,466,467}
<ul style="list-style-type: none"> ▪ Usually takes 3 – 6 weeks but can last up to 12 weeks ▪ Consists of 36 one-hour sessions working with a rehabilitation team that may consist of cardiologists, specialty providers, nurses, dietitians, physical therapists, exercise specialists, occupational therapists, and mental health specialists⁴⁶⁸ ▪ Involves designing a patient-centered therapy plan that addresses three areas: <ul style="list-style-type: none"> • Exercise counseling and training, including: <ul style="list-style-type: none"> ○ Resistance training ○ Exercise training ○ Stability exercises ○ Coordination training ○ Yoga • Education and lifestyle modification, including: <ul style="list-style-type: none"> ○ Addressing smoking cessation ○ Blood pressure control ○ Diabetes control ○ Improving cholesterol ○ Weight control • Psychological intervention, including: <ul style="list-style-type: none"> ○ Counseling and education for reducing stress and anxiety ○ Developing strategies for relaxation
Post-CR ⁴⁶⁹
<ul style="list-style-type: none"> ▪ Supports individuals in building and maintaining independence and learning self-monitoring ▪ This phase can include:

-
- Exercises for flexibility, strengthening, and aerobic conditioning
 - Continuation of lifestyle modifications
 - Close monitoring by an individual's cardiologist
-

The overall goal of CR is to develop the optimal psychological and physical conditions to prevent CVD from progressing, and ideally reverse progression, as well as reduce the risk of sudden death and reinfarction.^{470,471} This includes incremental goals such as improving exercise tolerance, optimizing cardiac risk factors, lowering cholesterol levels, improving weight, lowering blood glucose levels, reducing blood pressure, stopping smoking, improving diet, and controlling diabetes symptoms.⁴⁷²

CR has been shown to improve exercise capacity, control of cardiovascular risk factors, quality of life, hospital readmission rates, overall and cardiovascular mortality rates, mood, and medication adherence for all ages of individuals following a cardiac event or diagnosis, with older adults or individuals with lower baseline exercise tolerance experiencing the greatest relative benefit.^{473,474} CR has also been shown to decrease health care costs, increase VO₂max,^{xc,475} improve endothelial function, reduce body weight, lower blood pressure, and decrease symptoms of depression.⁴⁷⁶ Research shows that individuals who attend 36 sessions of outpatient CR have a 47% lower risk of death and a 31% lower risk of heart attack compared to those who only attend one session.⁴⁷⁷

Despite the proven benefits of CR, participation has remained low, with only 19% – 34% of eligible individuals participating in 2016. Many patients face financial barriers related to the cost of copays and others may face barriers related to transportation, language, and/or support. Another significant factor influencing participation rates in CR programs is the referral process. Referral rates to these programs are lower among women, racial and ethnic minorities, older adults, and individuals with co-occurring medical conditions, even when they have cardiovascular disease or have recently experienced a cardiac event. These disparities in referral rates are notable, with eligible Black women 60% less likely than white women to be referred for CR and enrolled in a program and with individuals living outside of metropolitan areas 30% less likely to participate in these programs. Many individuals also face long wait times between hospital discharge and starting a CR program, which can lead to a lower likelihood that the individual will participate in the program. Research shows that every day of waiting between hospital discharge and starting rehabilitation leads to a 1% lower likelihood of the individual enrolling. To increase participation in CR programs, the Million Hearts® Program 2027, renewed in 2017 and led by the CDC and the Centers for Medicare & Medicaid Services (CMS), recommends physicians provide referrals to all of their eligible patients and emphasize the importance of completing CR. Additionally, the Million Hearts® Program recommends that CR providers ensure shorter times between hospital discharge and the initiation of rehabilitation, create culturally and linguistically appropriate programs, use language translation services, provide options for transportation, offer earlier and later

^{xc} VO₂max is defined as the maximum amount of oxygen the body can use during intense physical exercise.

appointment times, employ efforts to reduce the financial burden, and develop a diverse workforce of CR professionals.^{478,479}

Estimated Marginal Cost of the Mandate

Respondents to the carrier survey universally agreed that CR is a service that would be provided absent of this mandate due to its established effectiveness through clinical trials. This study therefore estimates the 2023 marginal direct cost of this mandate as \$0 and 0% of Commonwealth fully insured premium.

Certified Nurse-Midwives (CNMs)

The certified nurse-midwife (CNM) mandate requires carriers, subject to their network terms, to cover services rendered by CNMs that are within CNMs' lawful scope of practice, as long as the same services are reimbursed when performed by any other duly licensed practitioner.⁴⁸⁰

Effect of the Mandate on Health

Nurse-midwifery is an integral component of care related to pregnancy and childbirth that has been practiced for thousands of years.⁴⁸¹ CNMs are advanced practice registered nurses (APRNs)^{xci,482,483,484,485} who provide a full range of health care services for women, from adolescence to beyond menopause,⁴⁸⁶ and are one of the five clinical categories of APRNs regulated by the Board of Registration in Nursing.⁴⁸⁷ In Massachusetts, CNMs have full independent practice authority⁴⁸⁸ and do not legally require physician supervision to practice, prescribe, or bill⁴⁸⁹ but are required to have clinical relationships with an OB/GYN^{xcii} who is available for consultation, collaborative management, and/or referral, as needed, pursuant to M.G.L. Chapter 112 section 80G.⁴⁹⁰ In addition, CNM care is required to be consistent with the standards established by the American College of Nurse-Midwives (ACNM)⁴⁹¹ and may only be practiced in the clinical category(s) for which the CNM has attained and maintained certification. The CNM scope of practice as set forth by the board includes the provision of primary health care services in diverse settings to individuals throughout the lifespan, including the following:⁴⁹²

- Gynecologic care
- Abortion for pregnancy less than 24 weeks
- Family planning services
- Preconception care
- Prenatal and postpartum care
- Childbirth
- Care of newborn
- Treatment of the partner in the case of sexually transmitted diseases
- Transgender care

^{xci} APRNs are RNs who are authorized by the Massachusetts Board of Registration in Nursing to engage in advanced practice nursing activities.

^{xcii} An OB/GYN is a physician specialty with expertise in female reproductive health, pregnancy, and childbirth.

- Sexual and reproductive health

In the United States, there are three types of professional midwifery credentials: CNMs, certified midwives (CMs), and certified professional midwives (CPMs). The CNM credential is the only licensure recognized in Massachusetts.⁴⁹³ CNMs have education in both nursing and midwifery. CNM midwifery programs are part of colleges and universities located across the United States and include graduate education, often requiring one to two years of clinical experience before admission.⁴⁹⁴ Most CNM programs require a bachelor's degree in nursing (BSN), but some programs will accept RNs without a bachelor's degree and provide a bridge program to a BSN.^{495,496} Other programs will accept individuals with a bachelor's degree who do not have an RN license—these programs provide accelerated nursing education prior to entering the clinical midwifery experience portion of the program.^{497,498} Nationally, there are approximately 38 midwifery programs accredited by the Accreditation Commission for Midwifery Education (ACME) in the United States; in Massachusetts, there is currently one midwifery education program.^{499,500}

Relative to the number of births in the United States, there is an overall shortage of maternity care providers, both OB/GYNs and CNMs.⁵⁰¹ In most other high-income countries, CNMs greatly outnumber OB/GYNs; although the ACA requires Medicaid midwifery care coverage, many beneficiaries are unable to access services based on the supply of providers.⁵⁰² There are over 14,000 licensed CNMs nationwide and approximately 460 licensed CNMs in Massachusetts,^{xciii,503} who are practicing and providing a full range of services in 30 locations in the Commonwealth, including, but not limited to, hospitals, birth centers, and federally qualified health centers.⁵⁰⁴ In 2021, CNMs and certified midwives attended 10.6% of births in the United States;^{xciv,505} in Massachusetts, 17.9% of births were attended by CNMs during the same time period.⁵⁰⁶

Midwifery primarily focuses on health promotion, disease prevention, risk assessment and management, and individualized wellness education and counseling.⁵⁰⁷ CNMs provide a broad range of services, related to pregnancy, childbirth, and newborn care, as well as routine reproductive care and ongoing comprehensive diagnosis and treatment⁵⁰⁸ from adolescence to menopause and in multiple settings including hospitals, ambulatory care clinics, private offices, birth centers, clinics, and patients' homes.⁵⁰⁹ CNMs provide a holistic, patient-centered approach to the natural birthing process, while assisting individuals throughout prenatal, birth, and postpartum periods.⁵¹⁰

In a 2024 review of 17 studies, including 18,533 women in five countries,^{xcv} the authors concluded that women who received midwife models of care experienced the following outcomes:⁵¹¹

- They were less likely to experience a cesarean section or instrumental vaginal delivery.
- There was likely little to no difference in maintaining an intact perineum.
- They were more likely to experience a spontaneous vaginal birth.

^{xciii} The most recent data for CNMs is from May 2024. The national total includes 138 CMs.

^{xciv} In 2021, the percentage of births attended by all midwives was nearly 12%.

^{xcv} This review included Australia, Canada, China, Ireland, and the United Kingdom.

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,^{xvii,512} birth weight, and neonatal intensive care unit admissions—did not differ.⁵¹³ Furthermore, in a study of 83 systematic reviews specifically investigating interventions to decrease preterm birth, the authors concluded there was a clear benefit for midwife continuity models of care versus other models of care to prevent preterm birth or perinatal death. Midwifery care in low-risk pregnancies is associated with fewer preterm births and labor interventions.^{514,515,xvii}

Researchers have found that particularly for low- to moderate-risk women, CNMs supply a viable and safe alternative to maternity care in the United States.⁵¹⁶ Further, a study of planned home births found that when home births are attended by CNMs, women have safety profiles equal to or better than profiles of women who had hospital births in similar populations.⁵¹⁷ Similarly, a large outcomes study of CNM-attended homebirths concluded that women in the low-risk cohort experienced high rates of physiologic birth and low rates of intervention without an increase in adverse outcomes.⁵¹⁸

Midwifery is evolving and developing rapidly to address the changing landscape of health care and preferences of expectant individuals.⁵¹⁹ When CNMs play a central role in the provision of maternal care, patients consistently report higher satisfaction,⁵²⁰ and research has shown that the midwifery-led model of care can improve both infant and maternal health as well as result in other positive effects.⁵²¹

Estimated Marginal Cost of the Mandate

A shift of services performed by other providers to CNMs is unlikely to impact patients' childbearing care decisions, and CNMs are lower cost than most other providers who have similar scopes of services. Additionally, respondents to the carrier survey universally estimated that this mandate would not incur additional costs. This study therefore estimates the 2023 marginal direct cost of this mandate as \$0 and 0% of Commonwealth fully insured premium.

Certified Registered Nurse Anesthetists (CRNAs)

The certified registered nurse anesthetist (CRNA) mandate stipulates that carriers, subject to their network terms, must cover services provided by CRNAs if those services are reimbursed when performed by any other practitioner and fall within the lawful scope of practice of CRNAs.⁵²²

Effect of the Mandate on Health

^{xvii} The Apgar test is a quick, standardized test performed by a provider at least one minute and five minutes after birth to assess infant vitals and evaluate for resuscitation. Providers score infants based on how well they are breathing, their heartbeat/ rate, muscle tone, grimacing or reflexes, and color (pale, blue, or pink). The Apgar test is scored one through ten; infants scoring between seven and ten do not require intervention, infants scoring less than seven might require intervention, and infants scoring less than three require immediate attention.

^{xviii} Labor interventions include electronic fetal monitoring and methods to bring about labor with the goal of a vaginal birth.

A CRNA is an APRN specializing in administering anesthesia and related medications, as well as monitoring individuals during and after anesthesia administration. Anesthesia is a medical intervention that alleviates pain during medical procedures or surgery, achieved through different techniques. CRNAs undergo rigorous training to help ensure the safe and effective delivery of anesthesia. CRNAs have a range of responsibilities, including educating individuals about anesthesia, assessing their physical response, and identifying potential risks. CRNAs administer precise dosages of anesthesia and collaborate with various health care providers for anesthesia care across all surgical procedures and age groups. Particularly in rural areas and within the U.S. military, CRNAs often serve as primary anesthesia providers. They work in diverse settings such as hospital operating rooms, post-anesthesia recovery rooms, emergency rooms, outpatient surgery centers, labor and delivery units, and physician and dentist offices.^{523,524,525}

Becoming a CRNA involves extensive education and experience, typically spanning seven to eight and a half years. Individuals must obtain a baccalaureate or graduate degree in nursing or a related field and hold an unencumbered license as a registered professional nurse and/or APRN in the United States or its territories. Individuals must also complete at least one year of full-time work experience (or its part-time equivalent) as an RN in a critical care setting and graduate with a minimum of a master's degree from a nurse anesthesia educational program accredited by the Council on Accreditation of Nurse Anesthesia Educational Programs (COA).⁵²⁶ CRNAs are certified to practice as APRNs in Massachusetts within their specific authorized clinical category.⁵²⁷ In 2008, the National Council of State Boards of Nursing (NCSBN) embraced the Consensus Model for APRN Regulation to establish uniform regulations and legislation nationwide, its goal being to standardize licensure to practice, APRN program accreditation, national certification requirements, and educational standards.⁵²⁸

When administering anesthesia in a hospital, the federal CMS requires CRNAs to be supervised by the operating practitioner performing the procedure or an anesthesiologist if required by state regulations. The same supervision requirement applies when administering anesthesia in Critical Access Hospitals (CAHs) or Ambulatory Surgical Centers (ASCs), unless the state has opted out of supervision requirements pursuant to 42 CFR Parts 416, 482, and 485, as established by the CMS rule published in the Federal Register.⁵²⁹

In Massachusetts, CRNAs are eligible to engage in prescriptive practice as nurse anesthetists pursuant to M.G.L. c. 112, §§ 80B and 80H, and 244 CMR 4.00. To receive prescribing privileges, CRNAs must complete training required pursuant to M.G.L. c. 94C, § 18(e) and register with the DPH's Drug Control Program pursuant to M.G.L. c. 94C, and 105 CMR 700.00: Implementation of M.G.L. c. 94C. If applicable, CRNAs must also register with the U.S. Drug Enforcement Agency (DEA). A CRNA without prescriptive authority administers anesthesia under a registered prescriber's signed order. They can choose anesthetic agents based on mutually developed protocols with the prescriber responsible for the individual's perioperative care. Additionally, according to M.G.L. c. 112, § 80H, CRNAs can administer anesthesia directly to individuals without needing a prescription.⁵³⁰

The scope of CRNA practice in Massachusetts adheres to health care standards applicable in various settings, catering to individuals of all ages and health conditions. This includes providing care ranging from routine health maintenance to managing acute and chronic conditions, as well as addressing emergency situations and critical care

needs. CRNAs offer anesthesia care, acute and chronic pain management, palliative care, emergency care, resuscitative services, and sedation services, addressing a wide spectrum of health care needs.⁵³¹

A 2020 study examining the scope of practice regulations for CRNAs revealed significant variations in the likelihood of anesthesia complications based on patient characteristics, comorbidities, and specific procedures. However, the study found minimal evidence to suggest differences in complication rates based on scope of practice or delivery model.⁵³² A 2021 study found that the delivery of anesthetic care by CRNAs did not compromise patient safety or the quality of care. The study also noted preliminary evidence that care delivered by CRNAs may have helped reduce prolonged stays in the post-anesthesia care unit and reduce instances of hypothermia.⁵³³

Estimated Marginal Cost of the Mandate

A shift of services performed by other providers to CRNAs is unlikely to affect patient behavior and CRNAs are lower cost than most other providers who have similar scopes of services. Additionally, respondents to the carrier survey universally estimated that this mandate would not incur additional costs. This study therefore estimates the 2023 marginal direct cost of this mandate as \$0 and 0% of Commonwealth fully insured premium.

Chiropractic Services

The chiropractic services mandate requires coverage for chiropractic services.⁵³⁴ Massachusetts has separate mandates for chiropractic services (services and supplies mandate) and chiropractors (provider-based mandate). A licensed chiropractor or medical physician can provide chiropractic services.^{xcviii,535} The chiropractic services mandate applies to medical service corporations only; that is, the mandate applies to BCBSMA only. BCBSMA HMO Blue products are licensed as HMOs and are regulated under a separate chapter of Massachusetts law; as a result, the chiropractic services mandate only applies to BCBSMA plans that are *not* HMO Blue plans.

Effect of the Mandate on Health

Based on the core tenet that given proper support the body can heal itself, chiropractic medicine focuses on the link between the body's structure, particularly the spine, and its function.^{536,537} Chiropractic care typically involves manual therapy such as stretching and joint manipulation, with the purpose to improve joint motion and function. Chiropractic services can also include other forms of treatment, such as nutritional counseling and exercises.⁵³⁸ Although most often performed by chiropractors, spinal manipulation is practiced by a variety of other health care practitioners, including physical therapists and osteopathic physicians.^{539,540} Practitioners perform manipulation by using their hands or a device to apply controlled thrust to a joint with a varying amount of force.⁵⁴¹ The treatment goals of chiropractic care include relieving pain, improving physical functioning, and helping the body heal itself.^{542,543}

^{xcviii} As set forth in M.G.L. c.175 §108D, "...the insured or other person entitled to benefits under such policy, contract, agreement, plan or certificate shall be entitled to reimbursement for such services, whether such services are performed by a medical physician or a chiropractor licensed by the commonwealth, notwithstanding any provision contained in such policy, contract, agreement, plan or certificate to the contrary."

With an estimated 100 million visits annually, chiropractic care is the most frequently utilized type of complementary and alternative medicine (CAM) service in the United States, with national utilization rates among adults estimated between 10% and 14%.^{544,545,546} As defined by the National Institutes of Health (NIH), CAM is a group of diverse medical and health care systems, practices, and products that are not presently considered part of conventional Western medicine.⁵⁴⁷ Numerous studies have demonstrated relatively high satisfaction with CAM services;⁵⁴⁸ chiropractic care is the most common and established of CAM modalities.⁵⁴⁹ A cross-sectional study showed trends in increased use of chiropractic therapy from 2002 to 2017,⁵⁵⁰ with 10.3% of adults receiving chiropractic care in 2017 compared to 9.1% in 2012.⁵⁵¹

The usage 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.⁵⁵² 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.⁵⁵³ In addition to these benefits, chiropractic care has been shown to increase strength and may also improve overall health and quality of life for some individuals.⁵⁵⁴ The most common temporary side effects of spinal manipulation, which typically go away within 24 hours, are increased pain or discomfort, stiffness, or headache;⁵⁵⁵ serious complications, such as strokes and spinal or neurological problems, are very rare with no accurate estimates of their frequency.⁵⁵⁶ Although chiropractic care encompasses many different treatments, spinal manipulation is the most common treatment provided.^{557,558} Individuals with back pain are overall satisfied with chiropractic care.⁵⁵⁹ In a study of patients over 65, many patients reported that chiropractic services provided a therapeutic effect, especially among individuals with back and neck pain.⁵⁶⁰

Although chiropractic care is a frequently used form of treatment, the majority of available research is focused on singular modalities or conditions and has not focused on the entirety of chiropractic medicine.⁵⁶¹ Most research points to mild to moderate efficacy of chiropractic care for the treatment of low back pain.^{562,563} Outcomes from chiropractic care can be comparable to those obtained through physiotherapy but are slightly better than those obtained through acupuncture and educational materials.^{564,565,566} The outcomes of studies depend on various factors, including the specific condition under investigation (such as acute or chronic low back or neck pain, headache, or sciatica), the desired benefit (such as pain relief or improved functionality), the duration of the study (ranging from immediate to long term, including during or after treatment completion), and the comparison of treatments (including no treatment, placebo, pain medication, standard care, physiotherapy, massage, or adjunctive therapies).^{567,568}

A large meta-analysis of 25 separate evaluations of spinal manipulations for low back pain or neck pain found mixed results of chiropractor care effectiveness that ranged from significantly effective to not at all effective, depending on the specifics of the research design.⁵⁶⁹ A prospective observational study suggests that chiropractic care results improved functioning and well-being for individuals who have low back or neck pain.⁵⁷⁰ In addition to these research findings, chiropractic care has been shown to reduce opioid prescriptions by 50% over a six-year period for individuals with spinal pain compared to individuals with the same symptoms who did not receive chiropractic care.^{571,572} The opioid prescription reduction was even greater if the chiropractor was seen within 30 days of a spinal disorder diagnosis.⁵⁷³

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 Massachusetts APCD for BCBSMA products subject to the mandate and the 2023 PMPM costs of chiropractic services reported in the Massachusetts APCD for BCBSMA HMO Blue products. To derive the estimate, BerryDunn first calculated sample PMPM paid and allowed costs for chiropractic manipulative treatment for the two product types for paid claims with service dates in years 2019 – 2023.

The analysis found a slight variance between non-HMO and HMO BCBSMA paid and allowed PMPM costs for chiropractic services. The cost difference was ultimately determined to be immaterial because this mandate only applies to the small population of fully insured members in non-HMO Blue BCBSMA products. In addition, responses to the carrier survey consistently indicated these services would be covered in absence of the mandate with one large carrier indicating this coverage is required by the ACA. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Chiropractors

The chiropractor provider mandate requires coverage, subject to carriers' network terms, for chiropractic services, whether performed by a physician or by a chiropractor licensed by the Commonwealth.⁵⁷⁴ The related statute, M.G.L. c. 176B § 7, which requires coverage for chiropractic services, prohibits a medical service corporation from discriminating against chiropractors who provide chiropractic^{xcix} services.^c Chiropractors provide both chiropractic and non-chiropractic services, and chiropractic services may also be delivered by other qualified providers, such as physicians, when the service is within the lawful scope of practice of a chiropractor.

Table 12 provides a comparison of the chiropractor provider and chiropractic services coverage requirements as well as the provider types allowed to perform the services.

Table 12. Comparison of Coverage Requirements for Chiropractors Mandate and Chiropractic Services Mandate

MANDATED BENEFIT	REQUIRED COVERAGE	PROVIDER TYPES PERFORMING SERVICES
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^{xcix} As defined in M.G.L. c.112 §89, chiropractic means “the science of locating and removing interference with the transmission or expression of nerve force in the human body, by the correction of misalignments or subluxations of the bony articulation and adjacent structures, more especially those of the vertebra column and pelvis, for the purpose of restoring and maintaining health. It shall exclude operative surgery, prescription or use of drugs or medicines, the practice of obstetrics, the treatment of infectious diseases, and internal examinations whether or not diagnostic instruments are used except that the X-ray and analytical instruments may be used solely for the purposes of chiropractic examinations. Nothing in this definition shall exclude the use of supportive procedures and therapy, including braces, traction, heat, cold, sound, electricity, and dietary and nutritional advice, as treatment supplemental to a chiropractic adjustment.”

^c As defined in M.G.L. c.176B §1, chiropractic service means “the chiropractic services ordinarily provided by registered chiropractors in accordance with the accepted practices in the community where services are rendered.”

Chiropractors	Mandates coverage for any service that is within the lawful scope of practice of a licensed chiropractor licensed by the commonwealth	Multiple provider types; the chiropractor scope of practice is broad and includes, but is not limited to, examining, evaluating, and diagnosing patients of all ages for the purpose of determining the presence or absence of illnesses, injuries, conditions, or disorders ⁵⁷⁵
Chiropractic Services	Mandates benefits for the expense of chiropractic services to all individual subscribers and members within the Commonwealth and to all group members having a principal place of employment within the Commonwealth	Medical physicians if the service is within scope of a chiropractor

Effect of the Mandate on Health

Doctors of Chiropractic (DCs), often referred to as chiropractors or chiropractic physicians, diagnose and treat conditions primarily through manipulation, most commonly conducted on the spine, and realignment of the musculoskeletal and nervous systems.^{576,577} The goals of chiropractic care include restoration of normal joint function and muscle balance, with an emphasis on the body's ability to heal itself.^{578,579} Chiropractors are known for their whole-person, patient-centered approach and treat individuals of all ages with a variety of health conditions, including, but not limited to, back pain, neck pain, pain in the joints of the arms or legs, and headaches.⁵⁸⁰ When treating individuals with chronic pain, chiropractors frequently work in conjunction with primary care doctors, pain experts, and surgeons.⁵⁸¹

In order to obtain a DC degree, chiropractors must complete at least 90 semester hours or the equivalent of three years of undergraduate study.^{ci,cii,582,583,584} The undergraduate study is typically similar to a pre-medical undergraduate education with 24 semester hours in life and physical science courses, followed by four to five years of study at a doctoral graduate school program at a nationally accredited chiropractic college. Chiropractic college curriculum includes a minimum of 4,200 hours of classroom, laboratory, and clinical internship.⁵⁸⁵ 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.⁵⁸⁶ In order to be licensed in Massachusetts, graduates of a chiropractic college must pass Parts I, II, III, and IV—and the special physiotherapy section—of the national board examination administered by the National Board of Chiropractic Examiners, as well as the Massachusetts jurisprudence

^{ci} In some cases, a bachelor's degree may be required based on the academic admissions requirements of the chiropractic school.

^{cii} Pursuant to 233 CMR: Board of Registration of Chiropractors, 2.02 Requirements for Individual Registration by Examination, applicants must submit an official transcript "verifying that the applicant has completed at least two years (60 credit hours) of instruction leading to a baccalaureate degree in liberal arts or sciences at a college or university accredited by the United States Department of Education."

examination administered by the Massachusetts Board of Registration of Chiropractors (Board) or its designee.⁵⁸⁷ Chiropractors must also complete at least 12 hours of continuing education annually in courses or programs approved by the Board in order to maintain and renew licensure in Massachusetts.⁵⁸⁸

Manual manipulation of the spine to correct a vertebral subluxation^{ciii} performed by a licensed chiropractor is covered by Medicare.^{589,590} Medicare does not cover other services or tests ordered by chiropractors, including X-rays, massage therapy, and acupuncture (unless acupuncture is for the treatment of chronic low back pain).⁵⁹¹

Studies have found that individuals who have chronic back or neck pain generally have positive experiences with chiropractic care,⁵⁹² including experiencing improvements in functioning and well-being.⁵⁹³ A study comparing orthopedic surgeons, primary care providers (PCPs), and chiropractors found that the time to functional recovery, complete recovery, and return to work following treatment for lower back pain was similar across all three provider types.⁵⁹⁴ Although outcomes were similar among these provider types, satisfaction was highest for chiropractors.⁵⁹⁵ Due to its less invasive and more conservative treatment approach, access to chiropractic care has the potential to reduce overall health care costs while providing clinical benefits.⁵⁹⁶

Estimated Marginal Cost of the Mandate

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 Massachusetts APCD for non-HMO products subject to the mandate and the 2023 PMPM costs of chiropractor services reported in the Massachusetts 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 and extracted and summarized Massachusetts APCD claims for the years 2019 – 2023, where the billing or servicing provider National Provider Identifier (NPI) reported on the claim had a National Plan and Provider Enumeration System (NPES) primary taxonomy indicating the provider was a DC (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 service mandate) to avoid double-counting of 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 2019, 2020, 2021, 2022, and 2023. The differences between non-HMO products and HMO products for allowed and paid PMPMs are negligible for 2021 – 2023 for the three major sample carriers. Four of the carriers that responded to the survey stated they would cover chiropractors absent the mandate,

^{ciii} Subluxation is a partial dislocation or misalignment of the vertebrae.

and one of the carriers stated that the mandate does not apply to its products. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Clinical Trials (to Treat Cancer)

The mandate for clinical trials to treat cancer requires coverage for services for individuals enrolled in qualified clinical trials. This coverage extends to the same level as if the individuals were not participating in a trial. For coverage requirements, qualified trials must be aimed at cancer treatment and meet the additional criteria as outlined in the law.⁵⁹⁷

Effect of the Mandate on Health

Clinical trials are a component of clinical research that enable individuals the opportunity to volunteer and participate in the exploration of novel methods for preventing, detecting, or treating diseases.⁵⁹⁸

Researchers conduct various types of clinical trials to address different objectives. The NIH categorizes clinical trials into the following types:

- Prevention trials that focus on finding more effective ways to prevent diseases from occurring or recurring, utilizing approaches such as medications, vaccines, or lifestyle modifications
- Screening trials that investigate new methods for detecting diseases or health conditions at early stages
- Diagnostic trials that analyze and compare tests or procedures for diagnosing specific diseases or conditions
- Treatment trials that assess new treatments, novel drug combinations, or innovative approaches to surgery or radiation therapy
- Behavioral trials that evaluate or compare strategies aimed at promoting behavioral changes to enhance health outcomes
- Quality of life trials, also known as supportive care trials, that seek to enhance comfort and overall quality of life for individuals with various conditions or illnesses⁵⁹⁹

There are typically four phases of clinical trials. Phase I studies involve testing new treatments or drugs in a small group of individuals to determine safety and identify any potential side effects. Following this, Phase II studies evaluate treatments that have passed Phase I for safety but now require a larger human subject pool to monitor for adverse effects. Phase III studies, conducted on larger populations across various regions and countries, are often a prerequisite before the approval of a new treatment. Finally, Phase IV studies occur post approval and involve further testing in a broader population over an extended period.⁶⁰⁰ According to the NIH, Phase I trials include 20 – 80 people, Phase II trials include 100 – 300 people, Phase III trials include 1,000 – 3,000 people, and Phase IV trials

include the general population receiving the treatment or drug.⁶⁰¹ Many clinical trials involve placebo^{civ} control groups, and in these types of trials, neither individuals nor their doctors are aware of who receives the placebo and who receives the experimental treatment or drug. However, clinical trials for cancer and other serious and life-threatening conditions often do not include placebo groups, and in these cases, all participants receive the experimental treatment or drug.⁶⁰²

The National Cancer Institute identifies the benefits and risks of participating in clinical trials. Participants in clinical trials may gain access to innovative treatments not yet available outside the trial, which enables individuals to contribute to advancing cancer research. Individuals enrolled in clinical trials receive close monitoring and additional care from the research team. The risks of participating in clinical trials include the chance that the study treatment is ineffective or less effective than standard treatment, as well as the potential for experiencing serious side effects. Participants may also face increased doctor visits, additional tests, and extra expenses related to participation.⁶⁰³

Using national accreditation and enrollment data submitted to the Commission on Cancer, a 2024 study estimated that the overall participation rate in cancer treatment trials was 7.1% between 2013 and 2017.⁶⁰⁴ A 2023 survey examining individuals' perspectives on clinical trials found that 30% of survey respondents had been participants in a clinical trial, and 70% had not but would be open to participating in a trial in the future.⁶⁰⁵ Among adult individuals with cancer, it is estimated that less than 5% enroll in clinical trials. Individuals can face multiple barriers that preclude their participation in clinical trials. These barriers can include structural barriers, (e.g., the lack of an accessible clinical trial), clinical barriers (e.g., not meeting eligibility criteria), attitudinal barriers (e.g., both individuals' and physicians' perspectives), and demographic and socioeconomic barriers.⁶⁰⁶ Clinical trials focusing on children play a critical role in determining the most effective treatments tailored to their unique physiology and developmental stages. Unlike adults, children undergo significant changes as they grow, necessitating specialized medications and therapies.⁶⁰⁷ Collaborative efforts in multicenter cancer trials for children have yielded substantial progress, significantly elevating the five-year survival rate for childhood cancer from 28% in the late 1960s to 85% as of 2020.^{608,609}

Estimated Marginal Cost of the Mandate

According to the results of the carrier survey, it was universally agreed that this mandate would impose no additional costs. The ACA addresses coverage for clinical trials under Section 2709 in a manner similar to, but broader than, this mandate. Thus, coverage for these services would still occur absent this mandate. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

^{civ} Inactive substances resembling the actual experimental treatment.

Cytologic Screening

The cytologic screening mandate requires annual coverage of cytologic screening for cervical cancer for women aged 18 and over.⁶¹⁰

Effect of the Mandate on Health

Cytological screening, also known as a Pap test, Pap smear, or Papanicolaou test, is a medical test that uses a swab to collect cells from the cervix to detect any cell changes that may be precancerous or cancerous.⁶¹¹ The goal of the cytological screening mandate is to increase the overall cervical cancer screening rate in the Massachusetts population to reduce the prevalence of cervical cancer.

From 2016 to 2020 in the United States, the average incidence of cervical cancer was approximately eight cases per 100,000 women and approximately two cervical cancer deaths per 100,000 women.⁶¹² For the same period in Massachusetts, the average incidence was 5.2 cases per 100,000 women.⁶¹³ In the United States, cervical cancer is one of the leading causes of cancer-related death in women aged 20 – 39 years, the fourth most common cancer for women aged 15 – 44 years, and the 14th most common cancer among women overall.⁶¹⁴ According to data from the CDC's Behavioral Risk Factor Surveillance System in 2020, Massachusetts is currently ranked 44th among U.S. states for the percentage of women aged 21 – 44 who reported completing a Pap smear within the last three years at 72.6%, which is lower than the overall U.S. percentage of 77.1%.⁶¹⁵ Research has shown that regular screening for cervical cancer with a Pap smear reduces the odds of developing cervical cancer by at least 80%.⁶¹⁶ To lower the prevalence of cervical cancer in the United States, Healthy People 2030 has set a goal to increase the number of women aged 21 – 65 years who get screened regularly for cervical cancer, with the current target set at 79.2% and the most recent data showing 73.9% of women regularly getting screened.⁶¹⁷

Over 90% of all cases of cervical cancer are caused by persistent human papillomavirus (HPV) infection.⁶¹⁸ At least 85% of sexually active people will be infected with a strain of HPV at some point in their life, but in most cases the body is able to clear the virus without any issues.^{619,620} When HPV is not effectively cleared from the body, the virus can cause changes in cells that can eventually become cancer.⁶²¹ For the average individual, abnormal (precancerous) cells affected by HPV can take 15 – 20 years to become cancerous.⁶²² Certain risk factors, including infection with HIV, having a suppressed immune system, smoking tobacco, long-term use of oral contraceptives, and having multiple births, can increase the likelihood for an individual to develop cervical cancer from HPV infection.^{623,624,625} For individuals who have suppressed immune systems, precancerous cells may only take 5 – 10 years to develop into cervical cancer.⁶²⁶ A rare cause of cervical cancer unrelated to HPV infection is in-utero exposure to diethylstilbestrol (DES), a drug that was given to some pregnant women from 1940 – 1971 to prevent miscarriage and early labor.⁶²⁷

The USPSTF updated its cervical cancer screening recommendation in 2018 and is reviewing the recommendation for potential updates as of October 28, 2021. The current USPSTF recommendation for cervical cancer screening for individuals aged 21 – 65, as of August 21, 2018, is recommended with a grade of “A,” which means the USPSTF recommends this service with high certainty that the net benefit is substantial.⁶²⁸ The recommendation states that individuals should receive their first Pap test at age 21, regardless of sexual activity status, and once every three

years after, through age 29.⁶²⁹ The USPSTF recommends against screening before the age of 21 because it could increase anxiety and result in additional unnecessary testing and added cost for the individual, since most abnormalities identified with screening are likely to resolve on their own and the likelihood of developing cervical cancer at this age is very low.^{630,631,632,633} For individuals aged 30 – 65 years, screening for cervical cancer is appropriate either with a Pap smear every three years, an HPV test every five years, or an HPV and Pap smear co-test every five years.^{634,635} After age 65, continued screening may or may not be necessary depending on the individual's testing and health history.⁶³⁶ Cervical cancer can develop after age 65, so if an individual has never been screened previously or has not been screened regularly at the recommended intervals, it is recommended that they complete screening.⁶³⁷ Individuals over 65 should also continue with screening if they have risk factors for cervical cancer or have a history of abnormal screening results.⁶³⁸ If an individual has been screened regularly up to age 65 and does not have a history of abnormal results or cancer, the likelihood of an abnormal Pap test after age 65 is low, so the USPSTF recommends against these individuals continuing with screening.⁶³⁹ Individuals with risk factors for developing cervical cancer may need more frequent screening than the stated guidelines, along with individuals who have had recent abnormal cervical screening or biopsy results and/or who have a personal history of cervical cancer.^{640,641} Individuals with weakened or suppressed immune systems may require more frequent screening because it is more difficult for their systems to clear HPV infection, which can lead to more rapid cell changes.^{642,643} Individuals who have had a total hysterectomy (removal of the uterus and the cervix) and who do not have a personal history of cervical cancer or abnormal cells do not need to continue with screenings for cervical cancer, regardless of age.⁶⁴⁴

These recommendations diverge from the prior recommendation of universal annual testing because it has been determined that the potential harms of annual testing outweigh the potential benefits, since research has shown that cells can take many years to develop into cervical cancer for the average individual and can still be identified and treated while in earlier stages with testing completed every three years.^{645,646} More frequent testing can increase the burden of testing on the individual and health care providers, because more frequent testing requires more resources, can lead to additional procedures with potential risks, can produce higher costs, and may cause unnecessary anxiety for the individual.^{647,648}

The uptake of cervical cancer screening over the past several decades has supported a reduction in the prevalence of cervical cancer in the United States. From the 1970s to 2000s, the incidence of cervical cancer and deaths due to cervical cancer has decreased by over 50%, largely due to the increase in the number of individuals who are completing screening regularly and the introduction of the HPV vaccine^{cv,649,650} in 2006.^{651,652} It is estimated that up to 93% of cases of cervical cancer can be prevented through screening and vaccination against HPV.⁶⁵³ Despite previous progress in regular cervical cancer screening uptake from 1970 through the early 2000s, data from 2005 –

^{cv} The HPV vaccine can protect against new infections and is estimated to prevent 90% of HPV-related cancers. The CDC recommends the HPV vaccination for all children starting at age 11 – 12, and some people can receive the vaccine earlier, at age 9. The HPV vaccine is recommended for anyone younger than 26 who has not previously received the vaccine, but adults up to age 45 can still discuss the benefits of vaccination with their provider. As of 2016, Gardasil-9 is the only HPV vaccine administered in the United States and protects against nine types of HPV.

2019 has shown that the proportion of the population that is overdue for a cervical cancer screening test has noticeably increased from 14% in 2005 to 23% in 2019.⁶⁵⁴ Many factors contribute to this fact, including racial, ethnic, and other disparities along with various socioeconomic factors, with data showing that Hispanic and Asian women are more likely to be overdue for screening, along with individuals living in rural areas, individuals without health insurance, and individuals who identify as members of the LGBTQIA+ community.⁶⁵⁵ Over 50% of newly diagnosed cases of cervical cancer are found in individuals who have either never been screened or have not been screened recently, illustrating the important role of screening in cervical cancer prevention.⁶⁵⁶ One study found that a 10% increase in the population screening rate for cervical cancer is estimated to prevent 81 deaths per 100,000 people from cervical cancer.⁶⁵⁷

The ACA requires insurance coverage of preventive services like cytologic screening with no cost sharing for the member. Eliminating the insurance and cost barrier to cervical cancer screening likely aids in creating a more accessible process for individuals and increasing the likelihood that an individual will complete the screening process regularly.

Estimated Marginal Cost of the Mandate

Respondents to the carrier survey universally indicated that coverage for cytological screening would not change absent this mandate due to the service's effectiveness and relatively low cost. Additionally, the ACA mandates coverage for this service at a lesser frequency, meaning that some coverage would be mandated regardless. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the 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, subject to plans' network terms.⁶⁵⁸

Effect of the Mandate on Health

Dentists are doctors who can also be referred to as general or family dentists. They are health care professionals specializing in diagnosing and treating oral health conditions. Dentists maintain oral health through regular check-ups, cleanings, and treatments, e.g., fillings and crowns. As part of their medical training, dentists complete undergraduate education, followed by four years of focused training in an accredited dental school. Depending on whether the dentist specializes further, additional schooling may be required.⁶⁵⁹ The National Commission of Recognition of Dental Specialties and Certifying Boards recognizes 12 specialties: dental anesthesiology, dental public health, endodontics, oral and maxillofacial pathology, oral and maxillofacial radiology, oral and maxillofacial surgery, oral medicine, orofacial pain, orthodontics and dentofacial orthopedics, pediatric dentistry, periodontics, and prosthodontics.⁶⁶⁰

In order to be licensed, dentists must pass the Integrated National Board Dental Examination (INBDE). The INBDE is a licensure test during which candidates must apply their clinical expertise to solve dental problems. This is a two-day exam that replaces the previous two-part exam of National Board Dental Examinations Part I and Part II. The exam

evaluates whether candidates possess the required clinical skills for entry-level dental practice and assists U.S. dental boards in licensure decisions.⁶⁶¹ Included in the exam are sections addressing biomedical, clinical, and behavioral sciences.⁶⁶² The Joint Commission on National Dental Examinations (JCNDE) oversees the INBDE in partnership with the Department of Testing Services (DTS). All states and territories accept the INBDE, and it either fully or partially fulfills the written examination requirements for dental licensure depending on the state or territory.⁶⁶³

In Massachusetts, obtaining dental licensure necessitates passing a board-approved regional or state clinical examination. Additionally, candidates for dental licensure must successfully complete the Massachusetts Dental Ethics and Jurisprudence Exam.⁶⁶⁴ As of November 3, 2017, in accordance with M.G.L. c. 112, § 45⁶⁶⁵, dentists in Massachusetts must enroll with MassHealth as an Ordering, Referring, and Prescribing (ORP) non-billing provider before applying for or renewing a dental license, if they are not already enrolled with MassHealth as an approved billing provider.⁶⁶⁶

Oral health significantly impacts overall well-being and quality of life, with untreated dental issues leading to negative health outcomes. When individuals have tooth decay and periodontal disease, they can be at greater risk of developing serious conditions such as sepsis, diabetes, and heart disease. Despite the importance of dental care, many individuals may postpone or forego treatment, resulting in the need for more extensive and costly interventions. Without regular dental care, individuals may resort to EDs for their care, contributing to the high national cost of dental-related ED visits, which exceeded \$2 billion in 2017.⁶⁶⁷

Estimated Marginal Cost of the Mandate

This mandate requires services that were already covered when performed by a physician to be similarly covered when performed by a dentist. Thus, this mandate does not require coverage for additional services, only in cases where already covered care is performed by a dentist. Respondents to the carrier survey universally indicated that these services would be covered absent this mandate, and this mandate would impose no additional costs upon them. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Diabetes-Related Services and Supplies

The diabetes mandate requires coverage for a wide range of medically necessary services and supplies that have been prescribed by a health care professional legally authorized to prescribe such items for the diagnosis or treatment of insulin-dependent, insulin-using, gestational, and non-insulin-dependent diabetes, including blood glucose monitors; blood glucose monitoring strips for home use; 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 FDA for the purposes for which they have been prescribed; and outpatient self-management training and education, including medical nutrition therapy.⁶⁶⁸

Effect of the Mandate on Health

One of the leading causes of death and disability worldwide⁶⁶⁹ and the eighth-leading cause of death in the United States,⁶⁷⁰ diabetes represents one of the most significant public health challenges of the 21st century.⁶⁷¹ In 2021, 38.4

million people of all ages in the United States, or 11.6% of the population, had diabetes, including 29.7 million diagnosed and 8.7 million undiagnosed people.^{672,673} Among adults 18 years or older, an estimated 1.2 million new cases of diabetes were diagnosed and 97.6 million had prediabetes,^{cvi} representing 38% of adults, in 2021.⁶⁷⁴ The prevalence of diabetes in Massachusetts has been steadily increasing, more than doubling from an estimated 3.9% of residents with diabetes in 1993 to 8.9% in 2015.⁶⁷⁵

Diabetes mellitus refers to a group of diseases that impact how your body turns food into energy by breaking down sugar (glucose) and releasing it into the bloodstream.^{676,677} Diabetes is caused when the body cannot make enough or use insulin, a hormone released from the pancreas that acts like a key allowing blood sugar into the body's cells for use as energy, resulting in excess sugar in the blood.^{678,679} The three main types of diabetes are:⁶⁸⁰

- Type 1 diabetes, thought to be caused by an autoimmune reaction in which the body attacks itself by mistake, resulting in the pancreas no longer making or making very little insulin. About 5% – 10% of people with diabetes have type 1. Currently, no one knows how to prevent type 1 diabetes, but it can be treated effectively, and individuals with type 1 diabetes must take insulin every day to survive.⁶⁸¹
- Type 2 diabetes occurs when the body does not utilize insulin well and cannot keep blood sugars within a normal range. Type 2 diabetes most often develops in people 45 or older and can be prevented or delayed with lifestyle changes, such as eating a healthy diet, losing weight, and getting regular physical activity.⁶⁸²
- Gestational diabetes develops around the 24th week of pregnancy in women who have never had diabetes and typically goes away after the baby is born. Gestational diabetes increases the mother's risk for type 2 diabetes later in life with approximately half going on to develop type 2 diabetes.⁶⁸³

The longer an individual has diabetes and the less controlled their blood sugar, the higher the risk of long-term complications, which can be disabling or possibly life-threatening.⁶⁸⁴ Consistently high blood glucose levels that result from glucose staying in the blood and not reaching cells raise the risk for diabetes complications that affect the eyes, kidneys, nerves, heart, blood vessels, teeth, and gums; this is also linked to some types of cancer and potentially reduced overall life expectancy.^{685,686} In addition, diabetes can increase the risk of:^{687,688,689}

- Cardiovascular disease
- Chronic kidney disease
- Neuropathy
- Foot complications
- Skin complications
- Oral complications
- Hearing loss

^{cvi} Prediabetes occurs when blood sugar levels are higher than normal but not high enough to be considered diabetes.

- Diabetic ketoacidosis (DKA)^{cvii}
- Stroke

However, these serious health problems associated with diabetes can be prevented or delayed with correct treatment that includes managing blood glucose, blood pressure, and cholesterol levels and incorporates recommended lifestyle changes, such as eating healthy foods, getting more physical activity, and losing excess weight.^{690,691,692} Further, although type 1 diabetes cannot be prevented, these healthy lifestyle choices have the potential to prevent prediabetes, type 2 diabetes, and gestational diabetes.⁶⁹³

Managing overall health is an important part of treating diabetes, and depending on the type of diabetes an individual has, blood sugar monitoring as well as insulin and oral drugs may be part of treatment.⁶⁹⁴ Keeping blood glucose levels within a target range as much as possible helps prevent or delay the serious health problems associated with diabetes, and checking blood sugar numerous times a day is often necessary, depending on the type of diabetes.⁶⁹⁵ Numerous advances in diabetes technology^{cviii} have been introduced in recent years to allow patients to continuously monitor blood glucose, and in some cases, deliver insulin automatically.⁶⁹⁶

As the seventh leading cause of death in the United States, one of the goals of Healthy People 2030 focuses on reducing the burden of diabetes and improving the quality of life for those with, or at risk of developing, diabetes; the related key objectives include reducing the number of diabetes cases, complications, and deaths.⁶⁹⁷ The use of the diabetes supplies and services set forth in this mandate is necessary to effectively monitor and manage diabetes; when coupled with education and follow-up care, this diabetes technology can improve the lives and health of people with diabetes.⁶⁹⁸

Estimated Marginal Cost of the Mandate

According to BerryDunn's analysis and the respondents in the carrier survey, the care required by this mandate is both medically necessary and cost effective, meaning it would be covered absent this mandate. Additionally, the majority of carriers estimate no additional cost from this mandate. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

^{cvii} DKA is a life-threatening condition caused by an overload of ketones, a chemical that develops when fat is broken down to use for energy in your body.

^{cviii} Diabetes technology refers to the hardware, devices, and software that people with diabetes use to manage their condition. The technology is divided into two main categories: insulin administration by syringe, pen, or pump, and blood glucose monitoring or continuous glucose monitoring.

Early Intervention Services

This mandate stipulates the provision of coverage for EI services between birth and age three for children who are identified with handicapping conditions or who are deemed at risk for developmental delays due to biological, established, or environmental factors.⁶⁹⁹

Effect of the Mandate on Health

EI services are tailored to support children from birth to three years old and their families. The goal of these services is to minimize any potential delays in development and help prevent the need for institutional care. EI services offer a variety of support, including ST, OT and PT, social work assistance, psychological support, educational guidance, and nursing care, all aimed at nurturing the child's growth and well-being.⁷⁰⁰

The human brain undergoes a complex and dynamic process of development, starting before birth and continuing throughout adulthood. During the formative early years of life, research estimates that over one million new neural connections are formed every second, establishing the foundation for cognitive, emotional, and social capacities. These interconnected capacities are crucial for success across various domains of life, including education, employment, and community engagement. Genes provide the blueprint for brain development, but experiences, particularly responsive caregiving, play a crucial role in reinforcing neural circuits. The interplay between genes and experiences shapes brain architecture, which is essential for learning, behavior, and overall well-being. Exposure to toxic stress can disrupt this process, weakening neural connections and leading to long-term difficulties in learning, behavior, and health. Promoting supportive environments and relationships is essential for nurturing healthy brain development.⁷⁰¹

By a child's third birthday, their brain is 80% developed. From birth to age three, the brain undergoes its most rapid development. Brains are highly receptive to everyday interactions, including affection and play. These experiences play a crucial role in wiring the brain and laying the foundation for essential life skills such as language, literacy, and reasoning. Strong relationships lay the groundwork for development, and regular engaging interactions with parents and caregivers bolster brain development. However, for children who are born at risk of developmental delay or disability, or who are diagnosed with a developmental delay or disability, these interactions may be compromised, potentially impacting their lifelong growth and development.⁷⁰²

Part C of the Individuals with Disabilities Education Act provides EI services for infants and toddlers up to 36 months old, addressing developmental delays that exist or could develop. While EI services are funded through public programs, the mandate also requires private insurance to cover these services. This helps ensure that eligible children have access to necessary care regardless of the payer, with costs often coordinated between public and private coverage to maximize access. These services encompass a range of therapies, counseling, and support tailored to the child's requirements.⁷⁰³ EI services yield numerous positive outcomes for infants and young children, including improved motor, social, and cognitive skills, attainment of developmental milestones appropriate for their age, mitigated negative effects of disabilities, and reduced reliance on specialized education.^{704,705} While the outcomes from these EI services may vary individually, many children who receive EI services are able to develop comparable skills to their peers by the time they reach their third birthday; 54% – 62% of children who had received

EI services completed the program with age-expected abilities to form social relationships, use knowledge and skills effectively, and conduct actions in order to meet their own needs.⁷⁰⁶ Overall, children who are enrolled in high-quality EI services demonstrate enhanced health, language proficiency, cognitive and socio-emotional development, academic performance, and career success. Additionally, they exhibit lower rates of delinquency, criminal behavior, and dependence on social welfare programs.^{707,708}

Estimated Marginal Cost of the Mandate

Respondents to the carrier survey indicated that the services required in this mandate would be provided absent the mandate. EI services are medically critical health care, which carriers would cover regardless, and many of the services required by this mandate are also covered by the ACA. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Hearing Screening for Newborns

This mandate requires coverage for newborn hearing screening.⁷⁰⁹

Effect of the Mandate on Health

Hearing loss affects approximately 1 – 2 per 1,000 infants in the United States. When hearing loss is left undetected and untreated, it can hinder a child's speech, language, and overall development.⁷¹⁰ Hearing loss can also impede a child's social development.⁷¹¹ Research funded by the NIH indicates that the crucial phase for speech and language development occurs in the first three years of life, coinciding with significant brain development. Hearing loss during this period can impede language acquisition and reading skills. Early infancy is vital for establishing neural pathways essential for auditory comprehension.⁷¹²

According to the CDC, there are 11 risk factors for permanent congenital, delayed onset, or progressive hearing loss in childhood. The top factors are:⁷¹³

1. Caregiver concern or observation of potential hearing, speech, language, or developmental issues
2. Family history of childhood hearing loss
3. Extended neonatal intensive care stay (five or more days), especially when involving assisted ventilation or significant medical treatment
4. Prenatal infections such as cytomegalovirus (CMV), rubella, or syphilis
5. Craniofacial abnormalities (e.g., ear canal malformations, ear tags, or pits)

Note: Other medical conditions, syndromes, or treatments (e.g., chemotherapy, certain genetic syndromes, or meningitis) may also increase risk.

Initiating services for children who are deaf or hard of hearing (DHH) at an early age enhances their potential for developing full speech, language, and social skills. EI programs provide crucial assistance to young children with hearing loss in acquiring language and other essential skills. Studies demonstrate that EI services significantly enhance a child's overall development. It is essential for infants diagnosed with hearing loss to begin intervention services promptly, ideally before six months of age, to optimize their developmental outcomes.⁷¹⁴ The Joint Committee on Infant Hearing (JCIH) advocates for timely identification and intervention for infants who are DHH or at risk of becoming so. Early hearing detection and intervention (EHDI) programs aim to enhance language and communication skills, promote literacy development, and support the overall psychosocial well-being of these children.⁷¹⁵

Figure 1. JCIH, EHDI Benchmarks, 2019^{cix,716}



In 2019, out of 69,924 total births in Massachusetts, 99.5% (69,354) of infants received a hearing screen, and 0.5% (570) of infants were not screened. Among those not screened, 232 either passed away before screening or had parents who did not provide consent, and 338 were lost to follow-up with an unknown screening status. Of the screened infants, 97.9% (67,873) passed the screen and 2.1% failed (1,481). Among the 139 infants with hearing loss, 78.4% (109) were enrolled in EI services, and the remaining 21.6% (30) did not have documentation reflecting receipt of EI services due to reasons including declining services, moving, ineligibility due to health status, or unknown reasons.⁷¹⁷

To promptly identify infants with permanent hearing loss, EHDI programs have been implemented nationally in all states. These programs aim to ensure that all infants:

- Undergo hearing screening, preferably before reaching one month of age
- Receive diagnostic, audiologic evaluation if they do not pass the screening, preferably before reaching three months of age
- Participate in EI if permanent hearing loss is detected, ideally before reaching six months of age⁷¹⁸

^{cix} Part C of the Individuals with Disabilities Education Act provides EI services for infants and toddlers up to 36 months old, addressing motor delays and cerebral palsy (CP) diagnoses. These services encompass a range of therapies, counseling, and support tailored to the child's requirements.

Estimated Marginal Cost of the Mandate

Respondents to the carrier survey universally indicated that hearing screening for newborns would be covered in absence of this mandate. Additionally, the ACA requires coverage for these services. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

HIV-Associated Lipodystrophy Treatment

This mandate requires coverage for medical or drug treatments to correct or repair body composition disturbances caused by HIV-associated lipodystrophy (LDHIV) 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.⁷¹⁹ Coverage requires a statement from a treating provider that the treatment is necessary for correcting, repairing, or ameliorating the effects of LDHIV syndrome. Benefits may not be subject to any greater deductible, coinsurance, copays, or out-of-pocket limits than any other benefit provided by the insurer.

Effect of the Mandate on Health

Antiretroviral therapy^{cx, 720} is the only treatment currently available for people living with HIV;⁷²¹ it increases CD4^{cxii, 722} counts, suppresses viral load, and improves quality of life.⁷²³ LDHIV is mainly an adverse effect of certain antiretroviral drugs^{724,725} but can also be induced by HIV infection itself.⁷²⁶ Lipodystrophy refers to body shape abnormalities caused by changes in body fat distribution.⁷²⁷ LDHIV presents in one of three ways:

- Lipohypertrophy: Fat accumulation in the abdomen, mammary region, neck area, or as lipomas⁷²⁸
- Lipoatrophy: Fat loss in the face, buttocks, arms, and legs,⁷²⁹ possibly resulting in exaggerated muscles, bones, arteries, and veins⁷³⁰
- Both lipohypertrophy and lipoatrophy

LDHIV can be linked to feelings of shame, stigmatization,⁷³¹ depression, decreased self-esteem, sexual dysfunction, social isolation, decreased quality of life, and reduced adherence to antiretroviral therapy.⁷³² LDHIV can also increase morbidity and risk of cardiovascular disease and is associated with other complications, including neurological disorders, kidney and liver disease, bone disorders, and type 2 diabetes.⁷³³

While the exact cause of LDHIV is unknown,⁷³⁴ the leading risk factor for lipoatrophy is older antiretroviral therapy,⁷³⁵ thymidine analog nucleoside reverse inhibitors (NRTIs), most notably, zidovudine and stavudine.^{cxii,736,737} Other risk

^{cx} Antiretroviral therapy is the daily use of a combination of HIV medicines (called an HIV regimen) to treat HIV. A person's initial HIV regimen generally includes three antiretroviral drugs from at least two different HIV drug classes.

^{cxii} CD4 (also referred to as CD4+T) cells are lymphocytes, a type of white blood cell that supports the immune system by recruiting other cells to help fight infection. HIV infects and destroys CD4 cells, weakening a person's immune system.

^{cxii} NRTIs block HIV enzymes (reverse transcriptase) from replicating.

factors associated with LDHIV include age, hepatitis C, higher HIV viral loads, lower CD4 cell counts at the start of HIV therapy,⁷³⁸ and prolonged use of antiretroviral therapy.⁷³⁹ Lipohypertrophy sometimes occurs with protease inhibitors (PIs)^{cxiii,740} and antiretroviral therapy, but no evidence suggests that specific antiretroviral drugs lead to lipohypertrophy.⁷⁴¹ Additional risk factors for lipohypertrophy include age, gender, higher body fat percentage, and lifestyle factors (i.e., diet).⁷⁴² Lipodystrophy is no longer a concern for most people who start HIV treatment⁷⁴³ because of advances in newer antiretroviral drugs.⁷⁴⁴

As of 2022, approximately 1.2 million people in the United States have HIV.⁷⁴⁵ Within the population of people living with HIV, disproportionate disease prevalence and incidence occurs among racial and ethnic minorities, as well as among individuals who identify as gay or bisexual and men who have sex with men.⁷⁴⁶ As of 2022, approximately 23,643 people live with HIV infection in Massachusetts,⁷⁴⁷ reflecting similar prevalence and incidence disparities seen nationally.⁷⁴⁸ Suffolk County is part of the *Ending the HIV Epidemic in the U.S.* (EHE) plan as 1 of 57 priority jurisdictions where HIV transmission occurs most frequently.^{749,750}

Various studies estimate that LDHIV prevalence ranges between 11% and 83%.⁷⁵¹ Exact LDHIV prevalence estimates vary widely⁷⁵² because lipodystrophy does not have a universally accepted case definition, standardized diagnostic criterion, nor standardized follow-up time procedures in observational studies.⁷⁵³

LDHIV diagnosis is based on the patient's characteristic physical appearance. HIV patients on antiretroviral therapy should be routinely monitored for LDHIV development, with recommended evaluation and monitoring strategies such as monitoring changes in body weight and body mass index (BMI), measuring abdominal girth, hip, and mid-upper-arm circumference, evaluating lipid profile and glucose tolerance (every six months), and/or testing liver and kidney function.⁷⁵⁴ Ideally, measurements should be recorded before the initiation of antiretroviral therapy.⁷⁵⁵ Body weight and BMI monitoring are especially critical in early identification of LDHIV.⁷⁵⁶

Currently, no cure exists for LDHIV. LDHIV treatment can improve the patient's cosmetic appearance, self-esteem, and compliance with antiretroviral therapy.⁷⁵⁷ LDHIV treatment can also prevent other conditions associated with LDHIV.^{758,cxiv} Depending on the individual patient, different combinations of the following treatments might be recommended:⁷⁵⁹

- Modification of antiretroviral therapy
- Use of thiazolidinediones^{cxv} (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, lipectomy)

^{cxiii} PIs stop HIV from maturing and replicating, preventing HIV from infecting CD4 cells.

^{cxiv} Associated conditions include dyslipidemia, abnormal glucose metabolism, atherosclerosis, and diabetes mellitus.

^{cxv} The efficacy of using thiazolidinediones for LDHIV is still being studied.

- Lifestyle modifications, including diet, exercise, and smoking cessation
- Medical therapies with metformin for patients with HIV and type 2 diabetes to reduce visceral, abdominal, and subcutaneous fat
- Growth hormone releasing factor injections

Research shows that excluding stavudine and zidovudine and switching patients to newer antiretroviral therapy, such as abacavir and tenofovir, successfully stops lipoatrophy progression.⁷⁶⁰ However, lipodystrophy and other side effects of older antiretroviral drugs may persist long after discontinuation.⁷⁶¹ Even though antiretroviral medicines are less likely to cause lipodystrophy,⁷⁶² modifying antiretroviral therapy treatment might not be an option for some patients, because the treatment might not maintain virological control.⁷⁶³ Also, switching therapies after lipodystrophy has already progressed offers only limited benefit,⁷⁶⁴ and switching or discontinuing PI has not been shown to reverse lipohypertrophy.⁷⁶⁵

Surgical interventions (i.e., liposuction, lipectomy, implants, and fillers) provide varying durations of effects with common lipodystrophy recurrence.⁷⁶⁶ Facial fillers have proven to be helpful, yet temporary fillers only last 3 – 24 months and need to be injected multiple times.⁷⁶⁷ Permanent fillers can lead to cyst and/or granuloma^{cxvi,768} formation. Providers frequently use combinations of fillers and surgical procedures to achieve the best aesthetic results.⁷⁶⁹

Transfer of an individual's fat from one area to another area is a popular and effective method for patients with suitable donor sites.⁷⁷⁰ Patients require frequent touch-ups of these transfers with potential side effects, including hypertrophy of the cheeks,^{cxvii,771} bleeding, bruising, facial redness and swelling, contour irregularities, and infection.⁷⁷² Certain areas of excess fat accumulation can be surgically removed; however, abdominal fat accumulation with HIV is visceral (i.e., stored near vital organs), eliminating liposuction as a treatment option.⁷⁷³ Some areas, such as the area behind the shoulder blades, are suitable for suction-assisted lipectomy, but the area may reaccumulate fat.⁷⁷⁴

HIV was once considered a fatal disease, but with antiretroviral therapy compliance, early proper treatment, and monitoring, patients can have near average life expectancies.⁷⁷⁵ Newer antiretroviral therapy and antiretroviral drugs appear to cause fewer fat distribution issues, although this might not be the best treatment option for all people living with HIV. In the absence of a cure for LDHIV, restorative dermatologic and surgical interventions can help patients maintain a healthy appearance and lifestyle, reduce stigma, and alleviate psychosocial distress.

^{cxvi} A granuloma is a cluster of white blood cells trying to fight off something harmful (e.g., infection or foreign object) or perceived to be harmful, resulting in an inflamed area. Skin granulomas can be pink, red, or purple, and are often sore to the touch.

^{cxvii} Also known as “hamster cheeks.”

Estimated Marginal Cost of the Mandate

The HIV-associated lipodystrophy treatment claims cost in 2023 is less than \$0.01 PMPM. A decrease in cost is expected due to improved antiretroviral therapies resulting in decreased HIV-associated lipodystrophy prevalence and severity. Additionally, at least one carrier indicated these services would be covered in the absence of the mandate further lowering potential mandate claims cost. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Home Health Care

The home health care (HHC) mandate requires coverage for medically necessary health care services that are delivered by a home health agency in an individual's residence. When deemed medically necessary, these coverage requirements include nursing and PT and can extend to additional services, such as OT, ST, medical social work, nutritional consultation services, the assistance of a home health aide, and the provision of durable medical equipment and supplies, when these services are medically necessary facets of nursing and PT services.⁷⁷⁶

Effect of the Mandate on Health

HHC encompasses a broad spectrum of health care services provided in the comfort of one's home for managing illnesses or injuries. This option is often more cost effective, convenient, and equally efficacious compared to receiving care in a hospital or skilled nursing facility (SNF).⁷⁷⁷ HHC is provided for those who are recovering, disabled, or chronically or terminally ill, requiring medical, nursing, social, or therapeutic treatment and assistance with essential daily activities. For individuals who prefer to stay in their own residence but require ongoing care that cannot be effectively provided solely by family and friends, HHC is the optimal option for delivery of services.⁷⁷⁸ The staff who provide HHC can vary, depending on which home health agency is being utilized. Generally, HHC services can be provided by doctors, nurses, therapists, social workers, and home care aides. Services tend to be available to individuals 24 hours daily, seven days a week, and depending on the individual's needs, services can be provided part time, intermittently, or hourly.⁷⁷⁹

HHC services offer a range of benefits, including the convenience of receiving post-surgery therapy at home rather than in a rehabilitation center and the flexibility of scheduling skilled nursing visits in one's own environment. The care provided is personalized and tailored to individuals' needs, addressing medical, personal, and cultural considerations. Additionally, these services can be adapted to the home environment to enhance safety and accessibility, while also offering respite for family caregivers. HHC can promote faster recovery, reduce hospital visits, and provide peace of mind for individuals and their families. HHC encourages social interaction, assists with daily activities, and delivers hospital-level care without the need for hospital stays, contributing to overall well-being and comfort.⁷⁸⁰

Given the wide variety of services encompassed in HHC, summarizing the clinical efficacy of HHC is particularly challenging. However, research indicates that the delivery of well-defined, quality HHC is both cost effective and provides clinical benefits. A systematic review of the cost-effectiveness of HHC services for adults and older adults found that of the 14 studies included in the review, HHC, as compared to hospital care, was cost saving in seven

studies, cost effective in two, and more clinically effective in one.⁷⁸¹ A different systematic review of the clinical effectiveness of HHC found that nurse-led HHC was associated with statistically significant mortality reduction, as indicated by a meta-analysis of eight studies. This review's findings also reflected fewer falls among individuals receiving HHC. Studies included in the review also reported positive outcomes across various other health indicators, such as improvements in neurological conditions and cardiorespiratory conditions.⁷⁸² HHC has demonstrated notable efficacy in caring for terminally ill individuals. Studies indicate that individuals who are terminally ill who receive HHC experience reduced hospitalizations, nursing home admissions, and outpatient visits. These individuals are more likely to fulfill their desire to pass away at home and express greater satisfaction with their care.⁷⁸³ HHC services have also demonstrated improved quality of life measures for terminally ill patients and their caregivers. Additionally, patients with either terminal or non-terminal illnesses have reported higher satisfaction rates with their care.⁷⁸⁴

Estimated Marginal Cost of the Mandate

Respondents to the carrier survey universally indicated that this mandate would impose no additional costs, and all required services are already being covered. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Hormone Replacement Therapy

This mandate requires insurance coverage of hormone replacement therapy (HRT) services for peri- and post-menopausal individuals under the same terms and conditions as other outpatient services and drugs.⁷⁸⁵

Effect of the Mandate on Health

Individuals with internal reproductive organs experience a menstrual cycle, in which the body completes a monthly cycle of ovulation and increasing blood hormone levels to thicken the endometrial walls and create an environment able to facilitate pregnancy.⁷⁸⁶ If the individual does not become pregnant, the blood levels of estrogen and progesterone begin to decrease, which causes the endometrial lining to shed, resulting in menstruation (also known as a period).⁷⁸⁷ Individuals experiencing menstruation will typically experience this cycle from puberty through age 45 – 55.⁷⁸⁸ Around age 45 – 55, the ovaries will lose their follicular function,^{cxviii,789,790} and estrogen^{cxix,791} and progesterone^{cxx,792,793} levels will fluctuate, marking the end of the reproductive cycle.⁷⁹⁴ The ending of the reproductive cycle is known as menopause and is considered to have three phases:⁷⁹⁵

^{cxviii} Follicular function refers to the physiological processes involved in the growth and maturation of ovarian follicles, which are small, fluid-filled structures within the ovaries containing immature eggs.

^{cxix} Estrogen is a type of hormone that helps develop and maintain female sex characteristics and the growth of long bones.

^{cxx} Progesterone is a female steroid sex hormone that is produced in the ovaries to prepare the uterine lining for implantation. Progesterone is naturally produced in the body and progestins are a class of synthetic hormones created to mimic the effect of progesterone in the body. Progestogen is an umbrella term that encompasses both progesterone and progestins.

Table 13. Stages of Menopause

STAGE	DESCRIPTION
Perimenopause	<ul style="list-style-type: none"> ▪ Ovaries begin to lose follicular function and levels of estrogen and progesterone begin to fluctuate⁷⁹⁶ ▪ Individuals may experience a variety of menopausal symptoms ▪ Begins at the onset of menopausal symptoms and continues until one year after an individual's final period⁷⁹⁷ ▪ Different duration for every individual but usually lasts four to eight years⁷⁹⁸
Menopause	<ul style="list-style-type: none"> ▪ Marks the end of the reproductive years⁷⁹⁹ ▪ Occurs one year after an individual's final period⁸⁰⁰ ▪ Median age is 51.3 years in the United States⁸⁰¹
Post-menopause	<ul style="list-style-type: none"> ▪ Encompasses all the years beyond menopause⁸⁰²

During the perimenopause phase, also known as the menopausal transition, individuals can experience a variety of vasomotor, physical, and psychological symptoms.⁸⁰³ Vasomotor symptoms (VMS) are the most commonly experienced type of symptoms, with 75% – 80% of individuals experiencing them.⁸⁰⁴ These symptoms include hot flashes, night sweats, heart palpitations, and migraines caused by fluctuating levels of estrogen.⁸⁰⁵ The median length of duration for individuals experiencing VMS in the United States is seven years, and certain factors have been found to influence the risk of developing and the duration of VMS during the menopausal transition, including lower socioeconomic status, African American race, smoking, and general negative mood.⁸⁰⁶ Hot flashes are a frequent complaint, as many individuals who are perimenopausal or menopausal experience them multiple times a day, which can affect day-to-day quality of life and sleep.⁸⁰⁷ Fifty to seventy-five percent of menopausal individuals experience genitourinary symptoms, including vaginal dryness, burning, pruritus^{cxix,808}, irritation, increases in the frequency and urgency to urinate, urethral atrophy, and frequent urinary tract infections (UTIs).⁸⁰⁹ Along with vasomotor and physical symptoms, around 70% of menopausal individuals experience psychogenic symptoms that can include anger, irritability, anxiety, tension, depression, decreased concentration, low self-esteem, and low self-confidence.⁸¹⁰ The presence, combination, and severity of any of these symptoms can cause significant disturbances in daily life.

HRT is an effective treatment option to address bothersome menopausal VMS.⁸¹¹ HRT does not relieve all symptoms of menopause but has been found to relieve common symptoms such as hot flashes, vaginal dryness, and sleep disturbances, as well as prevent osteoporosis.⁸¹² HRT has been found to reduce the frequency and severity of hot

^{cxix} Pruritus is a medical term for itchy skin.

flashes and night sweats in perimenopausal and menopausal individuals by 75%.⁸¹³ There are two types of HRT: estrogen-only therapy and combined hormone therapy, which uses estrogen and progesterone/progestin.^{814,815}

- Estrogen-only therapy is indicated for use in individuals who have had their uterus removed through a hysterectomy.⁸¹⁶
- Combined HRT is indicated for use in individuals with a uterus because estrogen-only therapy can increase the risk^{cxix,817} for uterine (endometrial) cancer.⁸¹⁸

HRT can be administered via pills, patches, sprays, and gels to address systemic symptoms such as hot flashes and night sweats.^{819,820} HRT can also be administered locally through creams, rings, and suppositories to address urinary symptoms and vaginal dryness.^{821,822} HRT can increase the risk of blood clots, heart attack, stroke, breast cancer, and gallbladder disease.⁸²³ Individuals who are pregnant, have undiagnosed vaginal bleeding, have certain types of cancer, have a history of stroke or heart attack, have a history of blood clots, or have liver disease should not take HRT.⁸²⁴ Due to these potential risks associated with the use of HRT, the FDA recommends doctors prescribe medications for HRT at the lowest effective dose for the shortest amount of time necessary.⁸²⁵ Current professional guidelines state that the benefits of HRT for treatment of VMS and other menopausal symptoms generally outweigh the risks for healthy, symptomatic individuals who are under the age of 60 and within 10 years from their final menstrual period.⁸²⁶ Other non-hormonal treatment^{tcxxiii,827} options exist for individuals who cannot take HRT or are concerned about the risks associated with HRT.⁸²⁸

HRT was previously thought to aid in the prevention of certain chronic conditions and cancers.⁸²⁹ While HRT has been found effective in prevention of osteoporosis, current research concludes that HRT for the prevention of cardiovascular disease and other chronic diseases has no overall net benefit.⁸³⁰ The USPSTF does not recommend the use of combined estrogen and progesterone/progestin for the primary prevention of chronic conditions in postmenopausal individuals who have an intact uterus and does not recommend the use of estrogen alone for the primary prevention of chronic conditions in a postmenopausal person who has had a hysterectomy.⁸³¹ The USPSTF emphasizes the need for additional research on how age, timing of HRT initiation, population differences, and variations in HRT formulations and durations affect health outcomes during menopause.⁸³²

Estimated Marginal Cost of the Mandate

Respondents to the carrier survey universally reported that the services required by this mandate would still be provided absent the mandate. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

^{cxix} This increased risk for uterine cancer stems from the possibility of excess estrogen causing abnormal thickening of the uterine lining, so the addition of progesterone/progestins aids in preventing abnormal thickening of this lining by decreasing the amount of estrogen in the uterus.

^{tcxxiii} Examples of non-hormonal treatment options for menopausal symptoms include selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs).

Hospice Care

This mandate requires coverage for licensed hospice services for individuals who are terminally ill and have a life expectancy of six months or less.⁸³³

Effect of the Mandate on Health

Hospice care prioritizes comfort and quality of life for those with serious illnesses. It is typically opted for when medical interventions are no longer effective or desired. Like palliative care, hospice offers comprehensive support for patients and their families but with a focus on comfort rather than on curative treatments. Eligibility for hospice is based on a prognosis of six months or less to live. Hospice care is a holistic approach, is not confined to a specific location, and can be provided either at home or in facilities like nursing homes, hospitals, or dedicated hospice centers. A multidisciplinary team, including nurses, doctors, social workers, spiritual advisors, and volunteers, collaborates to offer medical, emotional, and spiritual support to the individual and their family. Support is available from a hospice team typically 24 hours a day, seven days a week, at a minimum by phone.⁸³⁴

There are generally considered to be four levels of hospice care:⁸³⁵

- Standard or routine home care: The individual's family and/or loved ones provide care for them in their own home, with regular visits from hospice providers.
- General inpatient care: The individual receives hospice services in a facility when they have severe symptoms that cannot be effectively managed at home.
- Continuous home care: The individual receives intensive, short-term care at home during a symptom crisis. This service is available to those eligible for inpatient care who prefer to stay at home.
- Respite care: The individual receives temporary hospice care in a facility to provide their primary caregivers with a reprieve.⁸³⁶

Hospice and early palliative care have been found to honor individuals' end-of-life preferences and enhance their quality of life. Research indicates that cancer patients in hospice care experience fewer hospitalizations, intensive care unit admissions, and invasive procedures in their final weeks of life compared to those not in hospice.⁸³⁷ A study revealed that only 11% of cancer patients in hospice passed away in a hospital, compared with 75% of non-hospice patients.⁸³⁸ Hospice care also provides support to individuals and their families regarding preferences for place of death. Studies have demonstrated consistently that most individuals would prefer to die in their own home, yet a significant proportion of individuals pass away in hospitals.⁸³⁹ This discrepancy may be attributed to short hospice stays, possibly indicating a shift in care toward supportive measures in hospitals. When individuals enter hospice only in their final days, there is little time to transition care to the home setting, leading to a continued reliance on hospital-based supportive measures. Additionally, some patients with advanced illnesses might not be referred to hospice at all, instead receiving palliative or comfort care within the hospital. Earlier hospice referral could better align care with individuals' preferences and reduce hospitalizations, thereby facilitating a more dignified end-of-life experience.⁸⁴⁰ A systematic review of hospice care research highlights abundant evidence illustrating the advantages of hospice care.

Its findings indicated that hospice services not only enabled families to sustain patient care at home but also fostered a renewed sense of meaning and purpose for patients.⁸⁴¹

Estimated Marginal Cost of the Mandate

Given the relatively low cost and large benefit to patient wellbeing, carriers reported they would cover these services absent a mandate. In addition, respondents to the carrier survey universally reported that this mandate would not increase their costs. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Human Leukocyte Antigen Testing

The human leukocyte antigen (HLA) testing mandate requires coverage for HLA or histocompatibility locus antigen testing essential for determining the compatibility of a BMT donor.⁸⁴² The mandate does not require carriers to cover any costs related to recruiting and matching recipients with donors.⁸⁴³

Effect of the Mandate on Health

The histocompatibility antigen blood test examines HLAs, proteins found on most cells that help the immune system distinguish between self and foreign substances. HLAs are particularly abundant on the surface of white blood cells. The HLA test is performed to identify suitable matches for tissue and organ transplants, such as kidney or bone marrow transplants. Additionally, it can diagnose certain autoimmune disorders, determine parent-child relationships in cases of uncertainty, and monitor treatment effectiveness with certain medications.⁸⁴⁴

A BMT, also referred to as hematopoietic stem cell transplants (HP SCTs)⁸⁴⁵, is a medical procedure used to replace damaged or diseased bone marrow with healthy bone marrow stem cells.⁸⁴⁶ Included within HP SCTs are also stem cell transplants or peripheral blood stem cell transplants and cord blood transplants. The type of transplant can vary depending on the source of transplant cells, and the most common types are:

- Autologous stem cell transplants that utilize cells harvested from the patient themselves
- Allogeneic stem cell transplants that employ cells donated by a third-party donor
- Syngeneic stem cell transplants that involve cells provided by an identical twin of the patient⁸⁴⁷

This mandate specifically pertains to BMTs and does not encompass other types of transplants, such as cord blood transplants or the more prevalent peripheral blood transplants. Thus, the analysis focuses solely on BMTs.⁸⁴⁸

Bone marrow is the soft, spongy tissue found within the center of most bones, rich in blood vessels. It exists in two types: red and yellow. Red bone marrow contains blood stem cells that can mature into red blood cells, white blood cells, or platelets. Conversely, yellow bone marrow is primarily composed of fat and contains stem cells capable of transforming into cartilage, fat, or bone cells.⁸⁴⁹ BMTs are often necessary for treating blood cancers such as leukemia. The goal with the transplant is to conduct cell infusion from a healthy donor to stimulate blood cell

production. Disorders affecting bone marrow include leukemia, multiple myeloma, aplastic anemia, polycythemia vera, and myelodysplastic syndromes, impacting blood cell production and leading to various health complications.⁸⁵⁰

The immune system's recognition of HLA differences poses a significant challenge to allogeneic hematopoietic stem cell transplantation. While having an HLA-matched sibling donor is considered ideal for the transplant, only about 30% of patients have this option. For the remaining 70% of patients, alternative sources of stem cells include finding a matched unrelated adult volunteer donor, using a haploidentical donor, or utilizing a cord blood unit.⁸⁵¹ There are national options for finding unrelated donors for stem cell transplants, such as Be the Match and the Blood & Marrow Transplant Information Network. Other international registries are also available, with matches often found among individuals with similar racial or ethnic backgrounds. While white individuals historically had a better chance of finding a match due to registry diversity, the chances for all ethnic groups have improved as more volunteers join registries. Despite improvements, finding an unrelated donor can still take months due to the extensive search process, which may involve millions of records.⁸⁵²

The National Marrow Donor Program (NMDP) and the Center for International Blood and Marrow Transplant Research (CIBMTR) 2019 guidelines state that patients and donors should undergo DNA-based typing at high resolution for specific genetic markers known as HLA-A, HLA-B, HLA-C, HLA-DRB1, and HLA-DPB1 loci. These markers help match donors with compatible recipients for stem cell transplants. While some additional markers like HLA-DQB1, HLA-DRB3/4/5, HLA-DQA1, and HLA-DPA1 might not have as significant an impact on patient survival individually, they can still be useful in selecting donors, especially for patients who are at risk of graft failure.⁸⁵³

BMTs can be associated with complications such as graft-versus-host disease, graft failure, organ damage, infections, cataracts, infertility, the development of new cancers, and potential mortality.⁸⁵⁴ To minimize the risk of these complications, HLA matching should be the primary criteria for donor selection for stem cell transplantation, but other factors are also considered. These include CMV status, sex, age, ABO (blood type) compatibility, prior pregnancies, and donor body weight. Recent studies have shown that older donor age is associated with poorer overall survival and higher recipient mortality.⁸⁵⁵

While the Massachusetts mandate does not specifically refer to testing for the HLA-C marker, it does require coverage for the cost of HLA testing or histocompatibility locus antigen testing that is necessary to establish BMT donor suitability.⁸⁵⁶ The mandate also references M.G.L. Chapter 111 Section 218, which stipulates that HLA testing must adhere to medical eligibility requirements and established test protocols by various agencies, including the NMDP registry.⁸⁵⁷ It is assumed that the mandate encompasses testing based on the current guidelines set by the NMDP for BMTs.⁸⁵⁸

Estimated Marginal Cost of the Mandate

The majority of respondents to the carrier survey indicated that this mandate would impose no additional costs. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Hypodermic Syringes or Needles

This mandate requires coverage of medically necessary hypodermic syringes or needles.⁸⁵⁹ This mandate was enacted within legislation aimed to address a variety of issues related to the prevention of blood-borne disease transmission, which includes needle distribution programs for users of illegal drugs.⁸⁶⁰ However, the language in this mandate is limited to the medically necessary use of needles covered by carriers, and while this could theoretically include scenarios involving illegal drug injection, addressing such scenarios is beyond the scope of this review.

Effect of the Mandate on Health

A hypodermic syringe or needle is a medical device used to administer medications that either cannot be administered orally because they cannot be effectively absorbed or because they need to be absorbed at a faster rate than oral administration allows.^{861,862} This device consists of a hollow needle, available in a variety of sizes, that is attached to a small, single-use syringe.⁸⁶³ Using a hypodermic needle allows for subcutaneous or intramuscular injection.⁸⁶⁴ Self-injection medications can be included in treatment plans for conditions such as diabetes, migraines, multiple sclerosis, rheumatoid arthritis, infertility, anemia, cancer, and HIV/AIDS.^{865,866,867} After a syringe and needle are used once, they are no longer sterile, so additional use increases the risk of infection, injury, and adverse side effects.⁸⁶⁸ Therefore, access to an adequate supply of hypodermic syringes or needles is imperative to ensure safe and effective self-injection of medications by individuals. The ability to self-administer medication provides convenience and a potential to increase treatment plan adherence, especially for individuals with conditions that require frequent injections. It allows the individual to spend less time and money travelling to and attending medical appointments, decreases the disruption of daily life by reducing the need for frequent clinic visits, and reduces the impact of administrative barriers such as appointment scheduling.⁸⁶⁹ While self-administration of injectable medications has many benefits, some individuals may be apprehensive about self-injections due to a fear of needles, or they may struggle with the mechanics of administering the injection.^{870,871} There are alternatives to hypodermic syringes and needles available that are outside the scope of this mandate, including prefilled syringes, prefilled injection pens, and autoinjectors.⁸⁷² These alternatives to self-injection have the potential to improve the individual's experience, adherence to their treatment plan, and outcomes due to increased ease of use, improved convenience, enhanced accuracy, and potential to reduce pain and anxiety associated with injection.⁸⁷³

Estimated Marginal Cost of the Mandate

Respondents to the carrier survey universally indicated that this mandate would impose no additional costs, and the services required by the mandate would be covered absent the mandate. Additionally, hypodermic syringes and needles are already required to be covered in many instances, such as when they are used in diabetes treatment, which is also included in a zero-cost mandate. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Lead Poisoning Screening

The lead screening mandate requires coverage of screening for lead poisoning for all children under age six and all children who may be at high risk of lead poisoning.⁸⁷⁴

Effect of the Mandate on Health

Exposure to lead during childhood can cause a variety of health and development issues that can persist across the lifespan. Treatment for lead poisoning can address symptoms and lower blood lead levels (BLLs), but the damaging effects of lead on behavior and the neurological system are irreversible.⁸⁷⁵ Society has gained a better understanding of lead and its harmful effects over the last several decades, which has fueled important actions, such as the 1978 ban on the manufacturing of lead paint in the United States, the passage of the Clean Air, Clean Water and Safe Drinking Water Acts, the creation of programs and initiatives like the CDC's Childhood Lead Poisoning Prevention Program, and others.^{876,877,878} These actions have led to significant progress in reducing the prevalence of lead poisoning and the chances of lead exposure for the general population.

In the United States, approximately 87,000 children are diagnosed with lead poisoning annually, and it is estimated that more than half of all children in the United States have some detectable level of lead in their blood.⁸⁷⁹ Prevention and mitigation efforts have significantly decreased the prevalence of lead poisoning in the general population. Significant sources of childhood exposure to lead include living in housing built prior to 1978 with deteriorating paint or a house that is being renovated, having a sibling or other close friend who has experienced lead poisoning, living in housing with lead-based pipes and plumbing fixtures, and living near airports or busy roads.^{880,881} Certain individuals remain at a higher risk for exposure to these sources, including people of color, people in households living below 130% of the federal poverty level, immigrants, and refugees. This heightened risk can be attributed to elevated prevalence of lead paint and fixtures in older and low-income housing, increased likelihood of other environmental exposures, and, for immigrants and refugees, origination from regions with less stringent lead regulations.^{882,883} Massachusetts state law requires lead paint to be removed or controlled for households with children under six years old and prohibits property owners from discriminating against families with children.^{884,885,886} Examples of lead paint control methods include regular home cleaning, paint encapsulation, and paint stabilization.⁸⁸⁷

The CDC recommends that any child who is at risk for lead exposure have their BLL tested.⁸⁸⁸ In Massachusetts, 105 CMR 460.050 requires that all children have their BLL tested between 9 and 12 months of age, again at age two, and again at age three.^{889,890,891} This law also says that children living in high-risk areas must also be screened at four years of age.⁸⁹² Proof of screening for lead poisoning is required by the state for entry into preschool, day care, or kindergarten.⁸⁹³ The first step in testing a child for lead is taking a finger- or heel-prick sample. If this result is higher than the CDC's blood lead reference value (BLRV) of 3.5µg/dL, a venous blood draw will be done to confirm the result.⁸⁹⁴ The CDC's BLRV was previously 5µg/dL, but it was lowered to 3.5µg/dL in October of 2021 based on data that showed 97.5% of the population aged one to five years old had a BLL at or below 3.5 µg/dL.⁸⁹⁵ Monitoring and adjusting this reference value based on collected data enables identification of children with higher BLLs compared to other children, so appropriate interventions can be implemented to prevent further exposure and to address any developmental or health issues.⁸⁹⁶ This reference value is also important for monitoring progress toward the Healthy

People 2030 objective to reduce BLLs in children aged one to five years, with the goal of having 97.5% of this population's BLL at or below 1.18 µg/dL.⁸⁹⁷

Children under the age of six are a primary focus for lead poisoning prevention efforts because children at this age are in a rapid phase of development and are able to absorb a higher percentage of lead than adults, which renders the potential negative impact from lead poisoning on their health and development much greater.⁸⁹⁸ During this rapid and critical phase of development, lead exposure can negatively impact the growth of critical brain and body structures, which can cause decreases in intelligence quotient (IQ) and cognitive function.^{899,900} Additionally, it has been found that the relative impact of elevated BLLs on cognitive function is strongest at lower levels of exposure, which means that the first units of lead exposure (i.e., lead exposure during childhood) are likely to cause the most harm.⁹⁰¹ Research demonstrates a dose-response relationship between lead exposure during childhood and downward social mobility during adulthood, with much of this relationship being attributable to lead decreasing IQ scores.⁹⁰² Small deficits in IQ can have a negative effect on educational and occupational achievement, health, socioeconomic status, and overall happiness.⁹⁰³ Other examples of developmental issues caused by lead poisoning include delayed growth, reduced growth, and delays in puberty.⁹⁰⁴ Later in life, lead poisoning may also cause health problems such as cardiovascular issues, reduced kidney function, fertility issues, and nerve disorders.⁹⁰⁵

Symptoms of lead poisoning will present differently in every individual across a range of BLL. While no level of lead in the blood is safe, a BLL of 3.5 µg/dL is the starting point for concern for lead poisoning.⁹⁰⁶ An individual may show symptoms of impaired ability, such as impaired learning, trouble with memory, impaired speech, and hyperactivity, at BLLs of 10 – 25 µg/dL.⁹⁰⁷ Noticeable symptoms of lead intoxication, such as irritability, fatigue, numbness, abdominal pain, constipation, headache, vomiting, and weight loss, can present at BLLs of 35 – 50 µg/dL in children and 40 – 60 µg/dL in adults.⁹⁰⁸ Symptoms and health effects of severe lead poisoning, such as severe abdominal cramping, seizures, loss of consciousness, coma, paralysis, and even death, are generally associated with BLLs of 70 µg/dL or greater in children and levels of 100 µg/dL or greater in adults.⁹⁰⁹ Lead negatively affects the body's ability to use iron and vitamin D, causing health conditions such as anemia and immunotoxicity and adversely impacting hearing, balance, and basic nervous system functions.^{910,911}

While lead poisoning screening is required for children in Massachusetts, the Massachusetts 2021 Surveillance Report shows that screening rates have fluctuated over the past several years, largely due to the COVID-19 pandemic and recalls on devices that measure BLL.^{cxxiv,912,913,914} This report also found that only 66% of elevated capillary (finger-prick) tests were followed by a venous blood test to confirm the elevated result.⁹¹⁵ Follow-up with a venous blood test after every elevated capillary test result is essential to accurately identify children who are currently being exposed to lead so that appropriate prevention and treatment can take place to reduce this exposure and prevent future harmful effects.⁹¹⁶

^{cxxiv} The devices recalled were LeadCare II devices produced by Magellan Diagnostics. These devices are point-of-care blood lead testing systems that are used in medical offices for capillary screening tests.

As of April 2019, the USPSTF concluded that the current evidence is insufficient to assess the balance between the benefits and harms of screening for elevated BLLs in children who are asymptomatic.⁹¹⁷ The ACA requires private carriers to cover preventive pediatric services recommended by the AAP, which are summarized in the “Bright Futures” periodicity schedule.⁹¹⁸ The AAP recommends providers conduct risk assessments at well-child visits for children at six, nine, 12, 18, and 24 months, and then yearly through age six.⁹¹⁹ The current Bright Futures periodicity schedule does not endorse universal screening; instead providers should only administer BLL tests for children who have a positive risk assessment, including living in areas with high prevalence of lead.⁹²⁰ children who receive Medicaid benefits are required to have their BLL tested at 12 and 24 months as part of the Medicaid Early and Periodic Screening, Diagnostic, and Treatment program.⁹²¹ Since there is no safe BLL and lead can cause serious health effects, continued implementation of mandatory screening requirements should continue to appropriately identify and treat children who are exposed to lead as well as prevent further exposure.⁹²²

Estimated Marginal Cost of the Mandate

Lead poisoning screening is a relatively low-cost and medically effective service, which respondents to the carrier survey indicated would be covered absent this mandate. Additionally, this mandate overlaps with required coverage for lead poisoning screening under the Affordable Care Act. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Mammography

The mammography mandate requires coverage for a baseline mammogram for women between the ages of 35 and 40 and for a mammogram on an annual basis for women 40 years of age or older.⁹²³

Effect of the Mandate on Health

In the United States, breast cancer is the second most common cancer (15.5% of new cancer cases),⁹²⁴ the second most common cause of cancer death among women^{cxv} (6.8%),⁹²⁵ and the overall fourth leading cause of cancer death (7%).⁹²⁶ Male breast cancer is rare, comprising about 1% of breast cancers, but has a high mortality rate.⁹²⁷ Unlike for women, in most breast cancer cases in males, lumps can be felt.⁹²⁸ Screening for breast cancer can help physicians detect cancers early, which makes treatment easier and can reduce morbidity and mortality.^{929,930} Most breast cancer in women is caught early (63.8%), because the cancer is localized and has not spread; localized breast cancer has a 100% five-year relative survival rate, and breast cancer overall has a 91.7% relative survival rate.⁹³¹

The types of tests and exams that can be used to screen for breast cancer are mammograms, breast magnetic resonance imaging, clinical breast exam, and breast self-awareness, which can help identify changes that may be of concern.⁹³² However, there is limited evidence that clinical breast exams or breast self-exams can detect breast

^{cxv} Although the mandate does not specify gender, much of the research focuses on cisgender women and people assigned female at birth. Although breast cancer can affect anyone, the prevalence of the disease is higher among people assigned female at birth, referred to as “women.”

cancer when women also get screening mammograms.⁹³³ To detect breast cancer, systematic reviews have found that screening mammography when compared to usual care is associated with reduced breast cancer mortality.⁹³⁴ The primary risk of screening mammography is a recall for additional imaging, and after a diagnostic evaluation, a resulting biopsy that yields a benign result.⁹³⁵ Women should be informed about the benefits and harms prior to undergoing mammography.⁹³⁶ The main benefit of screening is the reduction of breast cancer-related death.⁹³⁷

Mammograms, X-rays of the breast, can detect breast cancer when it is asymptomatic or not big enough to feel.⁹³⁸ There are two main types of mammography: two-dimensional (2D) digital mammograms and digital breast tomosynthesis (DBT), commonly known as three-dimensional (3D) mammography.⁹³⁹ DBT is often considered the better mammogram based on observed increases in specificity and breast cancer detection compared with digital mammography,⁹⁴⁰ resulting in decreased false-positive mammograms while simultaneously increasing cancer detection.⁹⁴¹ Further, many studies have found that DBT appears to lower the chances of being called back for follow-up testing as compared with standard (2D) digital mammograms.⁹⁴²

Among women ages 40 – 74 at average risk of breast cancer, studies have found that screening mammography can reduce breast cancer mortality.⁹⁴³ A recent systematic review of global guidelines for breast cancer screening found that the majority of the guidelines recommended mammographic screening for average-risk individuals aged 40 – 74 years with most suggesting annual or biennial screening.⁹⁴⁴ The American Cancer Society revised its breast cancer screening guidelines in 2015 to recommend annual screenings beginning at age 45.⁹⁴⁵ In 2024, the USPSTF updated its breast cancer guidelines to begin screening at age 40 instead of 50 based on findings that mammography screening in women aged 40 – 49 years has a moderate benefit by reducing breast cancer deaths.⁹⁴⁶ The most recent guidelines of five leading organizations are summarized below in

Table 14.

Table 14. 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) ⁹⁴⁷	Biennial screening mammography	Biennial screening mammography	Insufficient evidence to assess the balance of benefits and risks of screening mammography for recommendation	Current evidence suggests both digital mammography and DBT are effective primary screening modalities
American Cancer Society (2023) ⁹⁴⁸	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
American College of Physicians (2019) ⁹⁴⁹	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 (2021) ⁹⁵⁰	Begin screening annually at age 40	The age to stop screening should be based on each woman's health status rather than an age-based determination		Annual screening with mammography or DBT beginning at age 40
USPSTF (2024) ⁹⁵¹	Biennial screening mammography	Biennial screening mammography	Insufficient evidence to assess the balance of benefits and harms of screening mammography for recommendation	Current evidence suggests both digital mammography and DBT are effective primary screening modalities

The final recommendations of the USPSTF for mammography screening, released in 2024, give a “B” grade to the recommendation for women ages 40 – 74, and an “I” grade for women over 75.⁹⁵² A “B” grade indicates that the

USPSTF recommends clinicians offer or provide the service to eligible patients, and an “I” grade indicates that evidence is insufficient to recommend for or against routinely providing the service.⁹⁵³ Further, based on a collaborative modeling analysis by the USPSTF, for average-risk female persons, mammography screening strategies reduce breast cancer mortality and increase life expectancy;⁹⁵⁴ observational trials have demonstrated that organized mammography screening results in mortality reductions of 40% or greater.⁹⁵⁵

Estimated Marginal Cost of the Mandate

Respondents to the carrier survey indicated that the services required by this mandate would be covered absent the mandate. Breast cancer screenings are a critical part of preventing breast cancer, and these screenings are also mandated by the ACA independent of this mandate. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Maternity Health Care (Including Minimum Maternity Stay)

This 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 inpatient care following a vaginal delivery and a minimum of 96 hours of inpatient care following a caesarean section (C-section) for a mother^{cxvii} and newborn child.⁹⁵⁶ Early discharge^{cxviii} of the mother and infant must be made by the attending physician,^{cxviii} in consultation with the mother and in accordance with rules and regulations promulgated by the DPH. The mandate requires post-delivery care to include “home visits,^{cxix} parent education, assistance and training in breast or bottle feeding, and the performance of any necessary and appropriate clinical tests.” The first home visit must be conducted by an RN, physician, or CNM, with any subsequent clinically necessary visits conducted by a licensed health care provider.

Effect of the Mandate on Health

Federal legislation enacted in 1996, the Newborns’ and Mothers’ Health Protection Act of 1996 (NMPHA), requires carriers to provide a minimum maternity stay^{cxix} of at least 48 hours for a vaginal delivery or 96 hours for a C-section.⁹⁵⁷ The law provides an exception if the attending provider, in consultation with the mother, determines that either the mother or the newborn child can be discharged prior to the minimum stay.⁹⁵⁸ In addition, the ACA requires carriers to cover maternity and newborn care as EHB.⁹⁵⁹

^{cxvi} The language in this report strives to be respectful of individual identity. The term “mother” is used in the bill language and in relevant research. This mandate uses “mother,” “pregnant person,” and “birthing person” interchangeably.

^{cxvii} Early discharge is noted as less than 48 hours for vaginal delivery and less than 96 hours for cesarean delivery.

^{cxviii} Physician in this mandate is defined as an obstetrician, pediatrician, or certified nurse midwife.

^{cxix} This requirement will be explored in a separate mandate, *Universal Postpartum Home Visits*.

^{cxix} The minimum stay begins at the time of the delivery.

Prenatal care^{cxv},⁹⁶⁰ is one of the most used health services in the United States.⁹⁶¹ Prenatal care typically includes assessment and monitoring of the pregnant person and fetus, including medical and family history^{cxvii} as well as non-medical needs.^{cxviii},⁹⁶² This care serves as a secondary prevention tool, with researchers ascribing efficacy of prenatal care to its frequency, accessibility, and utilization of care.⁹⁶³ Access to and regular use of prenatal care can decrease the risk of pregnancy complications, help pregnant people manage existing conditions, prevent serious complications for the mother and infant,⁹⁶⁴ decrease hospital admissions, and lower pregnancy-associated morbidity and mortality.⁹⁶⁵

Research shows that inadequate prenatal care increases risk for adverse perinatal outcomes, including preterm births, low infant birth weights, and longer hospital visits after birth.⁹⁶⁶ Inadequate prenatal care has also been shown to result in significantly higher fetal and newborn mortality.⁹⁶⁷ Studies have shown improved maternal and birth outcomes for people receiving prenatal care with preeclampsia,^{cxix},⁹⁶⁸ gestational diabetes,^{cxv},⁹⁶⁹ and HIV.⁹⁷⁰

In the United States, 98.4% of births occur in hospitals.⁹⁷¹ The AAP does not provide a recommendation for specific LOS; instead, the AAP recommends the mother and newborn infant hospital stay should be long enough to enable identification of problems and to help ensure sufficient recovery of the mother.⁹⁷² Criteria for readiness of newborn discharge to reduce readmission include:⁹⁷³

- Physiologic stability
- Family preparedness and ability to provide care
- Parental availability of social support
- Parental or familial access to the health care system and resources

^{cxv} Prenatal care is defined as the health care, education, and counseling provided while pregnant.

^{cxvii} Medical needs include chronic conditions, mental health and substance use disorder history, surgeries, allergies, medications, oral health. Family history includes genetic conditions, chronic conditions, pregnancy loss or complications, and cancer.

^{cxviii} Non-medical factors include an individual's characteristics and social identity, especially as it pertains to historic marginalization, current level of social support, assessment of past trauma (including intimate partner violence), current access to housing, food, transit, and health care, financial status, education level, and current employment.

^{cxix} Preeclampsia is a pregnancy-related condition categorized by high blood pressure and affects 2% – 8% of pregnancies. Preeclampsia increases risk for serious morbidity and mortality for the birthing person and infant. Early identification and treatment of preeclampsia can improve outcomes, including reducing maternal mortality.

^{cxv} Gestational diabetes mellitus (GDM) develops around the 24th week of gestation in pregnant people without a prior medical record of diabetes. GDM increases the risk of cesarean deliveries and hemorrhaging during delivery and is an independent predictor of adverse pregnancy and neonatal outcomes. Prenatal care can reduce incidence of complications associated with GDM.

Various neonatal problems such as cardiopulmonary^{cxvvi,974} problems, jaundice,^{cxvii,975} ductal-dependent cardiac lesions,^{cxviii,976} and GI obstruction^{cxvix,977} may require more than 12 hours of observation before becoming apparent. Similarly, maternal complications, such as endometritis,^{cxl,978} might not become apparent until after the first day of delivery.⁹⁷⁹ Additionally, more than half of maternal deaths occur after the day of delivery.⁹⁸⁰ The AAP recommends that all efforts be made to help ensure simultaneous discharge of the mother and child.

Research demonstrates that early hospital discharges for newborns at any time ≤ 48 hours post birth increase the risk for readmission, including jaundice-related readmission.⁹⁸¹ However, one study evaluating decreasing the LOS (i.e., less than two days for vaginal birth and less than three days for C-section) during COVID-19 found no association with increased rehospitalization after discharge for healthy, full-term infants.⁹⁸² These findings suggest that shared family and clinician decision-making can reduce future infant hospitalizations.⁹⁸³ Additional research is needed to determine if decreased LOS is associated with reduced access to supplemental services such as lactation support.⁹⁸⁴ If a newborn is deemed eligible to be discharged before 48 hours after delivery, a follow-up exam should be scheduled within 48 hours of discharge, or early discharge should be deferred.⁹⁸⁵

Many services are performed in the postpartum pre-discharge stay, including newborn screenings and risk assessment; administration of immunizations; maternal and family counseling and assessments; education on issues such as breastfeeding, newborn sleep position, tobacco smoke exposure, car seat safety, mental health including PPD, and domestic violence; and outpatient follow-up care planning for mother and baby.⁹⁸⁶

The postpartum period is undefined in this mandate. The mandate seemingly applies to the first 24 hours postpartum, with no explicit mention of postpartum care coverage benefits outside of this period.

The American College of Obstetricians and Gynecologists (ACOG) reports that as of 2022, nationally, one third of maternal deaths and nearly one in seven cases of severe maternal morbidity (SMM)^{cxli,987} occur in the postpartum period.^{cxlii,988} Using data as recent as 2020, in Massachusetts, about 400 birthing people are affected by SMM, with disproportionately high rates among Black birthing people.⁹⁸⁹

^{cxvvi} Cardiopulmonary means having to do with the heart and lungs. Neonatal cardiopulmonary problems are usually related to the transition from intrauterine to the extrauterine environment.

^{cxvii} Jaundice in newborns is yellow skin color caused by a buildup of bilirubin, which is usually removed by the mother's liver in pregnancy.

^{cxviii} Ductal-dependent cardiac lesions are a type of congenital heart disease.

^{cxvix} GI obstruction is the most common surgical emergency in the neonatal period that can be fatal if not treated promptly.

^{cxl} Endometritis is inflammation of the uterine lining and is the most common postpartum infection.

^{cxli} SMM includes unexpected outcomes of labor and delivery that can result in significant short- or long-term health consequences. Birth-related examples include hemorrhages, amniotic fluid embolisms, cardiovascular conditions, hypertensive disorders, and/or infections.

^{cxlii} The postpartum period is defined as between seven days and one year after birth.

Research suggests that mortality and morbidity rates would decrease with holistic, patient-centered care.⁹⁹⁰ ACOG recommends contact between provider and birthing person within the first three weeks postpartum, followed by a comprehensive postpartum visit within twelve weeks after birth.⁹⁹¹

Estimated Marginal Cost of the Mandate

Respondents to the carrier survey indicated that the services required by this mandate would be covered absent the mandate. Additionally, maternity care and minimum maternity stay are mandated by the ACA independently of this mandate. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Nurse Practitioners

The nurse practitioner (NP) mandate stipulates that carriers, subject to their network terms, must cover NP services if those same services are reimbursed when they are performed by any other practitioner and fall within the lawful scope of practice for NPs. Additionally, Chapter 176R of the M.G.L.s authorizes NPs to function as primary care physicians and prohibits carriers from imposing reduced coverage limits on NPs.⁹⁹²

Effect of the Mandate on Health

NPs are APRNs who fulfill vital roles as both primary and specialized health care providers, delivering advanced nursing care to patients and their families. Their responsibilities include assessing patients, devising strategies to enhance or manage health, and integrating health promotion initiatives into patient care plans. NPs often specialize in specific patient populations, such as adults and the elderly, children and adolescents, or individuals with psychiatric and mental health needs.⁹⁹³ NPs can also specialize in acute care, adult health, family health, gerontology, neonatology, oncology, psychiatry, and women's health.⁹⁹⁴

To become an NP, individuals must complete a master's or doctoral degree program and undergo advanced clinical training beyond their initial RN training. Through didactic and clinical courses, NPs acquire specialized knowledge and clinical competency tailored for primary care, acute care, and long-term health care settings. They engage in continuous professional development and contribute to health care quality improvement through research and clinical practice application. NPs' training enables them to perform many services that doctors perform. NPs provide patient-centered care, focusing on disease prevention, healthy living, and addressing health concerns. They can work as primary or specialty care providers, serving specific patient populations, in various health care settings such as physicians' offices, clinics, hospitals, and nursing homes, among others.^{995,996}

As of 2022, there are over 385,000 NPs licensed in the United States.⁹⁹⁷ NPs can hold licenses in all states in the United States and in the District of Columbia (D.C.).⁹⁹⁸ The majority of NPs (88.0%) are certified in primary care, and over two thirds (70.3%) deliver services in primary care. NPs maintain prescriptive authority in all 50 states and in D.C.⁹⁹⁹ In 2018, there were 9,601 certified NPs in Massachusetts.¹⁰⁰⁰ In 2008, the NCSBN embraced the Consensus Model for APRN Regulation to establish uniform regulations and legislation nationwide, its goal being to standardize licensure to practice, APRN program accreditation, national certification requirements, and educational standards.¹⁰⁰¹

In Massachusetts, NPs are eligible to engage in prescriptive practice after completion of required training pursuant to M.G.L. c. 94C, § 18(e).¹⁰⁰² Pursuant to Mass. Reg. Code §244-4.07, NPs with under two years of experience require prescribing guidelines and supervision by a Qualified Health Care Professional (physician or NP with independent practice authority), after which they may prescribe independently.¹⁰⁰³

Studies have shown that the quality of care provided by NPs, and the health outcomes of individuals who receive care from NPs, are at a minimum comparable to those delivered by medical doctors (MDs). In a 2013 review comparing the quality and safety of care delivered by NPs to that provided by MDs, researchers discovered that outcomes for NPs were either comparable or superior across all 11 assessed criteria. A substantial body of evidence indicated that patient outcomes, including satisfaction with care, functional status, health status, ED visits, hospitalization rates, blood pressure, blood glucose, serum lipids, and mortality, showed no significant difference between NPs and MDs.¹⁰⁰⁴ A 2017 review of 15 articles examining the influence of advanced practice nursing in emergency and critical care contexts concluded that NPs delivered equivalent or superior quality of care in consultation time, treatment, patient satisfaction, and LOS compared to traditional service models. Furthermore, NPs exhibited comparable patient mortality rates to physicians.¹⁰⁰⁵ A 2021 systematic review of state regulations from January 2000 to August 2019 suggested that relaxed state regulations for NPs were linked to increased NP availability and enhanced health care access for rural and underserved communities, without compromising care quality. States that implemented Full Practice Authority (FPA) observed increased rates of primary care visits, mammograms, and community health center education and reduced rates of ED visits. Overall, states with FPA exhibited comparable or superior health care quality and outcomes compared to those without such authority.¹⁰⁰⁶

Estimated Marginal Cost of the Mandate

This mandate requires that services provided by an NP are covered if they would also be covered when provided by a physician. NPs are a lower-cost alternative to physicians and given that the services covered by this mandate would also be covered if performed by a physician, it is unlikely that any additional costs would result. Additionally, respondents to the carrier survey universally indicated that this mandate would impose no additional costs on them. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Off-Label Uses of Prescription Drugs to Treat Cancer

The mandate requires carriers that cover prescription drugs to also cover drugs used for cancer treatment, even if the drug's off-label use is not FDA approved—so long as the drug is recognized for that use in a standard reference compendium, medical literature, or by the Commissioner of Insurance based on recommendations from a medical review panel.¹⁰⁰⁷

Effect of the Mandate on Health

Off-label prescription drugs are prescribed to treat conditions other than those for which the drug has been approved as indicated on its official label.¹⁰⁰⁸ Use of off-label drugs can be classified into different categories, including:

- Unapproved indication
- Use in a special population
- Through an unapproved route of administration
- With a dose not specified in the label approved by the FDA¹⁰⁰⁹

The National Comprehensive Cancer Network (NCCN) continuously publishes and updates recommendations and guidelines for drugs used in cancer treatment and includes off-label prescriptions in its recommendations.¹⁰¹⁰

Because of the strength and reliability of these recommendations, any non-FDA-approved drugs recommended by the NCCN are considered “off-label” and are often later approved by the FDA.^{1011,1012} If the drug is not recommended by NCCN, it is considered “off-guideline.”¹⁰¹³

In Massachusetts, off-label drugs can be prescribed for treatment when they are recognized for the indication in the standard reference compendia or medical literature or if indicated by the Commissioner of Insurance based on the recommendation of a panel established to review the use of off-label drugs.¹⁰¹⁴ The review panel is made up of six medical experts, including 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 HMOs from a member plan.¹⁰¹⁵ The panel is responsible for reviewing 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 advising the commissioner in such instances on whether a particular off-label use is medically appropriate.¹⁰¹⁶

Off-label drug use that is based on little to no scientific evidence is deemed off-evidence drug use.¹⁰¹⁷ This practice is different than compassionate use or right to try in which a prescriber can facilitate the use of investigational treatments for individuals suffering from chronic, severely debilitating, or deadly diseases, or for individuals who might not have access to beneficial approved treatments or might not be eligible for clinical trials.¹⁰¹⁸

Drugs go through an extensive research and approval process with the FDA, which can take several years. The FDA's drug development and approval process consists of four phases followed by safety monitoring after approval:¹⁰¹⁹

1. Discovery and development
2. Preclinical research
3. Clinical research
4. FDA review
5. Post-approval safety monitoring

Pharmaceutical companies conduct research and clinical trials with a focus on a limited scope of specific conditions and indications for each specific drug, so approval from the FDA is only issued for those specific conditions and indications.¹⁰²⁰ After this approval, drug companies often do not continue to seek approval for additional indications, even if the drug could be effective in treating other conditions, due to time and financial constraints.¹⁰²¹ Despite this, once a drug is approved by the FDA, physicians have the ability to prescribe drugs off-label for any purpose if they believe it is appropriate for their patient.^{1022,1023} Physicians should consider their patients' characteristics and needs with available and reliable scientific evidence when considering whether to prescribe a drug off-label.¹⁰²⁴ The use of off-label prescription drugs is considered appropriate when it is in the best interest of the patient based on published scientific data that supports the use of that drug for the patient's indication and the risks of using the medication do not outweigh the benefits.¹⁰²⁵

Off-label prescribing of drugs is a practice often used in cancer treatment, across all types and stages of cancer, because it can provide evidence-based treatment options to individuals who have few or no alternative treatment options.¹⁰²⁶ Many chemotherapy drugs are prescribed off-label because they are prescribed with altered doses, in combination with other drugs, with altered schedules, different routes of administration, and for different durations than what was approved by the FDA.^{1027,1028} It would not be feasible for clinical trials to be conducted for every possible chemotherapy combination, dose, or route of administration.^{1029,1030} Drugs are also often prescribed off-label for cancer treatment due to the lag time between the availability of clinical trial results and FDA approval.¹⁰³¹ With the approval process taking an average of 12 years from preclinical testing to approval, the ability to prescribe drugs off-label allows physicians and their patients to utilize drugs with promising clinical trial results that could provide benefits.^{1032,1033} Use of off-label prescription drugs does not come without risks, as patient safety can be negatively impacted if the benefit-to-risk ratio is not fully considered.¹⁰³⁴ Physicians should always base these prescribing decisions on sound evidence and the informed consent of their patients.¹⁰³⁵ Many patients with advanced or metastatic cancer are willing to try drugs that come with an uncertain level of risk because they may have exhausted all other treatment options, and the off-label drug could offer prolonged survival.¹⁰³⁶

A 2024 study of 165,912 participants found that 18.6% of individuals who have gone through cancer treatment have been prescribed a drug off-label, and 4.4% have been prescribed a drug “off-guideline.”¹⁰³⁷ Of those with more than one type of cancer, 19.9% were prescribed an off-label drug, and 4.6% were prescribed an off-guideline drug.¹⁰³⁸ A 2016 literature review found that 13% – 71% of adult patients with cancer received at least one type of chemotherapy that was considered off-label.¹⁰³⁹ Outcomes and adverse events from off-label drug use are not well documented, so it is difficult to determine the overall effectiveness of this practice.¹⁰⁴⁰ Any outcome results from patients using off-label drugs that are documented are considered real-world data (RWD), and the FDA has increasingly used RWD to support approval for oncology drugs and label expansions, making the use of off-label drugs important in developing future cancer treatment options.¹⁰⁴¹

Estimated Marginal Cost of the Mandate

This mandate requires coverage for cancer treatment drugs even when prescribed off-label. While the ACA does not specify coverage for these situations, off-label prescriptions for cancer treatment are almost always medically necessary and therefore would be covered absent this mandate. Respondents to the carrier survey indicated that the costs required by this mandate are immeasurable; however, it is reasonable to estimate that prescriptions of off-label drugs that would not be covered absent this mandate are extremely rare. While this mandate may impose some additional costs on carriers, these costs are likely relatively immaterial. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

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

This mandate requires that carriers providing coverage for prescription drugs cannot exclude coverage for any drug for HIV/AIDS treatment on the grounds that the off-label use of the drug has not been approved by the FDA for that indication, if such drug is recognized for treatment of such indication in one of the standard reference compendia or in 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.¹⁰⁴²

Effect of the Mandate on Health

Off-label prescription drugs are prescription drugs that are prescribed to treat a different condition than what the drug is approved to treat as stated on its label.¹⁰⁴³ Use of off-label drugs can be classified into different categories, including:

- Unapproved indication
- Use in a special population
- Through an unapproved route of administration
- With a dose not specified in the label approved by the FDA¹⁰⁴⁴

In Massachusetts, off-label drugs can be prescribed for treatment when they are recognized for the indication in the standard reference compendia or in medical literature or if indicated by the Commissioner of Insurance based on the

recommendation of a panel established to review the use of off-label drugs.¹⁰⁴⁵ The review panel is composed of 11 medical experts, including three medical infectious disease specialists selected by the Massachusetts DPH, two physicians selected by the DPH, one physician representing a nonprofit hospital and medical service corporation, one physician representing HMOs, one physician representing commercial carriers, two consumers selected by the DPH, and one representative from an AIDS service organization or consumer advocacy group selected by the Massachusetts DPH.¹⁰⁴⁶ The panel is responsible for reviewing off-label uses of prescription drugs for the treatment of HIV/AIDS not included in any of the standard reference compendia, or in medical literature, and advising the commissioner in such instances whether a particular off-label use is medically appropriate.¹⁰⁴⁷

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; and complex reimbursement issues, especially in relation to insurance coverage for nonapproved pharmaceuticals.

A prominent use of off-label drugs in the treatment of HIV/AIDS is through the “parallel track” policy established by the FDA in 1992. Through this process, individuals with HIV/AIDS whose condition prevents them from participating in controlled clinical trials can utilize investigational drugs shown to be promising treatment options in preliminary studies.^{1048,1049} This policy enables individuals to access potentially beneficial drugs that otherwise would have been unavailable to them, thus presenting additional or alternative treatment options. Since many drugs have become approved for the treatment and prevention of HIV/AIDS, such as antiretroviral medications and pre-exposure prophylaxis (PrEP), it is difficult to determine the prevalence of off-label prescription drug use in the adult population.^{1050,1051} Research published in 2022 reports that use of off-label prescription drugs to treat HIV/AIDS in children is common practice, due to clinical studies often excluding the pediatric population.¹⁰⁵² Maraviroc is a drug that is not currently approved for use in children, but a 2015 study suggests the drug is useful for treatment of HIV/AIDS in children and adolescents, and its benefits may be increased when combined with other drugs.¹⁰⁵³ Several studies suggest that more research is needed to determine correct dosing for children, which could help minimize adverse effects.¹⁰⁵⁴

Estimated Marginal Cost of the Mandate

This mandate requires coverage for HIV/AIDS treatment drugs even when prescribed off-label. While the ACA does not specify coverage for these situations, off-label prescriptions for HIV/AIDS treatment are almost always medically necessary and therefore would be covered absent this mandate. Respondents to the carrier survey indicated that the costs required by this mandate are immeasurable; however, it is reasonable to estimate that prescriptions of off-label drugs that would not be covered absent this mandate are extremely rare. While this mandate may impose some additional costs on carriers, these costs are likely relatively immaterial. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Optometrists

The optometrist mandate requires coverage, subject to carriers' network terms, for optometrists' services if they are within the lawful scope of practice and are reimbursed when provided by physicians.¹⁰⁵⁵

Effect of the Mandate on Health

Optometrists are specialized health care professionals dedicated to the care of eyes. They are trained to examine, diagnose, and treat various diseases and disorders that affect eyesight. Unlike MDs or doctors of osteopathy (DOs), optometrists hold a Doctor of Optometry (OD) degree and attend optometry school instead of medical school. Becoming an optometrist typically requires four years to complete the OD degree, along with most optometrists having a four-year undergraduate degree. Additionally, some optometrists choose to pursue a one-year residency program after completing optometry school to further specialize in their field. Optometrists play a crucial role in diagnosing and treating eye diseases and vision problems. They conduct eye examinations to detect any issues affecting vision and can prescribe a range of treatments to address them. These treatments may include eyeglasses, contact lenses, low-vision aids, and medications to manage eye diseases.^{1056,1057}

To practice, optometrists must obtain state licensure, which entails passing a series of national examinations administered by the National Board of Examiners in Optometry (NBEO).¹⁰⁵⁸ In Massachusetts, to obtain a license, individuals must pass written and clinical examinations in theoretical and practical optometry, as well as a written examination on Massachusetts optometry statutes, rules, and regulations. The written examination is conducted by the NBEO, which determines the passing grade. The clinical examination assesses proficiency in optometric techniques, patient handling, pathology recognition, and other relevant areas as determined by the State Optometry Board.¹⁰⁵⁹ Optometrists licensed through examination are automatically eligible for certification to utilize or prescribe diagnostic pharmaceutical agents (DPA Certification) and therapeutic pharmaceutical agents (TPA Certification). The TPA Certification is issued simultaneously with their licenses.¹⁰⁶⁰ Optometry licenses must be renewed annually and must include evidence of completing continuing education requirements.^{1061,1062} Medicare considers a DO "a physician with respect to all services the optometrist is authorized to perform under State law or regulation."¹⁰⁶³

This review did not find published studies that measure the effectiveness of optometrists' work or studies that compare the quality of services provided by optometrists with varying levels of education or training or compare the quality of optometrists' services to those provided by other types of health care providers. A 2022 study found that optometry services delivered via telehealth, or tele-optometry, emerged during the COVID-19 pandemic and seem to be a feasible complement to in-person optometry.¹⁰⁶⁴

Estimated Marginal Cost of the Mandate

The optometrist mandate stipulates coverage for services provided by optometrists, aligning with the reimbursement criteria for services performed by physicians or optometrists within the legal scope of optometric practice.

Physician Assistants

The physician assistant (PA) mandate requires insurance carriers, subject to their network terms, to recognize PAs as participating providers and provide coverage on a nondiscriminatory basis for care provided by PAs for the purposes of health maintenance, diagnosis, and treatment. Carriers must provide coverage to the same extent as currently covered benefits for the same services provided by other health care providers. The mandate applies to PAs providing care in primary, intermediate, and inpatient care settings.^{cxliii,1065}

Effect of the Mandate on Health

A PA is a licensed medical professional who is a graduate of an approved program for the training of PAs, is supervised by a licensed physician, and has passed the Physician Assistant National Certifying Exam (PANCE) or its equivalent.^{1066,1067} PAs can work in specialty and primary care areas and may provide care that involves diagnosing and treating illnesses, assisting with procedures, conducting physical exams, obtaining medical histories, administering injections and immunizations, ordering tests, and prescribing medications.¹⁰⁶⁸ Although PAs are required to be supervised by a registered physician who bears the responsibility for the care provided, PAs may provide care within the scope of their license without a physician physically present.¹⁰⁶⁹ Massachusetts law requires a PA to only provide services that they are trained for, as determined by their supervising physician.¹⁰⁷⁰ Additionally, the services provided by a PA must also be within the scope of services for which the supervising physician can provide adequate supervision.¹⁰⁷¹

To become a licensed PA in Massachusetts, one must pass the National Commission on Certification of Physician Assistants examination, hold a bachelor's degree in any field, and have completed an accredited PA program (i.e., master's degree in PA studies).¹⁰⁷² PAs must apply to renew their license and complete 100 hours of continuing medical education (CME) every two years.¹⁰⁷³

In 2023, there were 178,708 board-certified PAs in the United States and 4,867 in Massachusetts.¹⁰⁷⁴ PAs are important members of the health care system and provide many benefits to the communities they serve, including improving access to quality health care. Recent data suggests a growing shortage of physicians, despite an increasing demand for them.¹⁰⁷⁵ Increasing the use of PAs, NPs, and other advanced practice providers can help ease this demand and fill gaps in the health care system.¹⁰⁷⁶ PAs and other advanced practice providers are often viewed as physician extenders, because these providers can render many services with the same quality of care as a physician. By maintaining the same quality of care without requiring a physician to be physically present, more appointments become available, expanding access and creating additional opportunities for individuals to receive the care they need.^{1077,1078}

^{cxliii} The mandate also qualifies PAs to serve as PCPs and allows enrollees to select a PA as their PCP if their carrier or plan requires designation of one.

According to a 2023 survey,^{cxliiv} 90% of people agree that PAs increase access to care and make it easier to get an appointment.¹⁰⁷⁹ Another way PAs improve access to health care is by helping to reduce health care costs. One study found the use of PAs and other advanced practice providers as PCPs for complex patients with diabetes was associated with less use of acute care services and lower overall health care costs, while maintaining the same level of quality outcomes.¹⁰⁸⁰ The effectiveness of PAs is difficult to pinpoint, but some research has found that PAs may produce better care outcomes than physicians in post-diagnostic care and similar quality outcomes to physicians in other areas.¹⁰⁸¹ The 2023 survey by the Harris Poll found that 89% of respondents believe PAs improve health outcomes.¹⁰⁸²

Estimated Marginal Cost of the Mandate

PAs are a lower-cost alternative to physicians and given that the services covered by this mandate would also be covered if performed by a physician, it is unlikely that any additional costs would result. Additionally, respondents to the carrier survey universally indicated that this mandate would impose no additional costs on them. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the 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, subject to carriers' network terms.¹⁰⁸³

Effect of the Mandate on Health

Podiatry is a field of medicine, practiced by podiatrists (also known as Doctors of Podiatric Medicine [DPMs]), that focuses on preventing, diagnosing, and treating conditions associated with the foot and ankle.¹⁰⁸⁴ The scope of practice for podiatrists in Massachusetts includes the diagnosis and treatment of the structures of the human foot by medical, mechanical, surgical, manipulative, and electrical means, without the use of anesthetics beyond local anesthetics, and excluding treatment of systemic conditions.¹⁰⁸⁵ Podiatrists in Massachusetts may not perform amputations of the foot or toes.¹⁰⁸⁶ The educational background of podiatrists includes an undergraduate degree, completion of a four-year graduate program at a podiatric medical college, and a three-year-long residency in podiatry.¹⁰⁸⁷

To become a licensed podiatrist in Massachusetts, one must graduate from an approved college of podiatric medicine, pass all parts of the American Podiatric Medical Licensing Examination (APMLE), pass the Massachusetts jurisprudence examination, complete a residency of a length of at least one year, complete a personal interview, and submit three letters of support attesting to the individual's good moral character.¹⁰⁸⁸ To maintain licensure, podiatrists must annually submit a renewal application that shows they meet statutes and regulations for renewal of their license

^{cxliiv} The survey was conducted by the Harris Poll on behalf of the American Academy of Physician Associates (AAPA).

and provide proof of completion of 15 continuing podiatric medical education credits.¹⁰⁸⁹ In 2024, it is estimated there are nearly 19,000 podiatrists in the United States.¹⁰⁹⁰

Once licensed, podiatrists can provide many services, including diagnosing foot and ankle conditions, ordering lab or imaging tests, prescribing medicines and medical devices, performing surgeries, and suggesting mobility aids.¹⁰⁹¹ Podiatrists treat a variety of conditions, including ingrown toenails, toe deformities, foot and ankle injuries, bunions, plantar warts, arthritis, diabetic foot problems, tendonitis, fractures, swelling, wounds, ulcers, sprains, bursitis, plantar fasciitis, and many other conditions and injuries affecting the foot and ankle.¹⁰⁹²

Podiatrists have an important role in monitoring, educating, and treating people with long-term conditions,^{cxlv} contributing to service-user mobility, reducing the risk of amputation in older individuals with comorbidities, and reducing foot pain.¹⁰⁹³ Podiatrists can often be the first to notice symptoms of diabetes or cardiovascular disease.¹⁰⁹⁴ The results of a study published in 2024 suggest that individuals with diabetes and kidney failure may experience improved outcomes when they receive care from a podiatrist prior to the development of diabetic foot ulcers.¹⁰⁹⁵ Studies also show that incorporating podiatrists into an orthopedic department can help increase the number of patients that can be seen and improve the utilization of orthopedic surgeons by podiatrists managing the treatment of cases that are less complex and may not require surgery.¹⁰⁹⁶

Estimated Marginal Cost of the Mandate

Podiatrists are an alternative to physicians and given that the services covered by this mandate would also be covered if performed by a physician, it is unlikely that any additional costs would result. Additionally, respondents to the carrier survey universally indicated that this mandate would impose no additional costs on them. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Prescription Eye Drops

This mandate requires coverage for refills of prescription eye drops (PEDs) in accordance with the Medicare Part D^{cxlvi},¹⁰⁹⁷ guidelines on early refills of topical ophthalmic products when the prescribing health care practitioner indicates on the original prescription that additional quantities of the PEDs are needed; 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 the PEDs prescribed by the health care practitioner are a covered benefit under the policy or contract of the insured.¹⁰⁹⁸

^{cxlv} Examples of long-term conditions include peripheral vascular disease, arthropathies, dementia, mental health issues, and musculoskeletal conditions.

^{cxlvi} The Medicare Part D guidelines allow patients to refill eye drops at 70% of the predicted days of use (i.e., for a prescribed medication with an expected duration of 30 days of use, the refill would be permitted at Day 21.) These guidelines ensure that the refill allowances are the same regardless where the eye drops are purchased and allows physicians to authorize earlier refills than 70% of days of use for particular individuals who struggle with using eye drops.

Effect of the Mandate on Health

Because this mandate impacts prescriptions that require refills, this review does not address the efficacy of PEDs. Instead, the research presented summarizes studies measuring patient eye drop prescription adherence, the potential adverse outcomes of non-adherence, and the relationship between patient adherence and insurance coverage rules regarding refills.

PEDs^{cxlvii} are used to treat a wide variety of conditions, both acute and chronic. Most often, eye drop treatments are for glaucoma,^{cxlviii,1099} uveitis,^{cxlix,1100} dry eyes syndrome,^{cl,1101} conjunctivitis (allergic, infectious, and/or chemical),^{cli,1102} and macular edema.^{clii,1103} Eye drop medications, both prescription and over the counter, are a preferred treatment method for eye conditions because they are effective, non-invasive, and relatively easy to use.¹¹⁰⁴ However, some patients have difficulty administering eye drops in their own eyes. These patients might not instill the correct number of drops successfully in the eye, or they might dispense too many drops at one time. One study found that nearly one third of patients miss their eye when applying drops, and another third of patients could not get any drops into their eye.¹¹⁰⁵

A known barrier to patient adherence^{cliii} using PEDs is an inadequate amount of medication available between prescription refills.¹¹⁰⁶ For patients with prescription medications, the time interval between refills is often set by their insurance carrier or by their 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.¹¹⁰⁷

In 2010, in response to patient and provider complaints and to address challenges associated with early PED refills, CMS issued a guidance memo for all Medicare Part D (pharmacy) plan sponsors noting the balance between managing costs without preventing patient access to needed care.¹¹⁰⁸ As a result, CMS advised carriers to allow

^{cxlvii} PEDs are also called topical ophthalmic solutions.

^{cxlviii} Glaucoma is a group of eye diseases that can cause permanent vision loss and blindness by damaging the optic nerve. About three million Americans have glaucoma. Glaucoma is the second leading cause of blindness worldwide. Currently, there is no cure for glaucoma, but treatment like eye drops can preserve vision and prevent further vision loss.

^{cxlix} Uveitis is inflammation inside the eye, which can cause pain, redness, and vision loss. Untreated uveitis accounts for about 10% of blindness in the United States. PEDs are the most common treatment to ease symptoms and prevent vision loss.

^{cl} Dry eye is a common condition that occurs when eyes do not make enough tears or when the tears do not work correctly. These conditions can be uncomfortable and lead to vision problems, including damage to the cornea.

^{cli} Conjunctivitis is inflammation of the conjunctiva (layer that covers the white of the eye) and inner eyelid. Conjunctivitis can be infectious (i.e., viral or bacterial) or non-infectious (i.e., allergen and toxin induced) and is also associated with some systemic illnesses.

^{clii} Macular edema is a swelling in part of the retina that can cause blurry vision. The most common cause of macular edema is diabetes.

^{cliii} A known barrier for patient adherence using PEDs in this instance applies to chronic topical glaucoma.

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.¹¹⁰⁹

As of 2024, 26 states have enacted legislation that allows commercially insured patients to refill eye drop medication prescriptions early under certain conditions.¹¹¹⁰ Additionally, because some medication often goes unused due to spills or other factors when patients self-administer eye drops, the American Academy of Ophthalmology's formal position is that patients should have the right to refill their eye drop prescriptions early.¹¹¹¹ The recent development of eye drop dispensers such as nose-pivoted drop delivery devices (NPDDs) has improved success of eye drop delivery into the eye, reduced the average number of drops dispensed, and reduced medication waste.¹¹¹² However, it is unclear how widespread the use of NPDDs is.

Treatment outcomes are dependent on the correct and consistent use of eye drops, which are more difficult to administer consistently than other medication types, such as oral medications. There is evidence that some patients have difficulty inserting 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.¹¹¹³

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.¹¹¹⁴ This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Preventive Care for Children Up to Age Six

This mandate requires insurance coverage of preventive care services for children from birth through age six. Preventive services covered under this mandate include physical examination, medical history, measurements, sensory screening, neuropsychiatric evaluation and developmental screening and assessment, six times during a child's first year of life, three times during the second year, and once annually until the child reaches age six.¹¹¹⁵ Preventive services under this mandate also include hereditary and metabolic screening at birth, appropriate immunizations, and tuberculin tests, hematocrit, hemoglobin, or other appropriate blood tests, urinalysis tests as necessary, EI services, and newborn hearing screening tests.¹¹¹⁶

Effect of the Mandate on Health

Preventive care is routine health care that includes several types of preventive services, such as screenings, physical exams, and counseling, that aim to prevent illness, disease, and other health issues or conditions.¹¹¹⁷ Preventive health care during childhood is important for early identification of diseases so appropriate interventions can be implemented, which can prevent more severe and other conditions later in life.¹¹¹⁸ Traditionally, childhood preventive care primarily focused solely on averting disease and injury but has since expanded to also include promoting health and well-being, physical, cognitive, and emotional development, and quality of life.¹¹¹⁹

Children have different health needs than adults, and these needs change frequently as they grow from infancy to adolescence. Many health conditions or illnesses in childhood, even common ones, can have significant impacts on an individual's health later in life. For example, a child with poorly controlled asthma has a greater likelihood of developing chronic obstructive pulmonary disease as an adult.¹¹²⁰ Or in the case of obesity, an obese child is likely to remain obese as an adult, which can lead to a greater risk of developing type 2 diabetes, heart disease, cancer, and stroke.¹¹²¹ The developmental stages that happen in a child's life from birth to age six are some of the most rapid phases of development that a human will experience. Thus, it is critical that children receive age-appropriate care for their current stage of development that will support them in maximizing their potential to live healthy lives into adulthood.¹¹²²

Over the past century, research has consistently promoted preventive medicine tailored to children, although standardizing an implementation approach has been challenging. The first version of the "Periodicity Schedule" published by the AAP in 1967 aimed to address this issue by outlining the recommended timing of childhood vaccinations but did not include recommendations for other preventive services.¹¹²³ In 1990, the Bright Futures Initiative^{cliv} started to standardize the consistency and quality of the delivery of childhood preventive care services.¹¹²⁴ This initiative is a health promotion and prevention effort that develops pediatric health guidelines, most notably through continuing the publication of the Recommendations for Preventive Pediatric Health Care, referred to as the "Bright Futures Periodicity Schedule."¹¹²⁵ This enhanced version outlines the screenings and assessments that should be completed for all children and the age when these should be completed.¹¹²⁶ In order to establish consistency in childhood vaccine administration, the CDC, AAP, and American Academy of Family Physicians (AAFP) published an immunization schedule in 1995 that outlined the recommended age and order of administration for important vaccines.¹¹²⁷ The CDC's Advisory Committee on Immunization Practices (ACIP) continues to update this schedule regularly as new vaccine developments are made and the prevalence of vaccine-preventable diseases changes.¹¹²⁸ Parents, guardians, and medical providers can use these schedules to make decisions and plans for care, helping ensure that every child can receive consistent and quality health care services. The Bright Futures Periodicity Schedule and the CDC Vaccination Schedule serve as the official guidelines for pediatric preventive care in the United States, and they were formally incorporated into the ACA as the basis for coverage requirements for preventive services for children.¹¹²⁹

As a result of children up to age six being able to receive preventive services with full coverage, children are likely to face fewer barriers in accessing recommended preventive services and receiving the necessary care to help them live healthy lives as children and into adulthood.¹¹³⁰ Common illnesses, conditions, and injuries can turn into long-term issues if they are not treated early, and thus enabling access to preventive services is essential to establish a foundation that allows children to grow into healthy adults.^{1131,1132,1133,1134}

^{cliv} The Bright Futures Initiative was started by HRSA and the Maternal and Child Health Bureau (MCHB) and later taken over by the AAP.

Estimated Marginal Cost of the Mandate

Preventive health services for children up to age six are medically necessary and cost-effective forms of care that respondents to the carrier survey indicated would be covered absent this mandate. In addition, the ACA separately mandates coverage of these services under section 2713.¹¹³⁵ This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Prosthetic Devices

The prosthetic device^{clv} mandate requires coverage under the same terms and conditions that apply to other durable medical equipment covered under a policy for prosthetic devices and repairs and restricts carriers' use of cost sharing and coverage limits for prosthetic devices.¹¹³⁶

Effect of the Mandate on Health

A prosthetic device, also referred to as a prosthesis,^{clvi,1137} is an artificial replacement body part that is designed to replace a missing limb or part of a limb that can assist with regaining independence^{1138,1139,1140} and "...can play a role in improving quality of life by helping with mobility and stability."¹¹⁴¹ Prosthetic devices assist people missing an arm or leg with performing daily activities (such as walking, eating, and dressing), and some artificial limbs enable people to function nearly as well as before they lost their limb.¹¹⁴² Loss of all or part of a limb, usually because of an amputation,^{clvii,1143} occurs for a number of reasons, such as vascular (blood vessel) disease, particularly from peripheral artery disease or diabetes, traumatic injuries, cancer, and birth defects.^{1144,1145}

In the United States, approximately 500 amputations are performed daily, and an estimated 2.3 million people are living with limb loss.^{1146,1147} Although amputation is often thought of as a trauma-only event, only 12.9% of amputations are caused by a trauma event.¹¹⁴⁸ The main cause of amputation is diabetes, with 57% of people with limb loss having had a preceding diagnosis of diabetes. Limb loss most often occurs in older adults, with those over 65 representing 44.7% of amputations.^{1149,1150} By 2060, it is estimated that the number of people living with limb loss in the United States is expected to more than double to approximately 5.7 million, with most limb loss caused by vascular disease and diabetes, which are projected to increase by 36% and 67%, respectively.¹¹⁵¹ In children, there are two main categories of limb loss: a congenital limb deficiency, which is present at birth with the complete absence of a limb or part of a limb, and acquired amputations, which can be the result of cancer, trauma, or severe infections.^{1152,1153}

Amputations are almost always a life-saving or life-preserving procedure¹¹⁵⁴ and are typically categorized as upper (involving the fingers, wrist, or arm) and lower (involving the toes, ankle, or leg and foot);¹¹⁵⁵ when determining how

^{clv} 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.

^{clvi} The broadest definition of a prosthesis includes external body parts as well as internal body parts like a mechanical heart valve or joint replacement.

^{clvii} An amputation is the surgical removal of a body part like a limb, usually due to a serious injury or disease that endangers the rest of your body.

best to perform an amputation, surgeons consider the impact on mobility, sensation, and appearance as well as proper prosthetic fitting if the rehabilitation plan includes a prosthetic device.¹¹⁵⁶ Recovery times from an amputation can vary, but it typically takes two to three months for surgical wounds to heal; PT will likely continue for six months after surgery, and training to use a prosthetic device can take even longer.¹¹⁵⁷ Amputation can result in surgical complications, including residual limb pain; phantom limb pain and sensation; stump osteomyelitis; stump overgrowth; soft tissue and muscle atrophy; skin problems; joint contracture; overuse syndromes in remaining extremities and proximal joints; heterotopic ossification, or an overgrowth of bone instead of scar tissue; psychological pain; and grief.^{1158,1159} After an amputation, a prosthetic device is often recommended to replace the body part, as they should allow a person to perform daily activities and have the potential to restore function to a level similar to what it was prior to the amputation.¹¹⁶⁰

Considered an extension of the body, a prosthetic device will differ depending on the level of amputation, the individual's physical abilities, and the individual's goals and needs.¹¹⁶¹ Many factors influence the 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, the social situation, and the relationship to the prosthetist,^{clviii,1162} which is critically important.^{1163,1164, 1165}

There have been many recent advances and improvements to prosthetic devices, some of which employ 3D printing and other digital techniques that allow a prosthetic device to be more individualized.¹¹⁶⁶ A recent study found that the newer digital-based design framework that creates custom prosthetic liner-socket interfaces resulted in improved comfort outcomes for individuals.¹¹⁶⁷ Target muscle reinnervation, which redirects nerves to a new “target muscle,” allows individuals to control a myoelectric^{clix,1168} arm and hand, and osseointegration integrates the prosthetic device with an individual's bone, making it easier to remove and attach.¹¹⁶⁹ Advances have also been made in the materials used in prosthetic devices, resulting in fewer repairs as well as more lightweight, durable, comfortable, and more naturally appearing devices.¹¹⁷⁰ In addition, neural, muscular, and skeletal interfaces allow individuals to control their prostheses with their thoughts, and a mind-controlled bionic arm with feedback technology enables users to have the feeling of touching and grabbing an object.¹¹⁷¹ These consciously controlled limbs involve implanting electrodes in the muscles and nerves of the amputated limb with a connector embedded in the end of a screw for an electrical interface causing the sensory input from the prosthetic device to be transmitted back to the person, allowing them to control movement through the mind.¹¹⁷² Ongoing research continues to push boundaries in this field, with one domain of interest being biomechanics, which studies human movement to assist in designing prosthetic devices to improve the quality of life for individuals, as well as research into strategies to prevent prosthetic joint infections.¹¹⁷³ Additionally, crucial to long-term success for individuals using a prosthetic device is ensuring that they are educated and well informed about its proper use and maintenance, as this plays a significant role in the recovery and healing process.^{1174,1175}

clviii The prosthetist is health care provider that makes and designs prosthetic limbs, creating a device that is custom made to fit a individual's functional and cosmetic needs.

clix A myoelectric prostheses is an electronic device that operates through electrical impulses generated by muscles.

Although functionality is important to individuals with limb loss, a cross-sectional study found that appearance-related beliefs are associated with distress and psychosocial adjustment difficulties for individuals dealing with limb loss.¹¹⁷⁶ Further, among people with amputation, a systematic review of observational studies found higher rates of depression, anxiety, and body image disorder.¹¹⁷⁷ Research suggests that prosthetic device use plays a social role in the lives of people with limb loss by allowing individuals to ward off social stigmatization, thus enabling social integration and reducing emotional problems surrounding these disabilities.¹¹⁷⁸ Despite the progress made in prosthetic technology 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.¹¹⁷⁹ One study found that for individuals with lower-limb amputations with phantom pain sensations, psychological interventions focusing on increasing body image and self-esteem might reduce the impact of the loss of a body part and improve the individuals' overall quality of life.¹¹⁸⁰

Estimated Marginal Cost of the Mandate

Respondents to the carrier survey universally indicated that this mandate will not impose any additional costs. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Scalp Hair Prostheses for Cancer Patients

The scalp hair prosthesis mandate requires health insurance policies that cover other prosthetic devices to also cover expenses for scalp hair prostheses—artificial substitutes for scalp hair—when hair loss results from cancer or leukemia treatments. This coverage is capped at \$350 per year and necessitates a written statement from the treating physician confirming the medical necessity of the prosthesis.¹¹⁸¹

Although this mandate imposes a dollar limit, federal regulations under the ACA have implications for such state-imposed caps for mandates enacted prior to January 1, 2012. Specifically, if the coverage for scalp hair prostheses is considered an EHB within the state's benchmark plan, carriers may not apply annual or lifetime dollar limits to these benefits. Instead, they might substitute an actuarially equivalent limit that is not a dollar limit (for example, one designated wig).¹¹⁸²

Effect of the Mandate on Health

Although not everyone loses their hair as a result of cancer treatment, hair loss, also called alopecia, is one of the most asked-about side effects that can be caused by cancer treatments, including chemotherapy, radiation therapy, hormonal therapy, immunotherapy/targeted drug therapy, and bone marrow/stem cell transplants.^{clx,1183} As a common and distressing side effect of cancer treatment, chemotherapy-induced alopecia (CIA) results from chemotherapy drugs damaging the fast growing cells in hair follicles, making hair fall out.^{1184,1185} CIA typically begins two to three weeks after the first cycle of treatment, with the amount of hair loss dependent on both the drug and dose

^{clx} Total hair loss typically results from stem cell or bone marrow transplant because of the types and doses of chemotherapy given before the transplant.

administered.¹¹⁸⁶ Although usually temporary, CIA is often the most traumatic side effect of chemotherapy, having a negative impact, irrespective of gender, on well-being, quality of life, and body image,¹¹⁸⁷ causing depression, loss of self-confidence, and humiliation in men and women of all ages.^{1188,1189,1190} With many women citing CIA as the most disturbing anticipated side effect of chemotherapy,¹¹⁹¹ CIA can take a significant emotional toll on patients, leading to treatment refusal in many cases.^{1192,1193} As with adults, hair loss related to cancer treatment can be traumatic as well as one of the most challenging aspects of a cancer diagnosis for children and their parents/caregivers;^{1194,1195} perceived changes in physical appearance have both direct and indirect effects on depressive symptoms and social anxiety.¹¹⁹⁶

CIA can have profound psychosocial consequences, resulting in anxiety, depression, a negative body image, lowered self-esteem, and a reduced sense of well-being,^{1197,1198} while also being a visible reminder of having cancer.¹¹⁹⁹ One study found that 55% of breast cancer patients reported high psychological stress due to CIA,¹²⁰⁰ and another found that patients who fear CIA may sometimes select regimens with less favorable outcomes or may refuse treatment.¹²⁰¹ Given the profound impact of hair loss on these patients, several treatments, either initiated prior to beginning chemotherapy or during treatment, have been studied that could potentially prevent hair loss resulting from CIA.^{1202,1203} Although no treatment has been found to be completely effective at preventing CIA, a recent meta-analysis reported that scalp cooling significantly reduces CIA;¹²⁰⁴ however, this treatment could result in a very small risk of cancer occurring in the scalp.¹²⁰⁵

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.¹²⁰⁶ Scalp hair prostheses offer some patients the possibility of mitigating the emotional side effects of hair loss and have been found to help improve self-confidence and quality of life for many people.¹²⁰⁷ Further, obtaining the scalp hair prosthesis before it is necessary often reduces anxiety.¹²⁰⁸ 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,¹²⁰⁹ and many women find that wearing a wig can provide a sense of normalcy and consistency during cancer treatment.¹²¹⁰

Estimated Marginal Cost of the Mandate

This mandate requires coverage of scalp hair prosthesis under policies that also provide coverage for any other prosthesis. This service is considered an EHB under the ACA because this mandate was in effect prior to the ACA. Additionally, respondents to the carrier survey indicated that the services required by this mandate would be covered absent this mandate. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Speech, Hearing, and Language Disorders

This mandate requires coverage for expenses related to the medically necessary diagnosis and treatment of speech, hearing, and language disorders by licensed SLPs or audiologists. However, it does not require coverage of the diagnosis or treatment of speech, hearing, and language disorders in a school-based setting.¹²¹¹

Effect of the Mandate on Health

A communication disorder refers to an impairment affecting an individual's speech, language, or hearing, which may involve deficits in more than one area and range from mild to profound difficulty in receiving, sending, or understanding communication. Communication disorders can manifest in various ways, impacting the ability to process and comprehend verbal, nonverbal, and graphic symbol systems. Communication disorders can be developmental or acquired, and individuals may exhibit one or multiple types, with severity ranging from mild to profound. These disorders can occur as a primary disability or secondary to other conditions.^{1212,1213} The cause of communication disorders is not always known, but some common factors include abnormalities in oral, pharyngeal, or laryngeal structures, oral-motor dysfunction, neurological issues or brain injury, learning difficulties, and hearing impairment.¹²¹⁴ Communication disorders are typically delineated into four main categories:^{1215,1216}

1. Speech Disorders

- Articulation and phonological disorders: Caused by structural changes in speech muscles and bones, resulting in atypical speech sounds
- Fluency disorders: Caused by genetic or neurophysiological disruptions in dialogue flow, such as stuttering or cluttering
- Voice disorders: Caused by abnormalities in pitch or resonance not aligned with individuals' age or gender

2. Language Disorders

- Form of language: Relates to sound, structure, and word combinations (phonology, morphology, syntax)
- Content of language: Pertains to word and phrase meaning (semantics)
- Function of language: Concerns how language elements are used to communicate (pragmatics)

3. Hearing Disorders

- Deafness: Severe hearing loss with little to no functional hearing due to auditory nerve damage
- Hard of Hearing: Difficulty hearing and communicating, with varying degrees of impairment that may be treatable

4. Central Auditory Processing Disorders (CAPDs)

- Difficulties in processing audible signals due to deficits in the central auditory nervous system (CANS), not caused by peripheral or intellectual impairments
- Challenges in analyzing, storing, and receiving information from audible signals¹²¹⁷

In the United States, almost 1 in 12 (7.7%) children aged 3 – 17 experienced a voice, speech, language, or swallowing disorder within the past year. Among them, 34% of those aged 3 –10 and 25.4% of those aged 11 –17

had multiple communication or swallowing disorders. Boys in this age group were more affected than girls, with a prevalence of 9.6% compared to 5.7%. The highest prevalence of these disorders was found in children aged 3 – 6 (11.0%). Additionally, 9.6% of Black children, 7.8% of white children, and 6.9% of Hispanic children were affected. Over half (55.2%) of children with these disorders received intervention services in the past year, with a higher percentage among white children (60.1%) compared to Hispanic (47.3%) and Black children.¹²¹⁸

SLPs can work with individuals who have communication disorders to address their communication needs effectively. This can include diagnosis, individualized treatment plan creation, continuous therapy, and ongoing support.^{1219,1220} SLPs employ various therapies to address issues like articulation, stuttering, and voice disorders. Additionally, SLPs assist individuals with comprehension difficulties stemming from developmental delays, hearing restoration procedures, or strokes. For those facing challenges in social interactions or returning to work post injury, SLPs provide support in developing social communication skills and daily living tasks. In cases in which individuals cannot use traditional communication methods, SLPs explore alternative approaches such as communication boards, voice restoration devices, eye-tracking computers, or alternative voice production methods post surgery.¹²²¹

Most reviewed studies indicate the efficacy of treatments for speech, hearing, and language disorders overall. One systematic review focused on the evaluation of randomized controlled trials of speech and language therapy interventions for children and adolescents experiencing primary speech and language delay/disorder. The review highlighted a positive impact of these interventions on expressive phonological and vocabulary difficulties, though findings for expressive syntax were varied. The review noted that further research is warranted to explore interventions for receptive language difficulties.¹²²² A 2021 systematic review examined specialized speech and language interventions for children who are DHH. The review found that results often lacked clarity due to inadequate reporting of intervention techniques and effect sizes. However, studies did highlight the potential benefits of caregiver-centered approaches, teleintervention, and integrating additional speech and language techniques into auditory-verbal therapy (AVT). The authors noted challenges in assessing intervention effects across different levels and types of hearing loss due to sample variability. The authors also emphasized that further research regarding specialized interventions is crucial for children from diverse demographics and hearing statuses to help ensure they receive optimal and tailored support, and future studies should aim to define speech-language therapy more precisely and explore factors influencing the choice of methodology by clinicians and families.¹²²³

Estimated Marginal Cost of the Mandate

Treatment and diagnosis of speech, hearing, and language disorders are medically necessary services, which most carriers would cover absent this mandate. Additionally, a majority of respondents to the carrier survey indicated that this mandate would impose no additional costs. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Substance Abuse Treatment Prior Authorization

This mandate prevents health insurance carriers from requiring prior authorization for substance [abuse] use disorder treatment if the provider is certified or licensed by the DPH.¹²²⁴ The law defines substance abuse treatment to include

“...early intervention services for substance use disorder treatment; a substance use disorder evaluation^{clxi}; 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].”¹²²⁵

Effect of the Mandate on Health

SUD, 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

This mandate requires that substance abuse treatment is covered regardless of preauthorization if the provider is certified or licensed by the DPH. While this additional coverage could increase costs, it is estimated that this will be neutralized by the constrained supply of substance abuse treatment services as well as a corresponding reduction in other treatments. Additionally, respondents to the carrier survey universally indicated that this mandate would impose no additional costs upon them. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

^{clxi} As defined in section 51 ½ of Chapter 111, a SUD evaluation, as conducted by a licensed mental health provider should include patient’s substance use history, family substance use history, documentation and efficacy of previous treatment received for SUD or other psychological disorders, psychological assessment including co-occurring disorders, trauma history and history of compulsive behaviors, and an assessment of the patient’s risk status for HIV, hepatitis C, and tuberculosis.

4.0 New Mandates

ABA Services for Down Syndrome

The ABA mandate requires insurance carriers to cover ST, OT, PT, and ABA services for the treatment of Down syndrome. For the purposes of this mandate, “Down syndrome” means a chromosomal condition caused by an error in cell division that results in the presence of an extra whole or partial copy of chromosome 21. Carriers in the Commonwealth already cover ST, OT, and PT for the treatment of Down syndrome as well as ABA for individuals who are dually diagnosed with Down syndrome and ASD.^{clxii, 1226, 1227, 1228, 1229, 1230} Given this existing carrier coverage, the result of this mandate, approved on January 9, 2025, and taking effect on January 1, 2026, is to require coverage of ABA therapy service for individuals with a singular diagnosis of Down syndrome.¹²³¹

Effect of the Mandate on Health

Down syndrome, often also referred to as Trisomy 21, is the most common chromosomal cause of mild to moderate intellectual disabilities and results from having an extra chromosome 21 or an extra piece of that chromosome.^{clxiii, 1232, 1233} This extra chromosome changes how babies’ bodies and brains develop and can cause both physical and mental challenges.¹²³⁴ As a lifelong condition, individuals with Down syndrome have a greater risk for developing a number of health problems, some of which present at birth and can include heart defects, vision problems, hearing loss, infections, hypothyroidism, blood disorders, hypotonia, problems with the upper part of the spine, sleep disorders, gum and dental problems, epilepsy, and celiac disease, as well as mental health and emotional problems.¹²³⁵ In addition to these potential impacts on both physical and behavioral health, about 16% – 18% of individuals with Down syndrome also have ASD, a neurodevelopmental disorder characterized by social communication difficulties, restricted interests, and repetitive behaviors.^{1236, 1237, 1238}

There is no single standard treatment for Down syndrome. Treatments are based on the unique physical and intellectual needs of each individual, as well as their personal strengths and limitations, with the goal of helping children with Down syndrome develop to their full potential.^{1239, 1240} Services provided early in life,^{clxiv, 1241} usually

^{clxii} ST, OT, and PT are included in the ACA’s EHBs. For children under three years of age who have or are at risk of developmental delays, ST, OT, and PT are covered by the Massachusetts EI program. Once a child is three years of age, ST, OT, and PT are covered as short-term rehabilitation therapy. Early intensive behavior intervention (EIBI), which includes ABA therapy, is covered for children up to three years of age with a diagnosis of ASD but not for a singular diagnosis of Down syndrome.

^{clxiii} Chromosomes are small “packages” of genes in the body’s cells that determine how the body forms and functions.

^{clxiv} Based on the U.S. CDC “Learn the Signs. Act Early.”^{clxiv} guidelines, tracking a child’s development early by monitoring their milestones in how they play, learn, speak, act, and move, from birth to five years of age, can make a real difference for both the child and caregivers.

through EI^{clxv,clxvi,1242} programs that often include ST, occupational therapy (OT), and PT, can help babies and children with Down syndrome improve symptoms of physical and intellectual disabilities.^{1243,1244,1245,1246,1247} In addition to these treatment modalities, ABA therapy is also used to treat individuals with Down syndrome.¹²⁴⁸

Considered as an evidence-based^{clxvii} treatment by the U.S. Surgeon General,¹²⁴⁹ utilizing behavioral principles to set goals, reinforce behaviors, and measure outcomes, ABA therapy is a widely used treatment approach individually designed to meet the needs of each child based on their age, level of functioning, and specific needs that is often used to treat individuals with ASD as well as other conditions.^{1250,1251} Studied for decades and used since the 1960s to help children with ASD and related developmental disorders, the methods of behavior analysis have been used and have helped many kinds of learners gain different skills—from healthier lifestyles to speaking a new language.¹²⁵² ABA therapy can be provided in a variety of settings, or in a combination of settings, including educational, health, community, or home, with parents also being trained to support their child in different environments.^{1253,1254} Further, parental involvement plays a critical role in maximizing the benefits and reinforcing the skills learned from ABA therapy.¹²⁵⁵ Collaboration between parents and therapists increases consistency and the likelihood that the goals of ABA therapy will be met.^{1256,1257} ABA interventions have been shown to be effective for improving social skills, adaptive behaviors, language abilities, and cognitive skills as well as being helpful for reducing anxiety in children and adolescents.¹²⁵⁸

Having an increased risk to engage in challenging behaviors can be part of a behavioral phenotype characteristic of Down syndrome.¹²⁵⁹ With its use of a variety of techniques, such as positive reinforcement, to increase helpful behaviors and decrease damaging ones, ABA therapy can be effective in children with Down syndrome experiencing behavioral challenges.¹²⁶⁰ ABA therapy is designed to meet the unique behavior profiles of individuals with Down syndrome and has been shown to be a well-supported intervention that yields significant benefits in enhancing daily functioning and overall quality of life for children with Down syndrome.¹²⁶¹ As a comprehensive treatment strategy, ABA therapy helps children with Down syndrome address challenging behaviors while improving cognitive, language, social, and self-help skills.^{1262,1263} A recent systematic review targeting outcomes primarily involving communications and challenging behaviors suggests that the use of ABA interventions is promising for behavior changes in individuals with Down syndrome.¹²⁶⁴ As a lifelong condition, services provided early in life will often lead to improvement in physical and intellectual abilities for individuals with Down syndrome.¹²⁶⁵

Estimated Marginal Cost of the Mandate

The effective date of this mandate is January 2026, thus BerryDunn estimated the marginal cost of this mandate using a similar approach as was used in the 2023 prospective study.¹²⁶⁶ The cost of this mandate is driven by

^{clxv} As defined by the CDC, “Early Intervention” is the term used to describe services and supports that are available to babies and young children with developmental delays and disabilities and their families. The services provided are based on the needs of the child and their family.

^{clxvi} EI services are funded through a complex blend of federal, state, and local sources and are part of the Individuals with Disabilities Education Act (IDEA), originally enacted by Congress in 1975.

^{clxvii} Evidence-based means that ABA has passed scientific tests of its usefulness, quality, and effectiveness.

requiring coverage of ABA services for members with a Down syndrome diagnosis without an accompanying ASD diagnosis. Since ST, OT, and PT are already covered for members with a Down syndrome diagnosis without an accompanying ASD diagnosis, there is no additional cost estimated for the provision of ST, OT, and PT as set forth in the mandate. ABA therapy for individuals with a dual diagnosis of Down syndrome and ASD is already covered through fully insured commercial insurance as well.

The incremental cost of the mandate is estimated by determining the number of members with Down syndrome without an ASD diagnosis, the percentage of such members who would benefit from ABA services, the length of the indicated ABA therapy, and the cost of ABA services in any given year. Claims data from the Massachusetts APCD was used to determine the cost per user for ABA therapy. The number of members with a Down syndrome diagnosis and no ASD diagnosis, the anticipated utilization of ABA therapy, and the length of the indicated ABA therapy were estimated using a combination of claims data from the Massachusetts APCD, population data, expert interviews, and academic literature. Carriers in Massachusetts are not required to cover ABA therapy for members without an ASD diagnosis, so the utilization for members with a singular diagnosis of Down syndrome cannot be determined from claims data given the effective date of this mandate. In addition, literature is limited regarding the percentage of the population for whom ABA therapy would be indicated, and the recommended duration of ABA therapy. BerryDunn received input from clinical experts to help estimate these parameters. However, it is difficult to predict if the uptake would be greater when the services are covered by commercial insurance.

ABA therapy for those with Down syndrome is generally indicated for desensitization and behavioral dysregulation, with a different length of therapy indicated for each. BerryDunn focused on members under age 22 for the purposes of this study, because children in the Commonwealth can receive ST, OT, PT, and ABA therapy through the Massachusetts EI program¹²⁶⁷ (through age two) and their Local Education Agency (LEA)¹²⁶⁸ (ages 3 to their 22nd birthday). To estimate the cost of the mandate, BerryDunn first calculated the populations needing ABA services for desensitization by calculating the population of members with Down syndrome without an accompanying ASD diagnosis under age 22 covered by commercial insurance, using the Massachusetts APCD, and then multiplying by the percentage requiring ABA services for desensitization, as indicated by clinical experts. Massachusetts APCD claims data for members with an ASD diagnosis was used to calculate the cost-per-person-per-hour of \$52.46, which was then multiplied by the average number of years of ABA services for desensitization and the average number of hours per week, as indicated by clinical experts. The average annual incremental claims cost of ABA services for desensitization was then found by dividing the cost of short-term services over the first 22 years by 22.

Table 15. ABA Services for Down Syndrome Mandate Cost Associated with ABA Services for Desensitization

2023 MEASURES	ESTIMATED IMPACT
[a] Number of Sample Members with a Singular Down Syndrome Diagnosis Under Age 22	446
[b] Proportion Who Will Benefit from ABA for Desensitization	5.0%
[c] Estimated Number of Members Who Will Benefit from ABA for Desensitization = [a] x [b]	22
[d] Estimated Number of Years of ABA Services Needed	1
[e] Estimated Number of Hours per Year of ABA Services Needed	364
[f] Estimated Number of Life Years	22
[g] Cost-per-Person-per-Hour Assumption	\$ 52.46
Contribution to Total Annual Claims = [c] x [d] x [e] x [g] / [f]	\$ 19,357

The same process indicated above was used to estimate the average annual incremental claims costs of ABA services for behavioral dysregulation and is shown below.

Table 16. ABA Services for Down Syndrome Mandate Cost Associated with ABA Services for Behavioral Dysregulation

2023 MEASURES	ESTIMATED IMPACT
[a] Number of Sample Members with a Singular Down Syndrome Diagnosis Under Age 22	446
[b] Proportion Who Will Benefit from ABA for Behavioral Dysregulation	5.0%
[c] Estimated Number of Members Who Will Benefit from ABA for Behavioral Dysregulation = [a] x [b]	22
[d] Estimated Number of Years of ABA Services Needed	5
[e] Estimated Number of Hours per Year of ABA Services Needed	364
[f] Estimated Number of Life Years	22
[g] Cost-per-Person-per-Hour Assumption	\$ 52.46
Contribution to Total Annual Claims = [c] x [d] x [e] x [g] / [f]	\$ 96,783

Adding the results of the two tables above, requiring coverage for ABA services for members with a Down syndrome diagnosis without an accompanying ASD diagnosis by fully insured health plans would result in a 2023 PMPM marginal impact estimate for this mandate of \$0.01 in claims cost and \$0.01 with administrative loading. The estimated impact on total 2023 Massachusetts fully insured market premium is 0.001%. These results are summarized below in [Table 17](#).

Table 17. ABA Services for Down Syndrome Mandate Contribution to Premium

MEASURES	SAMPLE ESTIMATE
Sample Average Members	1,576,663
Paid PMPM	\$ 0.01
Paid PMPM With Admin*	\$ 0.01
Allowed PMPM	\$ 0.01
UPPER BOUND IMPACT	
Insured Population	2,150,129
Contribution to Total Annual Claims	\$ 158,382
Contribution to Total Annual Premium	\$ 178,941
Percent of Total Premium	0.001%

Abortion

This mandate requires health insurance carriers to cover abortion and abortion-related services. "Abortion" is defined as "any medical treatment intended to induce the termination of, or to terminate, a clinically diagnosable pregnancy except for the purpose of producing a live birth; provided, however, that 'abortion' shall not include providing care related to a miscarriage." Abortion-related care includes pre-operative evaluation/examination, pre-operative counseling, laboratory services (e.g., pregnancy testing and blood type), Rh (D) immune globulin, anesthesia (both local and general), post-operative care, follow-up services, contraception advice, and referral to family planning services. Additionally, coverage policies may extend to pregnancy-related care, including prenatal care, childbirth, and postpartum care, ensuring they are provided to the same extent as other medical conditions unrelated to pregnancy.¹²⁶⁹ The legislation includes a provision exempting coverage for abortion and related care in policies

offered by church employers or qualified church-controlled organizations,^{clxviii,clxix} upon the employer's request, with the condition that the employer provides written notice^{clxx} to prospective enrollees before plan enrollment.

Carriers may apply network and utilization review procedures but cannot impose unreasonable restrictions or delays. Additionally, these services cannot be subject to deductible, coinsurance, copay, or other cost sharing requirements, except under specific circumstances such as employer-requested exemptions due to religious reasons or High-Deductible Health Plans (HDHPs).^{1270,1271}

Effect of the Mandate on Health

There are two primary methods of abortion: a medication abortion, also referred to as a medical or chemical abortion, and a clinical abortion, also referred to as an in-clinic abortion or surgical abortion. A medical abortion is a non-surgical method used to terminate early-stage pregnancies. It most commonly involves taking two prescription pills: mifepristone and misoprostol. Mifepristone blocks progesterone, which is essential for maintaining pregnancy, while misoprostol induces cramping and bleeding to expel the contents of the uterus. This procedure is typically performed during the first trimester of pregnancy. If the pregnancy is beyond this stage, an in-clinic abortion via vacuum aspiration in which a suction is used to empty the uterus, or via a dilation and evacuation (D&E), in which suction and additional medical tools are used to empty the uterus, may be indicated.^{1272,1273} In-clinic abortion, also known as surgical abortion, is a medical procedure that uses suction to empty the uterus. The availability of in-clinic abortion varies based on health care providers' policies. It is generally recommended to undergo the procedure as early as possible, as finding a provider may become more challenging after the 12th week of pregnancy. In Massachusetts in 2022, the number of abortions increased by 5.8% to 17,757 from 16,795 in 2021. In 2022, chemical abortions accounted for 52% of total abortions in Massachusetts, rising from 8,311 to 9,276, marking an 11.6% increase. The Charlotte Lozier Institute (CLI) estimated, using data from the Massachusetts DPH, that the state's abortion rate was 12.6 abortions per 1,000 biological females aged 15 – 44, up 6% from 2021's rate of 11.9.

The increasing trend was seen in other states too, as by October 2023, 23 states had reported their 2022 abortion statistics, and over half (13 states) reflected an increase in abortions. Almost all (93%) of abortions in Massachusetts were performed on state residents. The remaining abortions were performed on biological females from out of state (5%) and on biological females whose residency was known (2%). Biological females in their thirties accounted for

^{clxviii} Pursuant to M.G.L. c.175 §47W, "church" refers to a church, a convention or association of churches, or an elementary or secondary school that is controlled, operated, or principally supported by a church or by a convention or an association of churches. A "qualified church-controlled organization" means an organization described in Section 501(c)(3) of the federal Internal Revenue Code, other than an organization that: (i) offers goods, services or facilities for sale, other than on an incidental basis, to the general public, other than goods, services, or facilities that are sold at a nominal charge that is substantially less than the cost of providing such goods, services or facilities; and (ii) normally receives more than 25% of its support from: (A) governmental sources; (B) receipts from admissions, sales of merchandise, performance of services or furnishing of facilities, in activities which are not unrelated trades or businesses; or (C) both clauses (A) and (B).

^{clxix} Pursuant to M.G.L. c.176A §8W, c.176B §4W, and c.176G §4O, the terms "church or qualified church-controlled organization" are defined in 26 U.S.C. Section 3121(w)(3)(A) and (B).

^{clxx} The notice shall list the health care methods and services for which the employer excludes coverage for religious reasons.

the highest proportion of abortions (35%), followed by those aged 20 – 24 (26%), those aged 25 – 29 (27%), and those aged 19 or younger (8%). Almost one half of abortions were performed on white biological females (46%); almost one quarter (24%) were performed on Black biological females. The remaining abortions were performed on Asian biological females (6%), on biological females of other races (14%), and on biological females whose race was unspecified (11%). CLI estimated that Black biological females had an abortion rate of 28.8 per 1,000 biological females aged 15 – 44, nearly four times the rate of white biological females (7.7). While data on prior abortions and live births was not reported for all cases, the CLI report found that almost half (48%) of abortions were performed on biological females who had no prior abortions, approximately one quarter (27%) were performed on biological females who had one prior abortion, and approximately one fifth (21%) were performed on biological females who had two or more prior abortions. Regarding live births, 43% of biological females had no previous live births, 21% had one, and 25% had more than one.¹²⁷⁴

The ACOG views abortion as a safe medical intervention. The risk associated with abortions is much lower than the risk associated with childbirth. Very few biological females who receive abortions experience complications associated with the abortion (approximately 2%), and most complications can be addressed with minimal follow-up. Compared to other frequently conducted medical procedures such as wisdom teeth extraction and screening colonoscopies, the mortality and complication risk associated with abortions is much lower.¹²⁷⁵ Medication abortion is associated with a complication rate of about 2%, first-trimester aspiration abortion is associated with a complication rate of 1.3%, and second-trimester or later abortions are associated with a complication rate of 1.5%.¹²⁷⁶ There is robust clinical evidence that demonstrates the safety of abortions conducted by medication, aspiration, D&E, or induction. The risk of serious complications is rare but does increase with longer gestation periods.¹²⁷⁷

Estimated Marginal Cost of the Mandate

According to carrier survey responses, abortion and abortion-related services would generally be covered in the absence of the mandate. The primary effect of the mandate is the elimination of member cost sharing for these services. BerryDunn estimated member cost sharing using 2023 claims data from the Massachusetts APCD. Member cost sharing is the difference between allowed expenses and carrier-paid expenses. Unlike other mandates, this mandate applies only to members who reside in Massachusetts, i.e., it does not extend to nonresidents covered by Massachusetts employers. Therefore, the membership used to estimate the member cost sharing PMPM includes only Massachusetts residents. Additionally, this mandate became effective upon renewal on January 1, 2023. Based on an assumed renewal distribution by month, by market segment, and by the Commonwealth market segment composition, 72.1% of the member months exposed in 2023 will have the proposed mandate coverage in effect during calendar year 2023. The annual dollar impact of the mandate in 2023 was calculated using the estimated PMPM and applying it to 72.1% of the member months exposed.

As noted earlier, HDHPs are exempt from the removal of cost sharing. Based on data in CHIA's annual report,¹²⁷⁸ BerryDunn calculated the proportion of fully insured membership that is enrolled in HDHPs by multiplying the enrollment by funding type and market sector by the HDHP enrollment by market sector. In 2023, 54.7% of the fully insured members were assumed to be enrolled in an HDHP. The remaining 45.3% of fully insured members were assumed to be enrolled in a non-HDHP. To effectively retain cost sharing for members enrolled in a HDHP,

BerryDunn also accounted for HDHP having typically higher cost share amounts. BerryDunn used a claims pricing model and calculated average member cost sharing amounts for a typical HDHP and for a typical non-HDHP. BerryDunn weighted the cost share amounts with the membership distribution from above and estimated that 80% of the cost share amounts were likely attributable to members in an HDHP, meaning only 20% of the cost would be removed.

BerryDunn calculated the portion of cost sharing not attributable to HDHPs for Massachusetts-resident fully insured and self-insured GIC members to be \$0.05 PMPM as summarized below in

Table 18. With administrative loading, the cost of the mandate remained at \$0.05 PMPM. This represents a 0.007% impact on the Commonwealth premium.

Table 18. Abortion Mandate Contribution to Premium

MEASURES	SAMPLE ESTIMATE
Sample Average Members	1,190,393
Paid PMPM	\$ 0.05
Paid PMPM With Admin*	\$ 0.05
UPPER BOUND IMPACT	
Insured Population	1,786,680
Contribution to Total Annual Claims	\$ 1,037,097
Contribution to Total Annual Premium	\$ 1,171,466
Percent of Total Premium	0.007%

Annual Mental Health Wellness Examinations

This mandate requires coverage for an annual mental health wellness examination in the form of a screening or assessment that identifies behavioral or mental health needs and the appropriate resources for addressing these needs. The examination can involve:

- 1) Observation, behavioral health screening, education on healthy lifestyle changes, consultation, referrals for treatment, mental health services, additional necessary supports, and discussion of medication options
- 2) Age-appropriate screenings or observations to evaluate a person's mental health history, personal history, and cognitive state, including relevant adult input through screenings, interviews, and questions when appropriate

The examination is required to be covered with no cost sharing and performed by a licensed mental health professional or a PCP as part of an annual preventive visit.^{clxxi1279,1280}

Effect of the Mandate on Health

Mental illnesses are prevalent among adults and children. As of 2023, close to one third (30.8%) of adults aged 18+ in Massachusetts experienced symptoms of anxiety and/or depressive disorder.¹²⁸¹ In 2020, nearly half (48%) of youth in Massachusetts aged 14 – 24 experienced prolonged feelings of sadness or hopelessness, leading them to disengage from their usual activities for two weeks or more. This percentage was higher among youth who identified as transgender (78%) or nonbinary (83%), as well as those with a mobility disability (81%) or cognitive disability (78%).¹²⁸²

Screening individuals for mental health conditions is a brief process that can take a few minutes.¹²⁸³ The USPSTF recommendations regarding mental health screenings are based on mental health condition and age:

- Screening for Anxiety:
 - Recommendation: Screen adults younger than 65 for anxiety.
 - Grade: B (Recommended)
 - Rationale: Early identification through screening can help connect individuals to necessary care.
- Screening for Depression:
 - Recommendation: Screen all adults, including pregnant and postpartum individuals, for depression.
 - Grade: B (Recommended)
 - Rationale: Screening can lead to early diagnosis and treatment, improving mental health outcomes.
- Screening for Suicide Risk:
 - Recommendation: No recommendation for or against screening all adults for suicide risk due to insufficient evidence.
 - Grade: I (Insufficient evidence to determine benefits and harms)
 - Rationale: More research is needed to determine the effectiveness of screening for suicide risk in preventing suicide.¹²⁸⁴

These are recommendations for screenings that are only used for identification of individuals who are likely experiencing an issue, not for diagnosis of individuals with a specific condition.¹²⁸⁵ Additionally, the USPSTF's recommendations apply to individuals without recognized signs or symptoms of these conditions.¹²⁸⁶

^{clxxi} "Cost-sharing shall be required if the applicable plan is governed by the Federal Internal Revenue Code and would lose its tax-exempt status as a result of the prohibition on cost-sharing for this service."

In children and adolescents, generalized anxiety disorder and social anxiety disorder are the most prevalent anxiety disorders. The DSM-5 also identifies five additional anxiety disorders: panic disorder, agoraphobia, specific phobias, separation anxiety disorder, and selective mutism.¹²⁸⁷ The USPSTF recommends screening children and adolescents aged 8 – 18 for anxiety (Grade B), while screening children aged 7 or younger for anxiety has insufficient evidence assessing the risks and benefits (Grade I).¹²⁸⁸ The USPSTF recommends screening for major depressive disorder (MDD, Grade B) for adolescents aged 12 – 18, while screening for MDD for children aged 11 or younger is rated as Grade I with insufficient evidence. The USPSTF also found inconclusive evidence (Grade I) to recommend screening children and adolescents for suicide risk.¹²⁸⁹ Anxiety disorders during childhood and adolescence are linked to higher risks of developing future anxiety disorders or depression. These conditions can lead to long-term effects, such as chronic mental and physical health issues, impaired psychosocial functioning, elevated risk of substance use, and premature mortality.¹²⁹⁰

Mental health screenings facilitate prompt mental health treatment, as people often wait years after symptoms appear before seeking help. Regular screenings enable early identification and intervention. Incorporating mental health screenings into physical checkups reduces stigma and integrates mental health with physical care, historically overlooked in medical exams.¹²⁹¹

Estimated Marginal Cost of the Mandate

The procedure code used for annual mental health wellness exams was first available March 31, 2024, so BerryDunn was unable to use Massachusetts APCD data to analyze the claims related to these services. In the carrier survey responses, one carrier provided a claim count for these services in 2024, which BerryDunn assumed to be a claim count for fully insured health plans. BerryDunn annualized this claim count, as the procedure code for this service was only available for nine months in 2024, to find an annual uptake rate of these services of 0.2%. This annual uptake rate was then applied to the rest of the carriers. The uptake rate was multiplied by the assumed cost per annual mental health wellness exam. The cost of this service was estimated as \$117.43 per wellness exam using Massachusetts APCD data for the average cost of psychiatric diagnostic evaluations lasting 16 – 90 minutes (Current Procedural Terminology [CPT®] code 90791) with provider types that could perform this service.

Based on the carrier survey responses, one carrier would have covered these services in the absence of the mandate. BerryDunn excluded this carrier from the cost analysis. Additionally, one carrier indicated that they would cover these services in the absence of the mandate but would not cover cost sharing. For this carrier, BerryDunn estimated the cost of the mandate as only the cost sharing for these services. According to the mandate, cost sharing cannot be covered for HDHPs.

Based on data in CHIA's annual report,¹²⁹² BerryDunn calculated the proportion of fully insured membership enrolled in HDHPs by multiplying the enrollment by funding type and market sector by the HDHP enrollment by market sector. In 2023, 54.7% of the fully insured members were assumed to be enrolled in an HDHP. The remaining 45.3% of fully insured members were assumed to be enrolled in a non-HDHP. To effectively retain cost sharing for members enrolled in an HDHP, BerryDunn also accounted for HDHPs having typically higher cost share amounts. BerryDunn used a claims pricing model and calculated average member cost sharing amounts for a typical HDHP and for a

typical non-HDHP. BerryDunn weighted the cost share amounts with the membership distribution from above and estimated that 80% of the cost share amounts were likely attributable to members who had an HDHP, meaning only 20% of the cost would be removed. Table 19 below shows the assumptions and calculations used to find the cost associated with carriers that would cover the cost of these services excluding cost sharing in the absence of the mandate.

Table 19. Annual Mental Health Wellness Examinations Mandate Cost Associated With Carriers That Would Cover the Cost of These Services Excluding Cost Sharing in the Absence of the Mandate

2023 MEASURES	ESTIMATED IMPACT
[a] Annual Claim Count Assuming Uptake Rate of 0.2%	10,689
[b] Cost per Mental Health Wellness Exam Assumption	\$ 117.43
[c] Estimated Paid to Allowed Ratio	74.2%
[d] Estimated Portion of Cost that is Cost Sharing	25.8%
[e] Estimated Portion of Cost Sharing that is Part of an HDHP	80.1%
Contribution to Total Annual Claims = [a] x [b] / [c] x [d] x (1 - [e])	\$ 86,753

For the remaining carriers that would not cover these services in the absence of the mandate, the full cost including cost sharing was estimated as part of the marginal cost of this mandate. The cost sharing was calculated using a paid to allowed factor determined using Massachusetts APCD data for psychiatric diagnostic evaluations lasting 16 – 90 minutes (CPT® code 90791) with provider types that could perform this service. According to the mandate, cost sharing cannot be covered for HDHPs. BerryDunn removed the cost of cost sharing for the proportion of fully insured health plans that are HDHPs, as explained above.

Table 20 below shows the assumptions and calculations used to find the cost associated with carriers that would not cover the cost of these services in the absence of the mandate.

Table 20. Annual Mental Health Wellness Examinations Mandate Cost Associated With Carriers That Would Not Cover the Cost of These Services in the Absence of the Mandate

2023 MEASURES	ESTIMATED IMPACT
[a] Annual Claim Count Assuming Uptake Rate of 0.2%	25,432
[b] Cost per Mental Health Wellness Exam Assumption	\$ 117.43
[c] Estimated Paid to Allowed Ratio	74.2%
[d] Estimated Portion of Cost that is Cost Sharing	25.8%
[e] Estimated Portion of Cost Sharing that is Part of an HDHP	80.1%
Contribution to Total Annual Claims = [a] x [b] / [c] x (1 - [d] x [e])	\$ 3,192,819

Adding the results from the two tables above, requiring coverage for annual mental health wellness exams by fully insured health plans would result in a 2023 PMPM marginal impact estimate for this mandate of \$0.13 in claims cost and \$0.15 with administrative loading. The estimated impact on 2023 Commonwealth total premium is 0.029%. These results are summarized below in Table 21.

Table 21. Annual Mental Health Wellness Examinations Mandate Contribution to Premium

MEASURES	SAMPLE ESTIMATE
Sample Average Members	1,576,663
Paid PMPM	\$ 0.17
Paid PMPM With Admin	\$ 0.20
Allowed PMPM	\$ 0.24
UPPER BOUND IMPACT	
Insured Population	2,150,129
Contribution to Total Annual Claims	\$ 4,472,421
Contribution to Total Annual Premium	\$ 5,051,877
Percent of Total Premium	0.029%

Collaborative Care

The collaborative care mandate requires coverage for mental health or SUD^{clxxii, 1293} treatment services that are delivered through the Psychiatric Collaborative Care model (CoCM).^{1294, 1295} Pursuant to M.G.L. c.175 §47QQ, c.176A §8RR, c.176B §4RR, c.176G §4JJ, and c.32A §22A, CoCM is defined as “the evidence-based, integrated behavioral health service delivery method in which a primary care team consisting of a PCP and a care manager provides structured care management to a patient, and that works in collaboration with a psychiatric consultant that provides regular consultations to the primary care team to review the clinical status and care of patients and to make recommendations.”

Effect of the Mandate on Health

As an established patient-centered treatment model, CoCM integrates behavioral health with primary care and is most commonly used to treat depression, anxiety, and SUD. CoCM care teams provide population-based patient care, led by PCPs, and include a behavioral health care manager (BHCM) and consulting psychiatrist.¹²⁹⁶ Using CoCM, each patient receives a treatment plan based on the individual’s specific diagnosis with tailored personal goals and associated clinical outcomes that are measured through evidence-based tools, including a registry to monitor progress and amend treatment plans accordingly. Providers who practice within CoCM are accountable for measurable outcomes and are paid for services based on quality of care and clinical outcomes.^{clxxiii}

CoCM is composed of five key elements as defined by the American Psychiatric Association:

1. Patient-Centered Team Care
2. Population-Based Care
3. Measurement-Based Treatment
4. Evidence-Based Care
5. Accountable Care¹²⁹⁷

The effectiveness and efficiency of CoCM is well documented with over 90 randomized control trials.^{1298, 1299} These studies indicate that CoCM is more effective than usual care^{clxxiv} for patients who have behavioral health diagnoses such as anxiety and depression.¹³⁰⁰ Integrating the management of psychological and medical illnesses, while also

^{clxxii} As defined by the National Institute of Mental Health, a SUD “is a treatable mental disorder that affects a person’s brain and behavior, leading to their inability to control their use of substances like legal or illegal drugs, alcohol, or medications.”

^{clxxiii} Carriers are required to take all necessary steps to notify providers about the appropriate methods to submit claims for reimbursement for services provided through CoCM, which shall include, but not be limited to, the acceptance of the following current procedural terminology billing codes established by the American Medical Association: (i)99492; (ii)99493; and (iii)99494.

^{clxxiv} “Usual care” refers to the traditional model of treating individuals’ physical and behavioral health separately—at separate appointments, with different providers (i.e., a behavioral health provider prescribes medication at a patient care visit, separate from primary care visits).

utilizing individualized treatment regimens, has been shown to improve outcomes for patients with comorbid mental and physical health conditions.¹³⁰¹ CoCM helps ensure patients are more engaged and has proven to be more cost effective than conventional treatment, saving an average of \$6.50 for every \$1 spent on treatment for depression in the United States.¹³⁰²

Evidence also supports CoCM's effectiveness across patients from differing racial and ethnic backgrounds, and it is increasingly being used as a means to improve access and promote the treatment of psychiatric diseases across diverse populations.¹³⁰³ A systematic review of depression outcomes for racial and ethnic minorities in the United States found that CoCM, with or without cultural and linguistic tailoring, has the potential to effectively improve depression outcomes in these populations, including those from low socioeconomic backgrounds.¹³⁰⁴ CoCM is an alternative to traditional approaches to treatment and has the potential to better engage minority populations in mental health care.¹³⁰⁵ CoCM has gained endorsement as a readily implementable and significantly more effective treatment than usual care for patients with depression in primary care settings. Although there are various models of integrated mental health care, CoCM distinguishes itself as an evidence-based practice that improves patient outcomes, team collaboration, and provider satisfaction in primary care settings.¹³⁰⁶ CoCM has been proven effective in "reduc[ing] depression, bipolar and anxiety disorders, SUD, suicidal ideation, and suicide completion."¹³⁰⁷

The demand for mental health treatment and SUD services is high nationwide. SAMHSA reports that almost one in five adults aged 18 or older in the United States lives with a mental illness,¹³⁰⁸ and behavioral workforce shortages may limit the ability to provide needed services to individuals with mental health conditions and SUDs. In the United States, 16.8% of the population aged 12 or older met the criteria for a SUD, and 23.4% of adults aged 18 or older experienced mental illness in 2024.¹³⁰⁹ Many studies report significant shortages of psychiatrists and other mental health providers, with shortfalls particularly noted in under-resourced urban and rural areas and in community mental health centers that often treat the most severe mental illnesses.^{1310,1311,1312} PCPs report that behavioral health care is the most difficult subspecialty medical service to obtain.¹³¹³ Reported obstacles to obtaining necessary behavioral health care treatment include affordability, accessibility, stigma of mental health diagnoses, and concerns about confidentiality.¹³¹⁴

Designed to extend the capacity of mental health providers to care for patients in need, CoCM not only addresses the shortage of mental health service providers relative to need within the population, but also offers a viable, cost-effective, accessible treatment pathway for individuals with mental health illnesses and shows effectiveness with diverse patient populations. CoCM is an evidence-based treatment model that provides patients with the ability to seek services for their specific condition(s) within the familiarity of their primary care practice and be supported by multidisciplinary care.

Estimated Marginal Cost of the Mandate

Carrier survey responses generally indicated these services would be covered in the absence of this mandate. The one carrier that indicated they would not cover these services in the absence of the state mandate has a small membership, and accordingly its impact to the Commonwealth fully insured premium is effectively zero. This study

therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Contraceptive Services

The mandate for contraceptive services requires coverage for outpatient contraceptive services, including consultations, exams, and procedures, on par with coverage for other outpatient services. Additionally, prescription contraceptive drugs and devices must be covered under the same terms and conditions as other prescription medications. While the mandate offers exclusions for church-affiliated employers,^{clxxv,clxxvi} it otherwise ensures comprehensive coverage for contraceptive services.¹³¹⁵

The Advancing Contraceptive Coverage and Economic Security In Our State (ACCESS) mandate expands on the Affordable Care Act's contraceptive coverage requirements by requiring carriers to cover a wider range of birth control methods, i.e., any FDA-approved contraceptive drug, device, or other product, and prohibits imposition of cost sharing on these methods. This includes a 12-month supply of most prescriptions after a 3-month trial, all FDA-approved emergency contraception, and female voluntary sterilization procedures. Emergency contraception that is FDA approved can be obtained over the counter, either with a prescription or from a licensed pharmacist, in accordance with the guidelines outlined in M.G.L. c. 94C, § 19A.¹³¹⁶ Male condoms are excluded from coverage requirements, as are FDA-approved oral contraceptives that lack a therapeutic equivalent. The mandate also requires coverage for patient education and counseling on contraception, as well as follow-up services related to chosen birth control methods.¹³¹⁷ Churches and qualified church-controlled organizations are exempt from these coverage requirements.

Effect of the Mandate on Health

Family planning remains a cornerstone of national health goals in both Healthy People 2020 and 2030. Established by the U.S. HHS, these initiatives highlight the importance of providing individuals with the resources and knowledge to make informed decisions about their families. By enabling desired birth spacing and family size, readily available family planning services contribute significantly to improved health outcomes for mothers and infants.¹³¹⁸

A significant decline in unintended pregnancy rates was observed in the United States between 2008 and 2011, according to a study based on data from the National Survey of Family Growth, surveys of abortion patients, national

^{clxxv} Pursuant to M.G.L. c.175 §47W, "church" refers to a church, a convention or association of churches, or an elementary or secondary school that is controlled, operated, or principally supported by a church or by a convention or an association of churches. A "qualified church-controlled organization" means an organization described in Section 501(c)(3) of the federal Internal Revenue Code, other than an organization that: (i) offers goods, services or facilities for sale, other than on an incidental basis, to the general public, other than goods, services, or facilities that are sold at a nominal charge that is substantially less than the cost of providing such goods, services or facilities; and (ii) normally receives more than 25% of its support from: (A) governmental sources; (B) receipts from admissions, sales of merchandise, performance of services or furnishing of facilities, in activities which are not unrelated trades or businesses; or (C) both clauses (A) and (B).

^{clxxvi} Pursuant to M.G.L. c.176A §8W, c.176B §4W, and c.176G §4O, the terms "church or qualified church-controlled organization" are defined in 26 U.S.C. Section 3121(w)(3)(A) and (B).

birth data, and a census of abortion providers. The rate dropped by 18%, from 54 to 45 per 1,000 women aged 15 – 44. Disparities persisted with women below the poverty line and those cohabiting experiencing two to three times the national average of unintended pregnancies. The study found particularly significant reductions among teenagers, women cohabiting, low-income women, women without a high school diploma, and Hispanic women, with each group experiencing a decrease of over 25% in their unintended pregnancy rate.¹³¹⁹

Contraception offers multifaceted benefits beyond preventing unintended pregnancy. It enables individuals to plan for healthier pregnancies by timing and spacing births, empowering women to pursue educational and career goals. This, in turn, fosters better health outcomes for mothers, newborns, families, and communities. Additionally, many hormonal contraceptives offer additional health benefits beyond preventing pregnancy, such as managing menstrual pain and excessive bleeding, as well as treating acne.¹³²⁰

A 2022 survey of women ages 18 – 64 in the United States conducted by the Kaiser Family Foundation (KFF) found that the vast majority (90%) of biological women aged 18 – 64 have used contraception at some point, and over three quarters of women (76%) have used multiple methods. While preventing pregnancy is the main reason for using contraception (85%), 4 in 10 women also use it for other reasons, such as managing hormonal or menstrual conditions. A smaller subset of methods—like condoms—can also reduce the risk of sexually transmitted infections, though not all methods covered under the mandate provide this protection. The study also revealed that 17% of women who are sexually active and who are not trying to get pregnant are not using any form of contraception. The reasons for not using contraception vary and can include concerns about side effects, lack of desire to use a specific method, openness to pregnancy while not actively trying, or religious beliefs.¹³²¹ In Massachusetts, 77.9% of women aged 18 – 49 were using contraceptives in 2019, a statistically significant increase from 2017 ($p < 0.05$) in which 71.7% of women aged 18 – 49 were using contraceptives.¹³²²

While the effectiveness of contraceptive methods varies, all play a significant role in family planning. Implants offer the highest typical-use effectiveness, as less than 1 in 100 women using implants experience pregnancy each year; implants are reversible and can last for up to three years. Intrauterine devices (IUDs) also have a high effectiveness rate, with pregnancies occurring among 100 women in one year from 0.2% to 0.8%, depending on the type utilized. IUDs can be hormonal, lasting three to eight years, or copper, lasting up to ten years. Sterilization, permanent for both men and women, is also very effective, resulting in pregnancies in 0.15% – 0.5% of 100 women in one year. Injectable contraceptives have a 6% failure rate and require a shot every three months. The pill, patch, vaginal ring, and diaphragm each have a typical-use failure rate of around 9%, requiring daily, weekly, or monthly use, respectively. Cervical caps and sponges have failure rates ranging from 12% to 24%, requiring use before each sexual encounter. Fertility awareness-based methods, requiring consistent tracking and sometimes additional barrier methods, have a 24% failure rate. Spermicide, another barrier method, has the highest failure rate listed at 28%. The least effective contraceptive methods include lactational amenorrhea, emergency contraceptive (EC), and the withdrawal method. The lactational amenorrhea method can be effective for the first six months postpartum with exclusive breastfeeding. Emergency contraception pills or copper IUDs can be used within five days of unprotected sex to reduce pregnancy risk. The withdrawal method results in pregnancies in 22 out of 100 women in one year.¹³²³

Several studies comparing the provision of a greater number of monthly pill packs versus fewer packs found that having more packs increased method continuation. However, one study showed no difference in continuation between providing one and then three packs versus providing four packs all at once. In addition to better continuation rates, having more pill packs was associated with fewer pregnancy tests, fewer pregnancies, and lower costs per person.¹³²⁴

The ACA has mandated contraceptive coverage for over a decade, aiming to remove financial barriers to birth control access. However, the KFF 2022 survey revealed that 41% of women of reproductive age are unaware that most insurance plans are required to fully cover birth control. Among those with private insurance, the majority (70%) indicated that their insurance covered the complete cost of their birth control; a quarter (25%) still encountered out-of-pocket costs for their contraceptives. This cost exposure could be due to various issues, including limitations in their plan's coverage (16%), out-of-network providers or pharmacies (15%), or simply a lack of clarity on why they were charged (50%). Cost remains a significant barrier for uninsured and low-income women. One in five uninsured women have stopped using contraception due to affordability concerns, while 17% of low-income women cite cost as the reason that they are not using their preferred method.¹³²⁵

ACOG is supportive of access to comprehensive contraceptive care and methods and views access as an essential facet of women's health care.¹³²⁶

Estimated Marginal Cost of the Mandate

The Massachusetts contraceptive services mandate, implemented in 2018, aimed to ensure comprehensive coverage for contraceptive services. This included consultations, exams, procedures, and both prescription drugs and devices. Coverage mirrored existing policies for other outpatient services and prescription drugs. However, the mandate allowed exemption for church-affiliated employers.

The federal ACA also mandates contraceptive coverage as an EHB and requires coverage with no cost sharing as a preventive health service. The ACA's general contraceptive coverage requirements are broader than the state mandate, encompassing all 18 FDA-approved methods—at least 1 per category—with no cost sharing for compliant plans. This portion of the Massachusetts mandate is redundant and superseded by the federal ACA and incurs no additional cost.

However, the ACCESS Act includes provisions that exceed federal requirements. These enhanced provisions contribute to a separate and measurable cost for carriers and drive the cost for the mandate. The enhanced provisions are no cost sharing for therapeutic equivalents of the 18 FDA-approved methods and emergency contraception, a 12-month dispensing requirement, and no cost sharing for voluntary sterilization for pre-ACA legacy health plans.

No Member Cost Sharing for Therapeutic Equivalents

The ACCESS Act required the elimination of cost sharing for therapeutic equivalents of the 18 FDA-approved methods, which is beyond the ACA requirements. Carrier survey responses indicated therapeutic equivalents would

generally be covered in the absence of the mandate with the exception of cost sharing. Therefore, the removal of member cost sharing for therapeutic equivalent-related claims is the impact of the mandate. BerryDunn estimated member cost sharing using 2023 claims data from the Massachusetts APCD and the 2015 data extracts from the prospective mandate review for pre-implementation cost sharing. In 2015, member cost sharing was 5.2% of allowed costs for the fully insured under-65 population for the three largest carriers.^{clxxvii,1327} In 2023, member cost sharing was 1.8% of allowed costs for the fully insured or GIC under-65 population across all available carriers. As a result, this mandate resulted in a 3.4% reduction in member cost sharing, which is worth \$0.03 PMPM.

No Member Cost Sharing for Emergency Contraceptives (ECs)

The ACCESS Act also required the elimination of member cost sharing for ECs. The carrier survey responses also indicated ECs would generally be covered in the absence of the mandate with the exception of cost sharing. BerryDunn estimated the member cost sharing using the same data as the therapeutic equivalents. As of the 2023 Massachusetts APCD, there was \$0.02 PMPM of ECs in the sample data, and when applying the change to member cost sharing from pre- to post implementation, the impact of the mandate is less than \$0.00 PMPM and considered negligible.

12-Month Dispensing Requirements

The ACCESS Act required the option for contraceptives to be dispensed for a 12-month period at one time. The cost impact of this requirement would be the potential waste of those who fill the prescription for the 12 months and then do not use the medication. BerryDunn reviewed the 2023 claims in the Massachusetts APCD for the prescriptions that were filled for 300 – 400-day supply in one transaction. The allowed claims for approximately 12 months of medication is \$0.01 PMPM; therefore, after applying assumptions around the wasted quantity, the impact of the mandate is less than \$0.00 PMPM and considered negligible.

No Member Cost Sharing for Voluntary Sterilization

The ACCESS Act required no cost sharing for voluntary sterilization for pre-ACA legacy health plans. The 2015 member cost sharing for pre-ACA legacy health plans was estimated to be \$133,252 or \$0.01 PMPM.¹³²⁸ Since the prospective mandate analysis, the market has seen further reductions in pre-ACA legacy health plans. The latest report from the KFF shows a reduction from 25% in 2015 to 13% in 2019 of covered workers enrolled in pre-ACA legacy health plans.¹³²⁹ Based on the KFF reporting and assuming Massachusetts legacy health plans would have experienced similar declines in membership, BerryDunn projected reductions to pre-ACA legacy health plan enrollment would continue into 2023, hence the PMPM impact is less than \$0.00 PMPM and has become negligible.

^{clxxvii} The 5.2% estimate is not directly comparable to the figure in the prospective mandate analysis due to minor differences in rounding.

Therefore the ACCESS Act requirements have a marginal direct cost due to no member cost sharing for therapeutic equivalents for contraceptives of \$0.03 PMPM. The other three components of the mandate did not result in an additional measurable marginal direct cost.

Table 22. ACCESS Act Contribution to Premium

MEASURES	SAMPLE AMOUNT PLANS SUBJ. TO MANDATE
Sample Average Members	1,576,663
Paid PMPM	\$ 0.03
Paid PMPM With Admin	\$ 0.04
Allowed PMPM	\$ 0.03
UPPER BOUND IMPACT	
Insured Population	2,150,129
Contribution to Total Annual Claims	\$ 881,139
Contribution to Total Annual Premium	\$ 998,815
Percent of Total Premium	0.006%

Emergency Services Programs

The ESPs mandate requires coverage on a nondiscriminatory basis for all medically necessary ESPs.^{1330,1331} ESPs are medically necessary services provided through designated, contracted providers and are available seven days a week, 24 hours a day to provide treatment for any individual who is experiencing a mental health and/or SUD crisis.¹³³²

Effect of the Mandate on Health

Behavioral health encompasses the state of mental, emotional, and social well-being, as well as the behaviors and actions that affect one's well-being.¹³³³ Mental health is considered a component of behavioral health and refers specifically to the state of mental, emotional, and social well-being.¹³³⁴ Mental illnesses are conditions that can affect thoughts, emotions, mood, and behavior and can affect people of all ages and backgrounds.^{1335,1336} In the United States in 2021, one in five adults experienced mental illness, and one in twenty adults experienced SMI.¹³³⁷ The characteristics of a mental or behavioral health crisis include situations in which an individual's behaviors or symptoms create a risk of hurting themselves or others and/or prevent them from functioning effectively.¹³³⁸ Individuals with mental illness may experience a mental or behavioral health crisis requiring treatment.¹³³⁹ Timely interventions and treatment for individuals experiencing crisis episodes can help minimize or prevent potential harm to themselves or those around them.¹³⁴⁰

Often, when an individual is experiencing a mental health crisis, they present to an ED or contact emergency medical services (EMS).¹³⁴¹ Individuals use these resources because they may be unaware of other treatment options, or they cannot readily access an alternative treatment option.¹³⁴² EDs excel at providing immediate care and stabilizing a patient's condition, but several barriers exist to ED staff being able to provide the highest-quality care for individuals who are experiencing a mental health crisis.¹³⁴³ ED staff training primarily focuses on providing emergency medical care, not emergency mental health care.¹³⁴⁴ Additional barriers include:

- Lack of expertise among ED and EMS staff in treating mental health conditions¹³⁴⁵
- Lack of resources, such as appropriate staffing levels, budget, and space, to treat mental health conditions^{1346,1347,1348}
- Excessive overall strain on EDs and EMS¹³⁴⁹
- Lack of psychiatric hospital beds¹³⁵⁰
- High cost of care associated with ED visits and EMS¹³⁵¹

These barriers create a significant challenge for patients and ED staff in achieving positive patient outcomes and satisfaction.¹³⁵² Additionally, individuals experiencing a mental health crisis typically need follow-up care, and EDs and EMS are not well equipped for connecting individuals with the appropriate resources, which makes it difficult to prevent repeat mental health-related ED visits and establish an effective long-term care plan.^{1353,1354}

The American College of Emergency Physicians (ACEP) reports that patients presenting to the ED with psychiatric emergencies wait three times longer on average in the ED than those with medical emergencies.¹³⁵⁵ Further, psychiatric patients are more likely to be subject to ED boarding^{clxxviii} than those presenting at the ED with physical health conditions.^{1356,1357} Psychiatric patients who experience ED boarding often experience increased frustration, longer inpatient stays, increased likelihood of leaving without being seen, and overall decreased satisfaction with their care.¹³⁵⁸ Many studies show a connection between ED boarding and an increased risk of illness and death for patients with any type of emergency, especially for psychiatric patients. In general, individuals experiencing a psychiatric emergency who seek help through EMS or EDs are likely to need emergency care again, use ancillary support such as security officers, experience law enforcement involvement, and face incarceration due to the sensitivity, volatility, and misperception of their condition.^{1359,1360,1361} For these individuals, the heightened levels of stress and agitation exacerbated by the experience of ED boarding can result in problems such as violence against ED staff, adverse outcomes, and increased cost for the hospital.^{1362,1363,1364}

clxxviii ED boarding refers to when a patient is kept in the ED while waiting for a bed to be available in the hospital inpatient department.

ESPs are programs managed under contract with the Massachusetts Behavioral Health Partnership that specialize in responding to mental and behavioral health emergencies by providing behavioral health crisis assessment, intervention, and stabilization services, including the following:^{1365,1366}

- Assessment uses face-to-face evaluation of an individual experiencing a behavioral health emergency to assess their needs, including evaluation of their need for hospitalization.
- Intervention includes the provision of counseling services for the individual to stabilize the emergency they are experiencing.
- Stabilization is short-term behavioral health treatment provided in a structured environment with continuous observation and supervision for individuals experiencing a behavioral health emergency who do not require hospital care.

ESPs have the resources and expertise to effectively respond to crises.¹³⁶⁷ In Massachusetts, most ESPs are provided through Community Behavioral Health Centers (CBHCs), which provide a range of mental health and substance use services and treatment options.¹³⁶⁸ ESPs provided by CBHCs include:

- Mobile Crisis Intervention (MCI):
 - MCI is a service available 24 hours a day, seven days a week to children and adults who are experiencing a mental health or substance use crisis.¹³⁶⁹
 - MCI services are provided by trained mental health professionals and paraprofessionals who will travel to the location of the individual in crisis to assess their needs, provide assistance, and determine the appropriate next steps for the situation.^{1370,1371,1372}
- Community Crisis Stabilization (CCS):
 - CCS is an alternative to inpatient hospitalization for individuals in need of crisis care and is available to children and adults.¹³⁷³
 - CCS services include:¹³⁷⁴
 - Individual therapy
 - Group therapy
 - Family therapy
 - Medication management
 - Crisis intervention
 - Future crisis prevention planning

Beyond the primary goal of providing relief to individuals who are experiencing a mental or behavioral health crisis, ESPs aim to:^{1375,1376,1377,1378}

- Safely de-escalate and stabilize situations
- Reduce the immediate risk of danger
- Avoid unnecessary ED visits
- Avoid unnecessary inpatient psychiatric hospitalization
- Avoid law enforcement involvement in mental health crisis situations
- Provide care in a setting that is comfortable for the individual
- Connect individuals to appropriate follow-up care and resources

Individuals who receive crisis care through ESPs are more likely to participate in necessary follow-up care and are less likely to require hospital admission.^{1379,1380} Additionally, due to a lower likelihood of law enforcement involvement, individuals who receive crisis care through ESPs are less likely to face incarceration.¹³⁸¹ ESPs improve patient care experience and outcomes as they eliminate long wait times in ED waiting rooms, ED boarding, and high costs associated with ED visits.^{1382,1383,1384} ESPs can respond rapidly to behavioral health crises, improve access to mental and behavioral health services for underserved communities, and reduce strain on local EDs and EMS.^{1385,1386}

Without access to the care provided by ESPs, the symptoms and severity of the conditions of individuals experiencing mental health crises may worsen or be prolonged.¹³⁸⁷ A 2022 study on the Boston Emergency Services Team (BEST) program, a psychiatric emergency services provider that evaluates and treats psychiatric crises through several channels including specialized psychiatric EDs, a 24/7 hotline, psychiatric urgent care centers, and mobile crisis units, found that efforts to serve patients with mental health conditions in non-ED settings decreased the proportion of encounters taking place in EDs from 70.6% in 2005 to 58.5% in 2016.¹³⁸⁸ The results of this study show that ESPs have the potential to reduce the burden of mental health emergencies in the ED, improve patient diversion to appropriate mental health care instead of the ED, and increase access to licensed mental health care professionals and services, leading to an increased likelihood of symptom reduction and long-term recovery.¹³⁸⁹

ESPs serve as important care delivery methods to provide timely and high-quality interventions and treatment for individuals experiencing psychiatric emergencies. These programs address the challenges experienced by patients and providers related to the treatment of mental health conditions in EDs and by EMS. Through the treatment provided by ESPs, individuals are more likely to achieve positive outcomes, have positive patient experiences, and experience an increased likelihood of long-term recovery, while decreasing the strain on EDs and EMS.

Estimated Marginal Cost of the Mandate

This mandate requires coverage on a nondiscriminatory basis for all medically necessary emergency services. Most carrier survey responses indicated that the affected emergency services would be covered in the absence of the

mandate. BerryDunn reviewed emergency service claims for carriers that would not cover the services in the absence of the mandate using the Massachusetts APCD. This mandate became effective in November 2022. Therefore, BerryDunn estimated the impact of the mandate as the increase in Massachusetts APCD sample paid claim PMPM cost of emergency services for 2021 (prior to the mandate) to 2023 (after the mandate) after controlling for medical inflation.¹³⁹⁰ It is uncertain if the increase in claims volume is fully attributable to the mandate, because there are other possible drivers for an increase in emergency services, e.g., a greater awareness of available and covered treatment. However, for this analysis, BerryDunn conservatively assumed the entirety of the increase is attributable to the mandate.

BerryDunn calculated the incremental cost for fully insured and self-insured GIC members to be \$0.03 PMPM in 2023 as summarized below in Table 23. With administrative loading, the cost of the mandate remained at \$0.03 PMPM. This represents a 0.005% impact on the Commonwealth premium.

Table 23. Emergency Services Programs Mandate Contribution to Premium

MEASURES	SAMPLE ESTIMATE
Sample Average Members	1,576,663
Paid PMPM	\$ 0.03
Paid PMPM With Admin	\$ 0.03
Allowed PMPM	\$ 0.03
UPPER BOUND IMPACT	
Insured Population	2,150,129
Contribution to Total Annual Claims	\$ 730,326
Contribution to Total Annual Premium	\$ 824,949
Percent of Total Premium	0.005%

Additionally, it is possible for the cost of the mandate to be offset by a reduction in ED services. This is outside the scope of this analysis and would potentially reduce the financial impact of the mandate.

Fertility Preservation Services

This mandate requires coverage for standard fertility preservation services,^{clxxix} including procurement, cryopreservation, and storage of reproductive tissues such as gametes and embryos. These services must be covered when an individual has a diagnosed medical or genetic condition that may directly or indirectly cause infertility^{clxxx} by affecting reproductive organs or processes. This coverage must be provided to the same extent as other pregnancy-related procedures under policies issued or renewed in the Commonwealth.¹³⁹¹

Effect of the Mandate on Health

Fertility preservation refers to the process of saving sperm, eggs, or reproductive tissue for future biological reproduction.¹³⁹² Common techniques rely on cryopreservation, which involves freezing sperm, eggs, and/or embryos for later use, and often require ART to achieve pregnancy.^{1393,1394}

Cryopreservation can include:

- Sperm freezing: Collecting, freezing, and storing sperm for future use, with the option of testicular sperm extraction if needed
- Oocyte (egg) and/or embryo freezing: Stimulating the ovaries to develop multiple eggs, which are then retrieved through a minor procedure; these eggs can be frozen unfertilized or fertilized through IVF to create embryos for freezing¹³⁹⁵

Cryopreservation methods for gametes (sperm and eggs) and embryos are well studied for effectiveness in cell survival and achieving live births.¹³⁹⁶ Research shows that long-term storage of semen does not impact fertilization potential, and oocyte storage duration also does not affect pregnancy rates.^{1397,1398} Younger individuals tend to yield more oocytes and achieve higher live birth rates, indicating age is a factor in fertility success.^{1399,1400} Embryo cryopreservation is often preferred to oocyte cryopreservation.¹⁴⁰¹ A 2021 meta-analysis investigating the relationship between the duration of embryo cryopreservation and pregnancy outcomes found that long-term storage (up to eight years) of cryopreserved embryos did not negatively impact pregnancy outcomes, including live birth rates. However, factors such as temperature fluctuations, gamma radiation exposure, and procedural handling may influence embryo

^{clxxix} “Standard fertility preservation services” are defined as “procedures or treatments to preserve fertility as recommended by a board-certified obstetrician gynecologist, reproductive endocrinologist or other physician; provided, however, that the recommendation shall be made in accordance with current medical practices and professional guidelines published by the American Society for Reproductive Medicine, the American Society of Clinical Oncology or other reputable professional organizations.”

^{clxxx} “Directly or indirectly cause impairment of fertility” is defined as “to cause circumstances where a disease or the necessary treatment for a disease has a likely side effect of infertility as established by the American Society for Reproductive Medicine, the American Society of Clinical Oncology or other reputable professional organizations.”

viability.¹⁴⁰² The study also emphasized the benefits of vitrification over slow freezing^{clxxxi, 1403} in terms of embryo survival and pregnancy outcomes, though the data is limited.¹⁴⁰⁴

The World Health Organization (WHO) defines infertility as a condition of the male or female reproductive system characterized by the inability to achieve pregnancy after 12 months or more of regular, unprotected sexual intercourse.¹⁴⁰⁵ According to the 2024 National Health Statistics Reports, in the United States from 2015 to 2019, 13.4% of biological females aged 15 – 49 and 15.4% of biological females aged 25 – 49 experienced impaired fecundity.^{clxxxii, 1406} Infertility in married biological females aged 15 – 44 rose from 6.7% to 8.7% during the same period. Infertility also affected 11.4% of biological males aged 15 – 49 and 12.8% of biological males aged 25 – 49 from 2015 to 2019. Both infertility and impaired fecundity were linked to age.¹⁴⁰⁷

Infertility can result from a range of biological factors affecting either or both partners. For both biological females and males, prior use of chemotherapy can cause, or increase the odds of, developing infertility.^{1408, 1409} Infertility in biological females can also result from issues affecting the ovaries, fallopian tubes, or uterus. Ovulation disorders, such as polycystic ovary syndrome (PCOS) and diminished ovarian reserve (DOR), are common causes of disrupted ovarian function. Conditions like primary ovarian insufficiency (POI) or functional hypothalamic amenorrhea (FHA) may also impair ovulation. Fallopian tube obstruction, often due to infections or conditions like endometriosis, can further hinder conception.^{clxxxiii, 1410} Uterine abnormalities, such as fibroids or congenital anomalies, can impact implantation.

In biological males, infertility is typically linked to issues with sperm production or delivery, hormonal disorders, or genetic conditions. Disorders like varicocele or trauma to the testes may impair sperm quality or production. Hormonal imbalances or conditions affecting the hypothalamus and pituitary glands, such as Cushing's syndrome, can disrupt sperm production.^{1411, 1412}

Infertility can also be influenced by a range of lifestyle factors that affect both partners. These include age, tobacco and marijuana use, alcohol consumption, being overweight or underweight, and a lack of exercise. In some cases, infertility is classified as unexplained, meaning no clear cause can be determined despite evaluation. A subset of infertility cases also arises from combined factors involving both partners.^{1413, 1414}

^{clxxxi} In slow freezing, a low amount of cryoprotectant is used, and the cooling process is done very slowly to prevent ice crystals from forming. In contrast, vitrification is a much faster freezing method that uses a high amount of cryoprotectant. It cools embryos in just a few seconds and does not need any special, costly equipment.

^{clxxxii} Individuals with impaired fecundity are either unable to get pregnant or carry a pregnancy to term or experience difficulty getting pregnant and carrying a pregnancy to term.

^{clxxxiii} The National Institutes of Health consider conception to be the beginning of pregnancy, specifically marked by the fertilization of an egg by a sperm, which initiates the process of embryo development.

Genetic conditions that can lead to infertility often involve single gene defects, in which mutations affect specific genes. These conditions include, but are not limited to, cystic fibrosis, Tay-Sachs disease, spinal muscular atrophy, Canavan disease, sickle cell disease, and Thalassemias.^{clxxxiv, 1415}

Fertility preservation, which entails the cryopreservation of sperm, eggs, or embryos for potential future use, is a medically recognized option for individuals at risk of infertility due to medical treatment or other factors.^{1416, 1417}

However, access to these services is often limited by factors such as cost and lack of insurance coverage. To the extent that the mandate expands access, it enables individuals to preserve reproductive material and maintain the possibility of biological reproduction despite facing potential infertility.¹⁴¹⁸

Estimated Marginal Cost of the Mandate^{clxxxv}

Carrier responses indicated that they would cover fertility preservation services in the absence of the mandate. However, most carriers indicated they would have limits on storage time. Therefore, BerryDunn estimated the cost of this mandate to be the impact of additional users and the impact of removing storage limits only for carriers that had restrictions prior to the mandate. BerryDunn used claims data from the 2023 Massachusetts APCD and academic literature to make assumptions on potential uptake rates and average storage length. Additionally, BerryDunn assumed childbearing ages to be 15 – 44 when estimating the cost of this mandate in alignment with the prospective mandate analysis.¹⁴¹⁹ Calculations are presented separately by sex (male/female) to reflect biological differences in fertility preservation services.^{clxxxvi}

BerryDunn calculated the impact of additional users by estimating the additional male and female users and multiplying by their respective average cost per user. The average cost per user was calculated using the 2023 Massachusetts APCD fertility preservation paid claim amounts divided by their respective users. The average cost per user was approximately \$602 for males and \$7,433 for females. To estimate the number of potential users that may not have sought these services without the mandate, BerryDunn focused on the number of cancer patients because they make up the majority of patients seeking fertility preservation services.¹⁴²⁰ Using the Cancer Incidence and Mortality Report from the Massachusetts Cancer Registry,¹⁴²¹ BerryDunn summed the incidence rates of cancer types most strongly associated with infertility risk.¹⁴²² BerryDunn then multiplied each incidence rate by its respective number of fully insured members in the Commonwealth by gender and age cohort, resulting in an implied incidence rate of approximately 0.021% of males and 0.074% of females. These implied incidence rates may overstate the

^{clxxxiv} Cystic fibrosis: A genetic disorder that can cause male infertility by obstructing the vas deferens, the tube that carries sperm.

Tay-Sachs disease: A genetic disorder that can affect reproductive health due to progressive neurological decline.

Spinal muscular atrophy: A neuromuscular disease that can lead to fertility challenges.

Canavan disease: A disorder that impacts the central nervous system and can indirectly affect reproductive capabilities.

Sickle cell disease: This blood disorder may cause fertility issues due to complications from treatment or the disease itself.

Thalassemias: Blood disorders that can impact fertility due to anemia and related health problems

^{clxxxv} Note: Individuals of diverse gender identities may also access these services, but claims data used in this analysis presents sex as a binary variable.

^{clxxxvi} Individuals of diverse gender identities may also access these services, but claims data used in this analysis presents sex as a binary variable.

number of eligible users because one individual may have comorbid cancer diagnoses; such overstatement would not materially impact results. BerryDunn then estimated the number of eligible users by multiplying the incidence rate by the Commonwealth population aged 15 – 44, and adjusted proportionally for carriers that had limits on storage prior to the mandate. The estimated eligible users were 76 males and 280 females. Using the Massachusetts APCD, BerryDunn calculated the uptake rates based on the current coverage voluntarily provided by the carriers. BerryDunn found the Massachusetts APCD uptake by dividing the 2023 current users in the Massachusetts APCD by the estimated eligible users. For males, a 2017 study found that 80% of eligible men would opt to use fertility preservation services.¹⁴²³ Accordingly, BerryDunn assumed an uptake rate of 80% for this population. For females, BerryDunn found a study that indicated about 45% of eligible females would be highly motivated to pursue fertility preservation services.¹⁴²⁴ Because APCD uptake was already above 45%, BerryDunn conservatively assumed a total uptake of 49% by aligning the 15–24 age cohort with the average uptake of the 25–39 cohort, recognizing that storage limits may have previously discouraged younger users. Incremental uptake was defined as the difference between this assumed rate and the rate observed in the APCD. The number of additional users was estimated by applying the incremental uptake rate to the eligible population, and the total cost was calculated as the product of additional users and the average per-user cost of fertility preservation services.

To calculate the impact of removing storage limits, BerryDunn first calculated the average cost per user for storage using the 2023 Massachusetts APCD paid claim amounts divided by their respective users by sex. BerryDunn assumed the annual storage users to be the sum of the current fertility preservation users in the 2023 Massachusetts APCD plus the estimated additional users calculated above. A 2019 study found the median length of storage for cryopreserved sperm to be 8.5 years.¹⁴²⁵ Therefore, BerryDunn assumed the average storage length under the removal of storage limits to be 8.5 years for males. A 2021 study found the average length of frozen oocytes to be 5.9 years.¹⁴²⁶ Therefore, BerryDunn assumed the average length of storage for females to be six years. Carriers' limits for storage are two years or more prior to the mandate. BerryDunn found the incremental storage years by calculating the difference between the assumed average storage lengths and the minimum already covered storage length by the carriers. This may overstate the value of the mandate for carriers with limits greater than two years. The incremental cost of storage was calculated by multiplying the average cost per user of storage, the estimated annual storage users, and the incremental storage length by gender.

BerryDunn calculated the paid PMPM of fully insured and self-insured GIC members to be \$0.02 PMPM in 2023 as summarized below in

Table 25. With administrative loading, the cost of the mandate increased to \$0.02 PMPM. This represents a 0.003% impact on the Commonwealth premium.

Table 24. Fertility Preservation Services Incremental Cost of the Mandate

2023 MEASURES	ESTIMATED IMPACT	
Impact of Additional Users	Males	Females
[a] Commonwealth Population Ages 15-44	520,026	549,598
[b] Average Cost per User for Fertility Preservation Services	\$ 602	\$ 7,433
[c] Users Ages 15-44 in APCD	9	129
[d] Implied Incidence Rate	0.021 %	0.074 %
[e] Reference Percentage Members with Limits on Storage Due to Carrier Coverage	69 %	69 %
[f] Estimated Eligible Users = (a) x (e) x (d)	76	280
[g] Uptake Reflected in APCD = (c) / (f)	12 %	46 %
[h] Assumed Uptake	80 %	49 %
[i] Incremental Uptake = (h) – (g)	68 %	3 %
[j] Additional Users = (i) x (f)	51	8
[k] Incremental Cost from Additional Users = (b) x (j)	\$ 31,001	\$ 61,625
Impact of Removing Storage Limits	Males	Females
[l] Average Cost per User for Storage	\$ 291	\$ 323
[m] Annual Storage Users = (c) + (j)	60	137
[n] Assumed Average Storage Length	8.5	6.0
[o] Average Covered Storage Length	2.0	2.0
[p] Incremental Storage Length = (n) – (o)	6.5	4.0
[q] Incremental Cost of Storage = (l) x (m) x (p)	\$ 114,440	\$ 177,136
Total Incremental Cost by Sex = (k) + (q)	\$ 145,441	\$ 238,761
Total Incremental Cost (Males + Females)		\$ 384,202

Table 25. Fertility Preservation Services Mandate Contribution to Premium

MEASURES	SAMPLE ESTIMATE
Sample Average Members	1,576,663
Paid PMPM	\$ 0.02
Paid PMPM with Admin*	\$ 0.02
Allowed PMPM	\$ 0.02
IMPACT	
Insured Population	2,150,129
Contribution to Total Annual Claims	\$ 523,944
Contribution to Total Annual Premium	\$ 591,954
Percent of Total Premium	0.003%

Human Donor Milk

This mandate requires coverage for medically necessary pasteurized DHM and DHM-derived products subject to the following conditions:^{1427, clxxxvii}

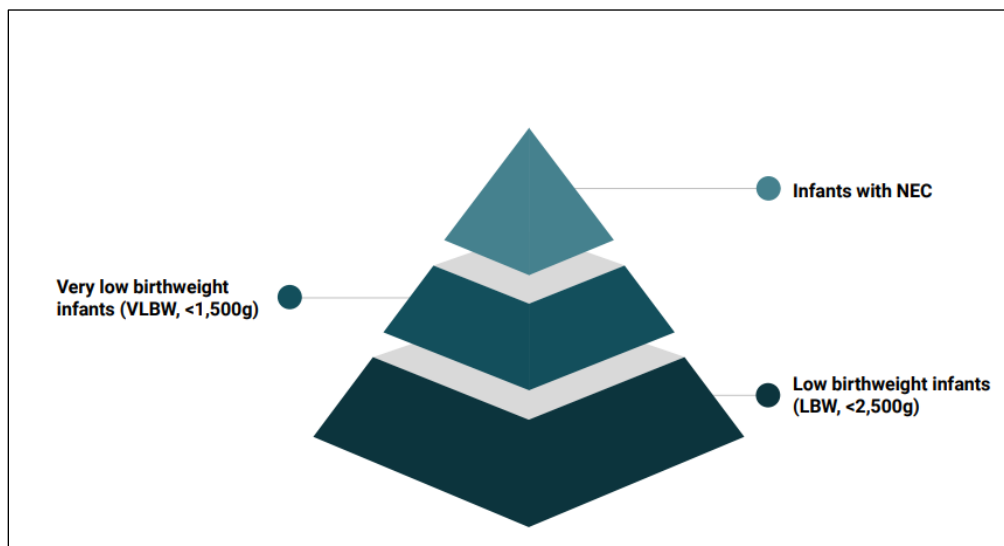
1. The donor milk is sourced from a human milk bank that adheres to DPH quality guidelines.
2. A licensed medical practitioner has issued a written order for DHM or DHM-derived products for the covered infant.
3. The covered infant is:
 - Under six months old
 - Receiving inpatient treatment for a congenital or acquired condition that places them at high risk for necrotizing enterocolitis (NEC) or could benefit from DHM, as determined by the DPH
 - Medically or physically unable to receive maternal breast milk or breastfeed or has a mother who, despite lactation support, cannot produce sufficient milk

clxxxvii If an inpatient stay is reimbursed through a diagnosis-related group (DRG) or other bundled payment arrangement, the commission shall factor in the cost of reimbursement for DHM and donor human milk-derived products when establishing the reimbursement rate for that diagnosis-related group or bundled payment.

Effect of the Mandate on Health

Pasteurized DHM is breast milk donated by mothers that undergoes screening, mixing, and testing before distribution to hospitals or families. The Human Milk Banking Association of North America sets standards for the screening, monitoring, and safety of DHM. In Massachusetts, the nonprofit Mothers' Milk Bank Northeast supplies most donor milk, primarily for hospitalized infants. Commercially available human milk-derived products, such as milk fortifiers, may also qualify for coverage under the mandate as a DHM-derived product.¹⁴²⁸ The AAP recommends providing appropriately fortified DHM to very low birth weight (VLBW) infants (weighing less than 1,500 grams) in neonatal intensive care units (NICUs) when the mother's own milk is unavailable or insufficient.^{1429,1430}

Figure 2. Infants With Medical Necessity for DHM According to AAP Guidelines



Preterm infants (born before 37 weeks) and those with low birth weight (LBW) (<2,500 grams or approximately 5.5 pounds) have a higher risk of NEC, with risk increasing for smaller and more premature infants.¹⁴³¹ NEC is among the top 10 leading causes of infant mortality in the United States, according to the CDC's National Center for Health Statistics.¹⁴³² While the survival rates of VLBW infants are rising due to advances in care, about 7% still develop NEC. Though rare, NEC can also affect full-term infants with conditions such as congenital heart disease or intrauterine growth restriction.¹⁴³³

For VLBW infants, DHM offers benefits such as a reduced risk of NEC. DHM may also lower the risk of other severe health issues and infant mortality.¹⁴³⁴ For healthy infants without specific medical needs, breastfeeding is generally recommended. However, when breastfeeding is not possible due to lactation challenges or low milk supply, infant formula is considered a suitable alternative.^{1435,1436}

In a 2024 study of infants born before 29 weeks or weighing less than 1,000 grams at birth, researchers compared outcomes between those fed formula and those fed pasteurized DHM. Both groups also received small amounts of their mothers' milk when available. The study found no significant differences in cognitive, language, or motor

development scores between the DHM and formula groups, including among those who received no maternal milk. Growth rates were slower in the DHM group, with these infants gaining weight more slowly than those on formula. However, DHM was associated with a significantly lower incidence of NEC (4.2% in the donor milk group versus 9% in the formula group), suggesting it may offer protective benefits like maternal milk.^{1437,1438}

Human milk-derived fortifiers are effective for supplementing nutrition in preterm infants but show no clear advantage over bovine-based fortifiers in comparative studies.¹⁴³⁹ Their high cost and limited evidence of superiority constrain widespread use compared to bovine-based options.¹⁴⁴⁰ Unlike DHM, which is primarily distributed by nonprofit milk banks, fortifiers are sold by for-profit manufacturers offering proprietary formulations. Evidence shows that fortifiers, whether human milk-based or bovine milk-derived, are generally effective for LBW infants.¹⁴⁴¹

Pasteurized DHM provides critical benefits for VLBW and preterm infants, particularly in reducing the risk of NEC, a leading cause of infant mortality.¹⁴⁴² While DHM-fed infants may experience slower growth compared to formula-fed infants, DHM offers protective effects similar to maternal breast milk.^{1443,1444} Human milk-derived fortifiers also show promise, but their high cost and lack of proven superiority over bovine alternatives temper their widespread adoption.¹⁴⁴⁵ Overall, DHM remains an important resource for vulnerable infants, delivering vital nutritional and health benefits when maternal milk is unavailable or insufficient.^{1446,1447}

Estimated Marginal Cost of the Mandate

Carrier survey responses did not indicate that these products would be consistently covered in the absence of the mandate. This mandate took effect in November 2024, making it difficult to review specific claims experience in the MA APCD. For the carriers that would not cover medically necessary pasteurized and DHM-derived products in the absence of the mandate, BerryDunn reviewed the number of infants in 2023 in the MA APCD who had an inpatient stay for seven or more days, whose inpatient stay began while they were less than six months of age, and who had the relevant diagnosis codes. For these infants, BerryDunn found the maximum inpatient stay in 2023. BerryDunn then began with a conservative scenario, assuming all 2023 infants for carriers that would not cover in absence of the mandate needed DHM or DHM-derived products, were all medically or physically unable to receive maternal breast milk or breastfeed, or had a mother who, despite lactation support, could not produce sufficient milk. The scenario assumed that in 2023 all infants had the maximum LOS and that their entire inpatient stays occurred before six months of age. The estimated pricing for DHM was sourced from the Mothers' Milk Bank Northeast, which supplies DHM for Massachusetts (among other states/regions)^{modxvii} and DHM-derived products was sourced from literature.^{modxviii} After removing the impact estimate for the nonprescription enteral formula mandate, the marginal direct cost of this mandate was \$0.00 PMPM and 0% of the Commonwealth fully insured premium. The enacted law differs significantly from the original mandate proposal, as it restricts coverage to infants receiving inpatient treatment, whereas the original bill did not specify a setting, implying broader eligibility. The inpatient requirement significantly reduces the potential population that would qualify for Human Donor Milk, and thus the cost associated with this mandate is commensurately reduced.

Medically Necessary Breast Screenings and Exams for Equity and Early Detection

As part of Chapter 231 of the Acts of 2024, An Act Relative to Medically Necessary Breast Screenings and Exams for Equity and Early Detection will go into effect January 1, 2026. The mandate requires non-legacy carriers that provide mammograms^{clxxxviii, 1448} to also cover DBT^{clxxxix, 1449} and medically necessary and appropriate screening via breast magnetic resonance imaging (MRI) and ultrasounds, all for the detection and diagnosis of breast cancer.^{cxc, 1450}

Effect of the Mandate on Health

As referenced in the Mammograms mandate, breast cancer is the second most likely cause of death for women in the United States. Additionally, nearly half of women have dense breasts,^{cxc, 1451} which increases the risk of developing breast cancer and makes mammograms more difficult to interpret.¹⁴⁵² One study found that Black women were more than 50% more likely to have dense breasts compared to white women;¹⁴⁵³ another study reports that dense breasts are most prevalent among Asian women.¹⁴⁵⁴ Compared to white women, Black women have a lower incidence rate^{cxcii, 1455} of breast cancer yet are 40% more likely to die from breast cancer.^{1456, 1457} Non-white women have a greater incidence of breast cancer at younger ages with more aggressive tumors compared to white women.¹⁴⁵⁸

In Massachusetts, there are over 1.5 million women aged between 40 and 74.¹⁴⁵⁹ The national incidence rate of breast cancer is 129.8 per 100,000 people, and in Massachusetts, the rate is higher at 136.2 per 100,000 people.¹⁴⁶⁰ In 2022, 77% of women aged 40 and older in Massachusetts reported having a mammogram in the past two years, compared to 70.2% across the United States.¹⁴⁶¹ Researchers found that nationally, approximately 10% of women required additional imaging after a mammogram, with most abnormal screenings addressed with additional imaging.¹⁴⁶²

The ACA requires coverage of screening mammography every one to two years as a preventive benefit for women and people assigned female at birth (including transgender men and nonbinary persons) over 40, without cost sharing.¹⁴⁶³ Screening mammograms and DBT are typically used for women who do not have symptoms of breast cancer.¹⁴⁶⁴ Screenings help providers identify lumps, masses, and calcification, all of which may be signs of breast cancer.¹⁴⁶⁵ Screening mammograms have been shown to decrease mortality by approximately 30%.¹⁴⁶⁶ Although

^{clxxxviii} Mammograms are X-rays of the breast that can show lumps or tumors that are too small to feel.

^{clxxxix} DBT, also known as 3D mammography, is a procedure that uses X-rays to make 3D pictures of the breast to check for cancer and other changes in the breast. DBT enables providers to see the breast, including dense breast tissue, more clearly than with 2D mammography.

^{cxc} Per the legislation, diagnostic examinations for breast cancer means “a medically necessary and appropriate examination for breast cancer” either after a previously reported abnormality or for individuals with a personal or familial history of breast cancer.

^{cxc} Dense breasts contain higher amounts of glandular tissue and fibrous connective tissue compared to fatty breast tissue. Dense breast tissue cannot be felt during self or clinical breast exams.

^{cxcii} Per Surveillance, Epidemiology, and End Results (SEER) data from 2017 to 2021, non-Hispanic Black women had an incidence rate of 129.3 per 100,000 compared to 139 per 100,000 for non-Hispanic white women.

screening mammograms are currently the best way to find breast cancer in individuals with average risk,^{cxci} these tests can produce high rates of false-positive^{cxciiv} results, especially in dense breasts, which can result in overdiagnosis or overtreatment.^{cxciiv, 1467} False-positive results can lead to psychological harms (like stress), further testing, invasive follow-ups, and/or additional radiation.¹⁴⁶⁸ False-negative results can also occur, especially among women with dense breasts; screening mammograms miss about 20% of breast cancers.^{cxciiv, 1469}

While additional screening for women with dense breasts increases rates of breast cancer detection, there is limited research on whether these screenings result in improved health outcomes.^{1470, 1471} Diagnostic mammograms are a more detailed X-ray used to check for breast cancer after symptoms have been reported (e.g., lump, pain, changes in size and/or shape), and they may be used after a screening mammogram to gain additional information or to screen denser breasts.^{1472, 1473} DBT helps detect breast lesions in dense breasts, can reduce false-positive rates, and can increase cancer detection rate.^{1474, 1475} DBT is currently used in 75% of facilities nationally.¹⁴⁷⁶ Ultrasounds may also be used independently or along with a mammogram to show whether a lump is solid or filled with fluid.¹⁴⁷⁷ Ultrasounds can help detect tumors in dense breasts but can be difficult to standardize across technicians, can be time consuming for patients, and can increase the number of false positives.¹⁴⁷⁸ Providers may also use MRI along with a mammogram or a biopsy to test if a fluid or tissue is cancerous.¹⁴⁷⁹ MRIs are often used for women with a high risk^{cxciiv} of breast cancer.^{1480, 1481} Research suggests the MRIs are the best supplemental imaging modality for women with dense breasts¹⁴⁸² and/or higher than average risk.¹⁴⁸³

The USPSTF issued a “B” grade recommendation^{cxciiviii, 1484} that all women and people assigned female at birth between age 40 and 74,¹⁴⁸⁵ regardless of breast density, be screened for breast cancer every other year.¹⁴⁸⁶ While the USPSTF acknowledges that mammograms may not work as well for people with dense breasts, the USPSTF currently concludes that there is insufficient evidence available to evaluate the benefits and harms of additional screenings such as breast ultrasounds or MRIs for screening mammograms with negative results.^{1487, 1488}

The American Society of Breast Surgeons (ASBrS),¹⁴⁸⁹ ACOG,¹⁴⁹⁰ the American College of Radiology (ACR),¹⁴⁹¹ and the Society of Breast Imaging (SBI)¹⁴⁹² all recommend women with an average risk^{cxciix} start routine mammograms at age 40. The ASBrS reports that among average-risk women under 40, there is currently insufficient evidence to

^{cxci} Screening mammograms can detect up to 98% of cancer in fatty breasts and 30% – 48% of cancers in extremely dense breasts.

^{cxciiv} False-positive results produce a positive screening when there is not actually a malignant finding.

^{cxciiv} Overtreatment is treatment of a cancer (e.g., surgery or radiation therapy) that may not have caused symptoms, problems, or may have resolved itself.

^{cxciiv} False-negative results produce a negative screening when there actually is a malignancy.

^{cxciiviii} High risk factors for breast cancer include certain gene mutations (BRCA1 or BRCA2), first-degree relative with a history of breast cancer, and certain genetic syndromes. Other high-risk factors include women with dense breasts, people with breast implants, and people who cannot tolerate compression from screening mammograms.

^{cxciiviii} “B grade” means that the USPSTF recommends a service at the population level because the available evidence sufficiently demonstrates moderate certainty that the net benefit of providing the service outweighs associated harms or potential harms.

^{cxciix} Average risk is for women without dense breasts and little to no hereditary susceptibility.

support additional screening.¹⁴⁹³ The ASBrS recommends that women aged 25 and older receive a formal breast cancer risk assessment,^{cc} and women with increased risk of breast cancer receive:¹⁴⁹⁴

- Annual MRI at age 25
- Mammography starting at age 30
- Access to supplemental imaging starting at age 35

ACOG does not recommend extra screenings for women with dense breasts and no other risk factors.¹⁴⁹⁵ The ACR recommends mammography screenings and/or DBT for adult females over age 30 with average, intermediate, and high risk.¹⁴⁹⁶ The ACR suggests that ultrasounds may be appropriate across risk categories and that MRIs, with and without IV contrast dye, may be appropriate for women of average and intermediate risk and are usually appropriate for high-risk adult females over age 30.¹⁴⁹⁷ Generally, screening recommendations for transgender and gender-nonconforming individuals are based on sex assigned at birth, risk factors, and hormone use, similar to recommendations for women.^{1498,1499}

Breast cancer is a common cancer with high mortality rates if not caught early. Screening mammograms are highly effective at detecting cancer in women with average risk. However, screening mammograms can miss cancers in women with higher risk, including women with dense breasts. While most professional societies recommend that women at average risk begin screening mammograms at age 40, more research is needed for uniform guidelines for high-risk patients. There is currently no consensus on the use of supplemental screening tools, such as ultrasound or MRI, for high-risk women, regardless of age. Some organizations recommend additional imaging, and others call for more research before endorsing supplemental screening more broadly.

Estimated Marginal Cost of the Mandate

The removal of member cost sharing for diagnostic breast cancer examination coverage is the impact of the mandate. BerryDunn estimated member cost sharing using 2023 claims data from the Massachusetts APCD. Member cost sharing is the difference between allowed expenses and carrier-paid expenses.

As noted earlier, HDHPs are exempt from the removal of cost sharing. Based on data in CHIA's annual report,¹⁵⁰⁰ BerryDunn calculated the proportion of fully insured membership that is enrolled in HDHPs by multiplying the enrollment by funding type and market sector by the HDHP enrollment by market sector. In 2023, 54.7% of the fully insured members were assumed to be enrolled in an HDHP. The remaining 45.3% of fully insured members were assumed to be enrolled in a non-HDHP. To effectively retain cost sharing for members enrolled in an HDHP,

^{cc} A risk assessment at age 25 includes a health care provider reviewing family and personal history of atypical hyperplasia (overgrowth of abnormal cells in the breast ducts), lobular carcinoma in situ (abnormal cells in the breast lobules that haven't spread), or history of chest or mantle radiation between the ages of 10 and 30. A risk assessment at age 30 also includes an assessment using the Tyrer-Cuzick model or a similar validated model that reviews family and personal history, breast density, and any biopsy results.

BerryDunn also accounted for HDHPs having typically higher cost share amounts. BerryDunn used a claims pricing model and calculated average member cost sharing amounts for a typical HDHP and for a typical non-HDHP. BerryDunn weighted the cost share amounts with the membership distribution from above and estimated that 80% of the cost share amounts were likely attributable to members in an HDHP, meaning only 20% of the cost would be removed.

BerryDunn calculated the portion of cost sharing not attributable to HDHPs for fully insured and self-insured GIC members to be \$0.19 PMPM in 2023 as summarized below in Table 26. With administrative loading, the cost of the mandate increased to \$0.22 PMPM. This represents a 0.033% impact on the Commonwealth premium.

Table 26. Medically Necessary Breast Screenings and Exams for Equity and Early Detection Mandate Contribution to Premium

2023 MEASURES	ESTIMATED IMPACT
[a] Cost Share Spending	\$ 18,496,375
[b] Weighted Proportion of Non-HDHP Plans	20%
Cost Share Spending Attributable to Non-HDHP Plans = [a] x [b]	\$ 3,681,374
Sample Average Members	1,576,663
Paid PMPM	\$ 0.19
Paid PMPM With Admin	\$ 0.22
Insured Population	2,150,129
Contribution to Total Annual Claims	\$ 5,020,367
Contribution to Total Annual Premium	\$ 5,670,816
Percent of Total Premium	0.033%

Mental Health Acute Treatment, Community-Based Acute Treatment, and Intensive Community-Based Acute Treatment

The mental health acute treatment (MHAT), community-based acute treatment (CBAT), and intensive community-based acute treatment (ICBAT) mandate requires insurance coverage of medically necessary treatment under these service types without requiring preauthorization before the individual receives treatment. As part of this mandate, the treating facility must notify the individual's carrier of the admission and provide the initial treatment plan to the carrier within 72 hours of the individual's admission.¹⁵⁰¹

Effect of the Mandate on Health

Expanding on the topic of mental and behavioral health discussed in the section covering the Emergency Services Programs mandate, many children and youth also experience mental and behavioral health conditions. Between 2018 and 2019, one in seven children ages 3 – 17 in the United States had a current, diagnosed mental or behavioral health condition, and of those children, more than one in three had two or more conditions.¹⁵⁰² In Massachusetts, 18.4% of youth ages 3 – 17 years reported having experienced anxiety or depression in 2020.¹⁵⁰³ As with adults, children and youth experiencing mental or behavioral health conditions might experience a crisis and require psychiatric treatment.¹⁵⁰⁴ The number of children and youth presenting to the ED with mental and behavioral health crises for reasons such as suicidal ideation, self-harm, eating disorders, SUDs, behavioral outbursts, aggression, and psychosis is increasing in the United States.¹⁵⁰⁵ It is important that any individual experiencing a crisis episode receive timely interventions and treatment to help minimize and avoid potential injury to themselves or others around them.¹⁵⁰⁶ Additionally, timely intervention during a crisis is especially important for children and adolescents because mental health issues can negatively affect social and emotional development.¹⁵⁰⁷

The mental health treatment interventions requiring coverage as a result of this mandate are defined as follows:^{1508,1509}

- **MHAT:** 24-hour medically supervised mental health services provided in an inpatient facility, licensed by the department of mental health, that provides psychiatric evaluation, management, treatment, and discharge planning in a structured treatment milieu
- **CBAT:** 24-hour clinically managed mental health diversionary or step-down services for children and adolescents that is usually provided as an alternative to MHAT at facilities properly licensed to provide such care according to recognized parameters established for such facilities
- **ICBAT:** Intensive 24-hour clinically managed mental health diversionary or step-down services for children and adolescents that is usually provided as an alternative to MHAT at facilities properly licensed to provide such care according to recognized parameters established for such facilities

MHAT is a clinical intervention for youth and adults for treatment of mental health diagnoses.¹⁵¹⁰ MHAT is provided in an inpatient (hospital) setting for individuals experiencing an acute psychiatric condition that has a sudden onset, a short and severe course, poses a significant danger to the individual or others, and/or has resulted in significant psychosocial dysfunction or grave mental disability.^{cci,1511,1512} Generally, patients admitted to MHAT pose a danger to themselves or others and need the added security of the MHAT environment.¹⁵¹³ For patients who do not pose a danger to themselves or others, research shows that residential treatment environments may provide a cost benefit and produce similar outcomes.¹⁵¹⁴

^{cci} Grave mental disability is a legal term that reflects an individual's inability to meet their basic needs due to a mental illness.

CBAT is a voluntary treatment option for children and adolescents who are experiencing a serious mental or behavioral health crisis and is usually provided as an alternative to MHAT.^{1515,1516} CBAT programs provide individuals with treatment in 24/7 secure and supervised group residential centers.¹⁵¹⁷ Programs like CBAT are typically preferable settings for crisis care because the environment is less clinical and more well suited to provide psychiatric care.¹⁵¹⁸ Programs like CBAT are good options for individuals who may be experiencing housing instability or a stressful home environment.¹⁵¹⁹ To meet medical necessity criteria for CBAT, an individual must:¹⁵²⁰

- Have symptoms consistent with a DSM-5-TR diagnosis that can be expected to respond to a therapeutic intervention
- Have emotional or behavioral problems in the home, school, community, and/or treatment setting and not be emotionally or behaviorally stable enough to be treated outside of a 24-hour therapeutic environment
- Have exhausted existing community supports
- Have a mental health status that prevents them from remaining in their home environment and receiving outpatient treatment for their condition
- Have cognitive capacity that allows responsiveness to active acute and time-limited treatment and interventions

ICBAT is also usually provided as an alternative to MHAT and as a more intensive form of CBAT, with more frequent psychiatric evaluation, i.e., daily psychiatric visits, more frequent medication management, and a higher staff-to-patient ratio. Individuals must meet all medical necessity criteria for CBAT and also meet one of the following criteria:^{1521,1522}

- Have indications of suicidal or homicidal ideation with a plan
- Display symptoms of command hallucinations^{ccii, 1523}
- Demonstrate symptoms of persecutory delusions^{cciii, 1524}
- Exhibit symptoms of fire-setting or sexually reactive behavior

^{ccii} Command hallucinations are auditory hallucinations that direct an individual to act in certain ways and can range in severity from harmless to life threatening.

^{cciii} Persecutory delusions are an extreme form of paranoia, in which an individual believes that other people have intentions of harming them or that they are being accused of wrongdoing when they have not done anything wrong. This belief impacts an individual's thoughts and behaviors.

- Have an impairment to the degree that the individual exhibits severe psychiatric symptoms that impact social and interpersonal functioning and has not responded to less-intensive treatment and/or management efforts

The therapeutic services offered through CBAT and ICBAT might include daily medication monitoring, psychiatric care, nursing, several types of therapy, case management, and discharge planning.¹⁵²⁵

Diversions services, such as CBAT and ICBAT, are mental health services that can provide an appropriate alternative to inpatient services, such as MHAT, or help support an individual's return to the community following an inpatient stay. CBAT and ICBAT are essential in providing effective crisis care. Crisis services are designed to meet individuals' needs in the least restrictive, least disruptive, and most community-integrated way possible by emphasizing patient autonomy and individualized treatment. This approach aims to reduce the need for more restrictive levels of care like ED or inpatient hospitalization.^{1526,1527} SAMHSA provides guidance for effective crisis care that illustrates services being comprehensive, coordinated, person centered, equitably accessible, effective, trauma informed, evidence based, and supportive in guiding an individual through the continuum of care.¹⁵²⁸ In providing youth behavioral health crisis services, SAMHSA encourages interventions to aim to keep youth in their home whenever possible, provide developmentally appropriate services for children, integrate family and youth peer support in the delivery of services, provide culturally and linguistically appropriate services, and ensure that all services are provided in an equity-driven manner.¹⁵²⁹

There is a lack of research related to the efficacy of MHAT, because randomized control trials are difficult for this type of service. The availability of MHAT services in Massachusetts is inadequate for the number of people that need mental and behavioral health crisis care.¹⁵³⁰ Additionally, there is little research directly evaluating the efficacy of community-based, residential mental health treatments, and the variety of community-based models complicates research, making it difficult to make valid comparisons and generalizations.¹⁵³¹ Research indicates community-based and residential treatment as cost-effective alternatives to MHAT with comparable outcomes.¹⁵³² Alternatives to MHAT, like CBAT and ICBAT, can help alleviate the demand for MHAT services while also generating cost savings due to the lower cost of these interventions compared to inpatient services and a decreased need for inpatient admissions.¹⁵³³

Improving access to less-restrictive environments, prioritizing patient autonomy, and using personalized treatment planning through the use of programs like CBAT and ICBAT can help improve access to and quality of mental health services for youth experiencing mental and behavioral health crises. Often, when children and adolescents experience a mental health crisis, they present to an ED for care and may eventually be admitted for acute inpatient psychiatric treatment.¹⁵³⁴ Before being admitted for acute inpatient treatment, children and adolescents are likely to experience ED boarding. ED boarding occurs in hospital EDs when there is a lack of availability of inpatient beds, where an individual is held in the ED until an inpatient bed becomes available.¹⁵³⁵ While an individual is boarded in the ED, they receive medical and stabilizing care but likely will not receive psychiatric care until they are placed in an inpatient bed.¹⁵³⁶ Psychiatric patients are more likely to face ED boarding and issues associated with it due to several reasons, including lack of resources in the ED, lack of psychiatric expertise by ED staff, the high complexity of psychiatric illnesses, and a lack of inpatient psychiatric beds.^{1537,1538} Children and adolescents presenting to the ED

for mental health conditions are more likely to be impacted by ED boarding, compared to children and adolescents presenting to the ED with medical issues, due to an increasing volume of children experiencing psychiatric emergencies as a result of insufficient availability of inpatient and outpatient pediatric mental health resources.^{1539,1540} The need for mental and behavioral health crisis care for children and adolescents is increasing, and the capacity of the health care system to screen, diagnose, and manage these individuals is decreasing.¹⁵⁴¹ This increasing volume of pediatric mental health emergencies, in conjunction with an overall lack of inpatient psychiatric beds and lack of psychiatric resources in the ED, challenges the capability of the ED in providing timely care for all patients and creates the issue of prolonged boarding times.¹⁵⁴² Children and adolescents are more vulnerable to the adverse conditions of the ED environment.¹⁵⁴³ The ED can be crowded and loud, the individual may face seclusion or physical restraint, and ED staff are likely not well equipped to provide optimal mental health care.¹⁵⁴⁴ Children and adolescents are still developing resiliency and coping skills, intensifying the magnitude of the consequences associated with the adverse conditions of the ED environment that can be detrimental for adults.¹⁵⁴⁵ A May 2024 report by the Massachusetts Hospital Association reports an average of 568 boarded patients awaiting a behavioral health bed a day from June 2021 to February 2024.¹⁵⁴⁶ According to a report from the Massachusetts Health Policy Commission (HPC), of children who were ultimately admitted to an inpatient psychiatric bed in 2023, 56% waited 0 – 24 hours in the ED, 24% waited 24 – 48 hours, and 20% waited more than 48 hours.¹⁵⁴⁷ In the same year among adults who were ultimately admitted to an inpatient psychiatric bed, 54% waited 0 – 24 hours, 33% waited 24 – 60 hours, and 13% waited over 60 hours.¹⁵⁴⁸ Use of programs like CBAT or ICBAT as an alternative to AT for children and adolescents is beneficial because these programs can provide care for the same level of acuity as AT but in a more suitable environment, consequently reducing ED boarding and allowing youth to receive effective and developmentally appropriate care that will meet their needs.¹⁵⁴⁹

While there is little research detailing the impact of the removal of prior authorization requirements in mental health crisis care specifically, research shows that use of prior authorization and other utilization management techniques reduces patient access to care, increases out-of-pocket costs for patients, causes patient harm, including significant impairment, hospitalization, and death, increases the likelihood of patients abandoning treatment, and causes poorer outcomes.^{1550,1551} The absence of these requirements eliminates a substantial barrier to patients receiving timely care and increases the chances of achieving optimal outcomes. Research also suggests that delays in initiating mental health treatment can lead to poorer outcomes, worsen mental health conditions, decrease responsiveness to treatment, increase the likelihood for developing additional comorbid conditions, increase the risk of premature death, and increase the risk of suicide.^{1552,1553} Mental health is important for creating and maintaining interpersonal connections and to help individuals adopt positive coping strategies, especially for children and adolescents.¹⁵⁵⁴ Youth's brains are more sensitive and vulnerable to the effects of mental health conditions during early childhood because they are in a foundational stage of development.¹⁵⁵⁵ Without timely treatment and support, the onset of mental health conditions during childhood can cause negative life-long effects for an individual's academic, social, emotional, and behavioral achievements.^{1556, 1557,1558} Considering the research detailing the effect of utilization management techniques on health care in general, the impact of delaying the initiation of mental health care, and the consequences of untreated mental health conditions in children and adolescents, the absence of prior authorization requirements for MHAT, CBAT, and ICBAT is likely to improve access to these critical services and ultimately improve patient outcomes. Timely care during a mental health crisis is essential, making the elimination of any

potential delays a central component of ensuring individuals are able to receive the care they need, when they need it.

Estimated Marginal Cost of the Mandate

Based on the carrier survey responses, some carriers indicated that these services would be covered in the absence of the mandate. A review of Massachusetts APCD data excluding those carriers indicated that both the PMPM cost and utilization of these services has trended down since the mandate went into effect. This study therefore estimates the 2023 marginal, direct cost impact of this mandate as \$0 and 0% of the Commonwealth fully insured premium.

Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS)/Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS)

The Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) mandate requires coverage for treatment for PANDAS/PANS that includes, but is not limited to, the use of intravenous immunoglobulin (IVIG) therapy.^{1559, 1560}

Effect of the Mandate on Health

Treatment for PANDAS and PANS can include cognitive behavioral therapy (CBT), antibiotics, IVIG, and plasmapheresis. It is hypothesized that reducing the spread of Group A Strep (GAS) could reduce the prevalence of PANDAS and PANS.¹⁵⁶¹ PANS is a condition marked by the abrupt emergence of symptoms like obsessive-compulsive behaviors (OCD) or dietary restrictions, alongside sudden behavioral decline across multiple domains. PANDAS is a subset of PANS and was initially identified by researchers at the National Institute of Mental Health in 1998.^{1562, 1563} Associated symptoms of PANS may encompass anxiety, heightened sensory perception, motor difficulties, regression in behavior, decline in academic performance, mood irregularities, urinary issues, and disrupted sleep patterns.^{1564, 1565}

Diagnosis of PANDAS is based on five distinct criteria, including the sudden onset of OCD or severe tics, a pattern of recurring symptoms, onset at a young age (typically six to seven years), neurological abnormalities, and a temporal connection between symptom onset and infection with GAS. These criteria often coincide with similar accompanying symptoms seen in PANS.^{1566, 1567} For both PANDAS and PANS, there are three levels of severity: Mild, Moderate, and Severe.¹⁵⁶⁸

Table 27. Diagnostic Criteria for PANDAS/PANS^{1569,1570,1571}

PANS DIAGNOSTIC CRITERIA	PANDAS DIAGNOSTIC CRITERIA
<p>A sudden and severe onset of obsessive-compulsive disorder or extremely restricted food intake</p> <p>Presence of additional neuropsychiatric symptoms with similarly severe and abrupt onset from at least two of the following categories:</p> <ul style="list-style-type: none"> ▪ Anxiety ▪ Emotional instability and/or depression ▪ Irritability, aggression, and/or severe oppositional behaviors ▪ Behavioral (developmental) regression ▪ Sharp decline in school performance ▪ Motor or sensory abnormalities ▪ Physical signs and symptoms, such as sleep disturbances, bedwetting, or frequent urination <p>Symptoms cannot be attributed to a known neurological or medical condition</p> <p>No specific age requirement</p>	<p>Display symptoms of OCD and/or tics, especially multiple, complex, or unusual tics</p> <p>Symptoms must have an abrupt onset and follow an episodic (relapsing-remitting) course</p> <p>There must be an association with neurological abnormalities</p> <p>Symptoms must appear between the ages of three and puberty</p> <p>There must be an association with GAS infection</p>

A 2023 retrospective review of three academic medical centers in the United States found that among the study population of 95,498 individuals from 2017 to 2019, there were 357 potential cases and 13 actual cases. Based on these findings, the authors estimated the annual incidence of PANDAS/PANS as 1 in 11,765 for children aged 3 – 12 years.¹⁵⁷² Advocates assert that the true prevalence of PANDAS/PANS is unknown but higher than studies suggest.^{cciv}

For acute episodes of PANDAS, the optimal course of action is to test for the presence of strep bacteria via a throat culture and then, if strep is present, treat the bacteria with antibiotics. If the presence of strep bacteria is not detected via a throat culture, follow-up tests may be conducted to test for the presence of bacteria in the anus, vagina, or urethral opening of the penis. While the presence of strep in areas other than the throat is rare, it has been reported to trigger PANDAS in some patients and can be particularly problematic if they continue to result in the production of antibodies. The antibiotic course may be longer for these sites than for strep originating in the throat.¹⁵⁷³ Beta-lactams,^{ccv,1574} including penicillin, amoxicillin, and cephalosporins, are highly effective in treating GAS infections.

^{cciv} The PANDAS network estimates that the prevalence in the United States is 1 in 200 children.^{cciv}

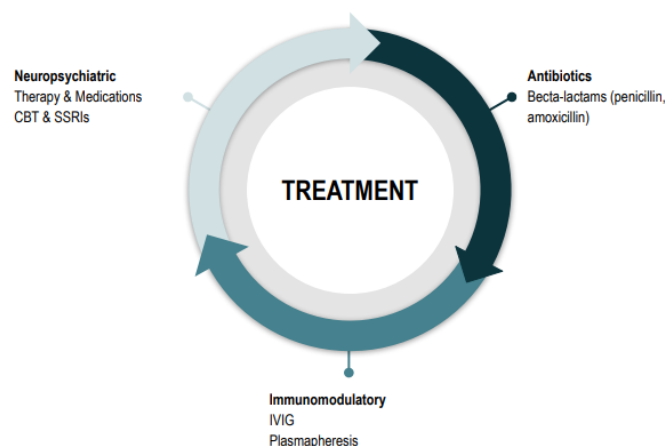
^{ccv} A lactam is a ring-shaped chemical made from certain building blocks of proteins. It includes a special kind of connection called an amide bond, and the rest of the ring is made of simple carbon parts. Lactams come in different sizes and can be used in the development of medicines and plastics.

Other antibiotics such as erythromycin, azithromycin, and clindamycin exhibit variable effectiveness, influenced by regional resistance patterns.¹⁵⁷⁵

To treat the neuropsychiatric symptoms of PANDAS and PANS, such as OCD, behavioral therapies, including CBT, and/or medications may be indicated. For most individuals with PANDAS who are exhibiting OCD symptoms, a combination of CBT and selective serotonin reuptake inhibitor (SSRI) medications is often the most effective approach in managing symptom severity.^{1576,1577}

Additional treatment for PANDAS/PANS can include IVIG or therapeutic plasma exchange (TPE, also known as plasmapheresis). While research has demonstrated that both treatments can improve global functioning and address depression, as well as OCD symptoms, there can also be disruptive side effects from these treatments, such as nausea, vomiting, headaches, and dizziness.¹⁵⁷⁸ Small clinical trials have found marked and enduring symptom improvement, including a 2022 study of 10 children who received three monthly IVIG treatments. However, three children (one third) experienced moderate to severe temporal side effects.¹⁵⁷⁹ In a 2022 study of 16 late adolescents and adults with PANDAS/PANS receiving TPE, improvement in symptoms was noted in four out of the seven individuals who had documented post-TPE responses.¹⁵⁸⁰ IVIG and TPE treatments introduce an increased risk of infection, and accordingly, the National Institute of Mental Health (NIMH) recommends that only individuals who are severely ill receive this treatment from a qualified health care team.¹⁵⁸¹ A 2015 retrospective study of the effectiveness of TPE among 35 individuals with PANDAS found that symptoms improved significantly after short- and long-term follow-up. Notably, the length of time the individual had been ill before receiving TPE did not impact the magnitude of symptom improvement.¹⁵⁸² Although tonsillectomies were previously part of treatment for children with PANDAS, they are no longer supported by research.¹⁵⁸³

Figure 3. Treatment Types for PANDAS and PANS



The PANDAS and PANS mandate requires coverage for treatment, including intravenous immunoglobulin (IVIG) therapy.¹⁵⁸⁴ PANS is characterized by abrupt symptom emergence such as obsessive-compulsive behaviors (OCD), while PANDAS is a streptococcal-associated subset.¹⁵⁸⁵ Treatment options for PANDAS and PANS encompass cognitive behavioral therapy (CBT), antibiotics, IVIG, and plasmapheresis.^{1586,1587} Diagnosis relies on criteria such as sudden OCD onset, recurring or episodic symptoms, young age at onset, neurological abnormalities, and temporal connection to Group A Strep (GAS) infection.^{1588,1589,1590} Prevalence estimates suggest about 1 in 200 children in the U.S., with studies indicating an annual incidence of 1 in 11,765.^{1591,1592}

Estimated Marginal Cost of the Mandate

At the time of this report, the marginal cost of this mandate is immeasurable due to several limitations. The absence of dedicated ICD-10 codes for PANDAS/PANS necessitates reliance on proxy diagnoses such as OCD, tic disorders, autoimmune conditions, or neuropsychiatric symptoms, which introduces the risk of both overestimating and underestimating the affected population. Overestimation could occur if individuals with similar but unrelated conditions are included, while underestimation could occur if individuals with undiagnosed cases or those coded under broader categories are excluded. Additionally, the lack of universally accepted diagnostic and treatment protocols leads to inconsistent coding across specialties such as neurology, psychiatry, immunology, and pediatrics. The individualized nature of treatment—spanning antibiotics, IVIG, steroids, and psychiatric interventions—further prevents the establishment of clear identification patterns and a standard course of treatment. Moreover, high-cost interventions like IVIG, plasmapheresis, and long-term psychiatric care are widely used for other autoimmune and neuropsychiatric disorders, rendering it impossible to attribute utilization and costs specifically to PANDAS/PANS. The broad language of the mandate, which does not define PANDAS/PANS by diagnostic codes, age limits, or specific covered treatments, adds to the complexity of measurement, making it difficult to determine the precise scope of coverage and associated cost. Multiple carriers explicitly report that services to treat PANDAS/PANS are often not uniquely coded and were already covered based on symptoms rather than condition-specific labels. As a result, claims data does not provide a reliable way to track or quantify utilization. The absence of specific diagnosis and procedure codes, paired with the broad and individualized nature of treatment, makes it unfeasible to attribute services and costs solely to PANDAS/PANS. Given these challenges, the marginal cost of PANDAS/PANS coverage cannot be reliably measured using existing claims data.

Pharmaceutical Access, Costs and Transparency

As part of Chapter 342 of the Acts of 2024, An Act Relative to Pharmaceutical Access, Costs and Transparency went into effect April 8, 2025.¹⁵⁹³ Starting July 1, 2025, the legislation will require carriers to provide coverage for one generic and one brand name drug to treat asthma and the two most prevalent heart conditions among its enrollees.

¹⁵⁹⁴ The mandate also requires coverage for one brand name drug to treat diabetes, which is identified as

insulin.^{ccvi,1595,1596,1597} This mandate prohibits cost sharing for insulin and generic drugs and restricts coinsurance or copays to no more than \$25 per a 30-day supply for brand name drugs and all types of insulin.

Effect of the Mandate

This mandate aims to reduce barriers to accessing high-value medications for chronic conditions that are significant contributors to total health care spending. Annually, carriers are required to evaluate covered drugs based on their potential to reduce hospitalizations or ED visits, slow disease progression, or improve quality of life. They must also consider the cost effectiveness of the drug, risk of use, and current utilization for treatment of the applicable chronic condition.¹⁵⁹⁸ Carriers may update their drug selections once per year unless the drug is withdrawn from the market or the drug price significantly changes.¹⁵⁹⁹

Americans routinely pay up to 2.6 times more than people in other countries^{ccvii} pay for prescription drugs.¹⁶⁰⁰ Across MA, pharmacy spending was one of the largest contributors to health care spending, with an overall increase of 17.5%.¹⁶⁰¹ Commercial pharmacy spending increased 7.4% or 9% PMPM from 2022 to 2023.¹⁶⁰² From 2019 to 2022, prescription drug spending grew more than 7% per year in Massachusetts, 10 times faster than in previous years.^{1603,1604} In Massachusetts, commercial spending among brand name prescription drugs grew 10% from 2017 to 2022 while the price of generic drugs remained stable.¹⁶⁰⁵ According to CHIA, the increase in pharmacy spending was driven by the increase in the cost of prescriptions rather than by an increase in utilization.¹⁶⁰⁶

Immunosuppressants (used to treat conditions like asthma), hormones and synthetic substances (used to treat conditions like diabetes), and cardiovascular agents (used to treat heart conditions) are part of the top 10 therapeutic classes that account for 90.7% of prescription drug expenditures across the Commonwealth.¹⁶⁰⁷ On average, out-of-pocket spending increased by nearly 30% from \$38 in 2017 to \$48 in 2022^{ccviii} for a 30-day supply of prescription drugs for common chronic conditions.¹⁶⁰⁸ In 2023, more than 25% of Americans reported difficulty affording necessary medication;¹⁶⁰⁹ lack of affordability reduces patient adherence to treatment, which can lead to poorer health outcomes, higher acuity, and increased health spending.¹⁶¹⁰ CHIA reported that 1 in 10 Massachusetts residents reported forgoing needed prescription drugs due to their cost.¹⁶¹¹

Diabetes is a chronic condition that occurs when blood glucose is too high and does not reach cells because the body cannot make enough insulin (type 1) or does not use insulin properly (type 2).¹⁶¹² As of 2024, approximately 38 million people in the United States had diabetes (about 1 in 10), with about 90% – 95% having type 2 diabetes.¹⁶¹³ In 2022, around 9.2% (almost 593,000 people) of adults in Massachusetts had a diabetes diagnosis, compared to 8.4% nationally.¹⁶¹⁴ About one in four people with diabetes in the United States ration their insulin due to its high cost (in some cases as high as \$900 per patient per month), which can lead to severe complications, including death.¹⁶¹⁵

^{ccvi} Insulin is a biologic, made from living cells. Unlike generics, which are chemically identical to brand-name drugs, biologics have biosimilars—highly similar alternatives that undergo strict regulatory review.

^{ccvii} Comparable countries include those in the Organizations for Economic Co-operation and Development (OECD). Per capita, the United States spends \$1,310 per person, compared to \$646 per person in other OECD countries.

^{ccviii} The out-of-pocket spending for insulin peaked in 2020 at \$54 for a 90-day supply.

Asthma is a common chronic condition resulting from an overactive immune system.¹⁶¹⁶ As of 2021, approximately 11.7% (over 661,000 people) of adults in Massachusetts currently have asthma,¹⁶¹⁷ compared to 8% across the United States.¹⁶¹⁸ Asthma is usually treated with quick-relief medications, like inhalers for an asthma attack, or prevented through long-term medications such as steroids and other medications that help reduce immune responses and/or prevent airway swelling.¹⁶¹⁹ Although not uniquely prescribed for asthma, spending for immunosuppressants was the largest driver of prescription drug spending between 2018 and 2022 in Massachusetts.

ccix,¹⁶²⁰

Heart disease is the leading cause of death in the United States, with about one in five people dying from a heart condition in 2022.^{1621,1622} Nationally, the most common cardiovascular disease, coronary heart disease,^{ccx,1623} affects about one in twenty (5%) adults 20 and older.¹⁶²⁴ As of 2022, nearly 6.2% of adults 35 and older in Massachusetts were diagnosed with angina (chest pain) or coronary heart disease at some point during their lives, and 5.8% experienced myocardial infarctions (heart attacks).¹⁶²⁵ Medications that can help manage heart conditions include those that lower blood pressure, decrease how hard the heart pumps, or help control high blood cholesterol, blood thinners, and drugs that help control blood sugar or support weight management.¹⁶²⁶

Cost of the Mandate Not Estimated

At the time of this report, DOI had issued guidance to carriers on drug selection under the mandate; however, carriers had not yet submitted their covered drug lists. Some of the identified drugs were already inexpensive and widely available, making generic alternatives unnecessary in certain cases.

Postpartum Depression Screenings

This mandate, as part of Chapter 186 of the Acts of 2024, requires PCPs, obstetricians, gynecologists, certified nurse-midwives, licensed certified professional midwives, and pediatricians who provide health care services to postnatal individuals^{ccxi,1627} to offer screenings, without cost sharing, for PPD or MDD in accordance with evidence-based guidelines to postnatal individuals.¹⁶²⁸ If a health care provider determines, based on the screening methodology administered, that the postnatal individual is likely to be suffering from PPD or MDD, the provider must discuss available treatments for PPD or MDD, including pharmacological treatments, and provide an appropriate referral to a mental health clinician.¹⁶²⁹ Pursuant to DOI guidance, this screening should be considered as part of a regular visit or as part of a negotiated bundled reimbursement and is not subject to cost sharing.¹⁶³⁰

Effect of the Mandate on Health

ccix Spending for immunosuppressants increased by \$70 to \$80 million dollars every year, in part due to the lack of generic equivalents and lack of market competition for these types of drugs.

ccx Coronary heart disease is when arteries are blocked from plaque, resulting in a lack of oxygen in the heart muscle.

ccxi "Postnatal individual" refers to an individual who: (i) is within 12 months of giving birth; (ii) is a biological parent or an adoptive or foster parent that is within 12 months from assuming custodial care of a child; or (iii) has lost a pregnancy due to a stillbirth, miscarriage or a medical termination within the previous 12 months."

MDD is among the leading causes of disability in people 15 years and older.¹⁶³¹ PPD is an MDD that begins after childbirth¹⁶³² and is one of the most common complications of pregnancy during the postpartum period.¹⁶³³ PPD is a mood disorder that can affect individuals within one year after childbirth.¹⁶³⁴ PPD is more severe than “baby blues”^{ccxii,1635} and often manifests as persistent sadness, lack of interest, low self-esteem, sleep disturbances, loss of appetite, anxiety, irritability, self-blame, feelings of hopelessness, worthlessness, and/or humiliation, and difficulties bonding with the baby.¹⁶³⁶ PPD can be diagnosed when an individual exhibits at least five depressive symptoms^{ccxiii} for at least two weeks.¹⁶³⁷

PPD can result in negative short- and long-term consequences for both the birthing person and child.¹⁶³⁸ Effects include reduced parental^{ccxiv}-infant attachment, sleep disruption, recurring and intrusive negative thoughts, suicidal ideation, increased substance use,¹⁶³⁹ social relationship problems, breast/chestfeeding^{ccxv,1640} problems, and/or persistent depression.¹⁶⁴¹ Additionally, children born to individuals with PPD are more likely to have “poor cognitive functioning, behavioral inhibition, emotional maladjustment externalizing disorders, or psychiatric and medical disorders.”¹⁶⁴² Currently, there is no exact cause of PPD, but risk factors include psychological factors,^{ccxvi} obstetric risk factors,^{ccxvii} hormonal changes, social factors,^{ccxviii} genetic predisposition,^{ccxix} and lifestyle.^{ccxx,1643} Additional risk factors include poor self-esteem, childcare stress, prenatal anxiety, life stress, decreased social support, single/unpartnered relationship status, history of depression, difficult infant temperament, previous PPD, lower socioeconomic status, and unintended pregnancy.¹⁶⁴⁴

PPD often goes undiagnosed and untreated;^{ccxxi,1645} however, early identification, including screening, can lead to better outcomes for postnatal individuals, infants, and families.¹⁶⁴⁶ In the United States, PPD affects as many as one in seven (14%) pregnant and postnatal individuals,¹⁶⁴⁷ with a higher prevalence among Black postpartum individuals.¹⁶⁴⁸ Research suggests that nationally, fewer than 50% of postnatal individuals are screened for PPD.¹⁶⁴⁹

ccxii “Baby blues” is a common condition that usually starts two to three days after giving birth. Symptoms include feelings of worry, unhappiness, and fatigue that usually improves on its own within two weeks.

ccxiii PPD symptoms include depressed mood most of the day, loss of interest or pleasure most of the day, sleep disturbances, psychomotor issues, feelings of worthlessness or guilt, loss of energy or fatigue, suicidal ideation, attempt, or recurrent thoughts of death, impaired concentration or indecisiveness, and a significant change in weight or appetite.

ccxiv Edited from “maternal” to “parental” to align with the mandate and current best practices.

ccxv The term chestfeeding or bodyfeeding can be used alongside breastfeeding to be more inclusive. Nonbinary or trans people might not align with the term breastfeeding because of their gender or may have a dysphoric relationship with their anatomy. Chestfeeding is not meant to replace “breastfeeding” or “nursing” but is included as a term when discussing lactation.

ccxvi Psychological factors include a personal history of depression and anxiety, premenstrual syndrome, a negative attitude toward the baby, dissatisfaction with the baby’s sex, and a history of sexual abuse.

ccxvii Obstetric risk factors include a high-risk pregnancy, hospitalization during pregnancy, and traumatic events during childbirth including emergency cesarean section, in-utero meconium passage (passage of baby’s first stool before birth), umbilical cord prolapse, preterm or low birth weight infant, and low hemoglobin.

ccxviii Social factors include lack of social support, domestic violence (spousal, sexual, physical, or verbal), smoking, and young maternal age during pregnancy.

ccxix Genetic predisposition includes a family history of psychiatric disorders.

ccxx Lifestyle factors include poor eating habits, decreased physical activity and exercise, vitamin B6 deficiency, and lack of sleep.

ccxxi One study estimates 60% of pregnant and postpartum individuals with depressive symptoms do not receive a clinical diagnosis, and 50% of people with a diagnosis do not receive treatment.

In 2022, there were over 68,000 births in the Commonwealth.¹⁶⁵⁰ In 2020, 16.4% of Massachusetts individuals who delivered were screened for PPD and 13.8% of individuals had a positive screen.¹⁶⁵¹ The 2019 Massachusetts Pregnancy Risk Assessment Monitoring System (PRAMS) data revealed inequities in PPD screening and diagnosis.¹⁶⁵² Postnatal individuals with less than a high school education and Hispanic postnatal individuals were less likely to be screened for PPD compared to white non-Hispanic postnatal individuals and those with a college degree.¹⁶⁵³ The Massachusetts DPH notes that PPD data is currently significantly underreported within the state.¹⁶⁵⁴

In 2019, the USPSTF issued a “B” grade for providing or referring pregnant and postpartum persons who are at increased risk of perinatal^{ccxxiii} depression, which includes PPD, to counseling interventions.^{ccxxiii, 1655} In 2023, the USPSTF reinforced prior guidance and issued a “B” grade recommendation for screening for depression in the general adult population, including pregnant and postpartum people.¹⁶⁵⁶ The USPSTF found convincing evidence that screening in primary care settings helps accurately identify depression among adults with depression, including pregnant and postpartum patients.^{1657, 1658} The USPSTF found that depression screening along with adequate support systems improve clinical outcomes (i.e., reduction or remission of depression symptoms) in adults, including pregnant and postpartum people^{ccxxiv} with little to no associated harm.¹⁶⁵⁹ Additional research demonstrates that treating people^{ccxxv} at risk for pregnancy-related depression may prevent the long-term negative consequences on maternal and child health and well-being.¹⁶⁶⁰ However, an established barrier impacting screening rates is the availability of screening for non-English speaking patients.¹⁶⁶¹

ACOG, AAP, and the American Academy of Family Medicine (AAFP) all recommend screening every eligible person for PPD using a standardized and validated tool.¹⁶⁶² The ACOG recommends either the Edinburgh Postnatal Depression Screen (EPDS) or the Patient Health Questionnaire-9 (PHQ-9) to screen for depression.¹⁶⁶³

Research also shows that pediatric providers are in a unique position to screen and detect PPD, as well as to connect postnatal individuals and families to services. Typically, postnatal individuals see their obstetrician once about six weeks after giving birth; however, children have one-, two-, four-, and six-month well-child visits throughout the first year of life, providing ample opportunities for PPD screening and detection.¹⁶⁶⁴ The AAP recommends screening for depression at each well-child visit in the first postpartum year.¹⁶⁶⁵

In addition to federal requirements to cover screening, Massachusetts has enacted several laws that aim to improve awareness, destigmatize PPD, and increase screening for PPD within the state. In 2010, legislation^{ccxxvi} established a PPD Legislative Commission. In 2014, PPD regulations^{ccxxvii} began requiring providers and carriers to annually report

^{ccxxii} PND is a depressive disorder during pregnancy or up to one year after childbirth. The recommendation includes preventive counseling while an individual is pregnant and/or is in the postpartum (one year) period.

^{ccxxiii} This recommendation is currently being updated.

^{ccxxiv} Edited from “women” to “people” to align with the mandate and current best practices.

^{ccxxv} Edited from “women” to “people” to align with the mandate and current best practices.

^{ccxxvi} Chapter 313 of the Acts of 2010, An Act Relative to Postpartum Depression

^{ccxxvii} PPD Regulations-105 CMR 271.000

PPD screenings from people who had given birth within the previous six months¹⁶⁶⁶ to CHIA for the Massachusetts APCD.¹⁶⁶⁷

PPD is a common pregnancy-associated complication and mood disorder that impacts as many as one in seven postnatal individuals. The USPSTF, ACOG, AAP, and AAFP all recommend PPD screening for perinatal individuals. Research supports certain providers conducting screenings,^{ccxxviii} along with adequate support systems for individuals who screen positive. Early identification of PPD, through screening, can lead to better outcomes for postpartum individuals, infants, and families.

Estimated Marginal Cost of the Mandate

The ACA¹⁶⁶⁸ requires all non-legacy plans to cover screening and treatments that receive an “A” or “B”^{ccxxix,1669} grade from the USPSTF without cost sharing.¹⁶⁷⁰ Responses to the carrier survey consistently indicated that these services would be covered in the absence of the mandate. Additionally, the Massachusetts PPD screening mandate is superseded by federal law; therefore, the marginal, direct impact of the state mandate is \$0 and 0% of the Commonwealth fully insured premium.

Telehealth

This mandate requires coverage for behavioral health services, physical health services, and oral health services, delivered via telehealth. For the purposes of this mandate, “behavioral health services” encompass care for mental health, developmental, or substance use disorders. “Telehealth” includes the use of synchronous or asynchronous audio, video, electronic media, and other telecommunications for health services, such as interactive audio-video, remote monitoring, audio-only phone, and online adaptive interviews. Telehealth services are required to be covered if these services are covered in person and deemed appropriate for telehealth.^{ccxxx} Telehealth coverage may involve utilization review and prior authorization, assessed similarly to in-person services. Providers do not need to document barriers to in-person visits, and individuals can choose in-person services over telehealth if preferred.¹⁶⁷¹

Effect of the Mandate on Health

Research has found that telehealth services are effective for behavioral health clinical assessments and treatments.^{1672,1673,1674} A review of eight meta-analyses found that telehealth interventions are at least as effective as traditional in-person mental health care for a variety of mental health conditions, particularly when the treatments compared are otherwise equivalent. However, the effectiveness of the treatment can vary based on individual characteristics and on the telehealth service modality, e.g., phone versus video. While phone-based telehealth is a largely accessible method, it lacks visual nonverbal cues and may lead to distractions during treatment, rendering it

^{ccxxviii} Providers include a PCP, obstetrician, gynecologist, CNM, licensed certified professional midwife, or infant’s pediatrician.

^{ccxxix} The USPSTF assigns letter grades to describe the strength of recommendations. An “A” grade is the highest grade issued by the USPSTF, meaning the service is recommended and the expected net benefit greatly outweighs any potential harms. A “B” grade means the USPSTF recommends the service and the expected net benefit is moderate to substantial.

^{ccxxx} Carriers cannot overly rely on telehealth for network adequacy and must ensure timely in-person services upon request.

less equivalent to in-person care. Video-based telehealth clinical assessments for the purposes of diagnosing mental health conditions were found to yield similar scores and diagnoses compared to clinical assessments delivered in person.¹⁶⁷⁵

The comparability and effectiveness of telehealth versus in-person delivery for behavioral health treatment differs based on the therapeutic approach and the specific condition being treated. Three systematic reviews with meta-analyses found that telehealth is as effective as in-person treatment for general mental health symptom reduction. One review indicated that videoconferencing and in-person treatment had similar outcomes, but the effectiveness varied by an individual's diagnosis.^{1676,1677,1678} One meta-analysis examined CBT via videoconferencing versus in-person care, finding that while therapeutic rapport was lower in videoconferencing, the individual's clinical outcomes were not inferior. This suggests that despite a lower perceived connection between the individual and their therapist, the effectiveness of symptom reduction was similar between the two modalities.¹⁶⁷⁹

A 2022 survey commissioned by America's Health Insurance Plans (AHIP) and conducted by the National Opinion Research Center (NORC) at the University of Chicago explored use and satisfaction with telehealth services among commercially insured individuals. The findings indicate that 40% of respondents used telehealth in the past year, with 60% reporting satisfaction with the care received. Convenience was a significant driver, with 69% citing it as a reason for choosing telehealth over in-person appointments. Additionally, 78% of users agreed that telehealth made it easier to seek care, and 85% felt there were enough providers available to meet their needs. Notably, women were 1.6 times more likely than men to use telehealth, with many reporting that it addressed barriers like childcare or eldercare responsibilities. Income differences had a modest impact on usage rates, and most users accessed telehealth two to five times annually. These findings underscore the role of telehealth in improving access and flexibility for diverse populations.¹⁶⁸⁰

Recent studies on telehealth demonstrated significant utilization changes and cost savings across different patient populations. A 2023 study evaluated the indirect cost savings from telehealth use among 11,688 nonelderly cancer patients at a National Cancer Institute-designated center from April 2020 to June 2021. By substituting in-person visits with telehealth, patients saved 3.8 million miles in travel, 75,000 hours of driving time, and \$1.6 million in lost productivity. Estimated cost savings per visit ranged from \$147.4 to \$186.1, depending on mileage and wage models. A 2021 study analyzing over 36 million privately insured individuals compared ambulatory care utilization and costs from March to June 2019 and the same period in 2020. While in-person visits declined by 37%, telehealth increased from 0.3% to 23.6% of visits, reducing the total decrease in ambulatory contacts to 18%. Telehealth adoption was higher in urban areas, among patients with chronic conditions, and in high COVID-19 prevalence regions. Per-member monthly medical costs fell by 15% overall but remained higher for patients with telehealth visits due to their greater disease burden.¹⁶⁸¹

One significant advantage of telehealth services is its ability to extend care to a larger population of individuals who may otherwise lack access to mental health resources. Additionally, individuals can conveniently access these services from home or during breaks at work.¹⁶⁸²

Estimated Marginal Cost of the Mandate

Based on carrier survey responses, the cost of this mandate is the change in the cost of telehealth services due to telehealth services being required to be reimbursed at the same rate as services delivered in person. Carriers consistently indicated that telehealth services would be covered in the absence of the mandate, though likely not at parity with services delivered in person.

In Massachusetts, the DPH issued coverage requirements for telehealth services as part of the governor's declared state of emergency. The state of emergency was in place from March 10, 2020, to June 15, 2021, and required carriers to cover all medically necessary telehealth services and that such services be reimbursed at the same rate as in-person services.¹⁶⁸³ In 2019, telehealth services were not required to be reimbursed at the same rate as in-person services, so BerryDunn used Massachusetts APCD data to compare the weighted average cost per claim for telehealth services in 2019, trended forward to 2023, to the average cost per claim, and weighted by 2019 claim counts, of telehealth services in 2023. The cost per claim was considered by provider type and service and only for those provider type and service combinations that had 15 or more telehealth claims in 2019 as well as an increase in cost per claim from 2019 to 2023. Provider type and service combinations for which the cost per claim decreased from 2019 to 2023 were not considered as these were primarily related to behavioral health services, and it was assumed that the mandate did not cause these costs per claim to decrease. The increase in the weighted average cost per claim in telehealth services from 2019 to 2023 was then multiplied by the total number of claims in 2019 for provider type and service combinations with material claim counts and an increase in cost per claim from 2019 to 2023. The Massachusetts APCD data did not show increased utilization of services when combining telehealth and non-telehealth services and comparing 2019 to 2023. Thus, BerryDunn assumed that the new services that are being delivered via telehealth in 2023, and were not being delivered via telehealth in 2019, occurred due to the COVID-19 pandemic when providers swiftly adopted telehealth into their routine practice, and patient acceptance of virtual visits increased dramatically for reasons unrelated to the mandate. Therefore, the increase in utilization of telehealth services was not considered as part of the cost of the mandate. The marginal cost of the mandate is thus the increase in cost per claim for services delivered via telehealth prior to the mandate.

Requiring coverage for telehealth services by fully insured health plans resulted in a 2023 PMPM marginal impact estimate for this mandate of \$0.04 in claims cost and \$0.04 with administrative loading. The estimated impact on total 2023 Massachusetts fully insured market premium is 0.006%. These results are summarized below in [Table 28](#).

Table 28. Telehealth Mandate Contribution to Premium

MEASURES	SAMPLE ESTIMATE
Sample Average Members	1,576,663
Paid PMPM	\$ 0.04
Paid PMPM With Admin	\$ 0.04
Allowed PMPM	\$ 0.05
UPPER BOUND IMPACT	
Insured Population	2,150,129

Contribution to Total Annual Claims	\$ 985,119
Contribution to Total Annual Premium	\$ 1,112,753
Percent of Total Premium	0.006%

Tobacco Cessation

This mandate requires all individual and group hospital service plans issued or renewed in Massachusetts to cover both tobacco cessation counseling and all generic FDA-approved tobacco cessation products. These products must be covered without cost sharing (i.e., no copays, deductibles, or coinsurance) when prescribed by a health care provider. Carriers may impose reasonable utilization management methods (e.g., limits on frequency or setting) if they comply with state and federal law and provide access to at least one tobacco cessation product without prior authorization.¹⁶⁸⁴

Effect of the Mandate on Health

According to CHIA's Behavioral Health in Massachusetts Technical Appendix, based on Behavioral Risk Factor Surveillance System (BRFSS) data, the prevalence of cigarette smoking among Massachusetts adults has remained relatively stable, with 10.6% reporting current smoking in 2021 and 10.4% in 2022.^{ccxxxi} These rates are notably below the 2022 U.S. median of 13.5%, indicating that Massachusetts continues to maintain a lower-than-average smoking prevalence among adults.¹⁶⁸⁵

Tobacco naturally includes nicotine, a highly addictive chemical, that makes quitting the use of tobacco, in any form, extremely difficult.¹⁶⁸⁶ The U.S. Food & Drug Administration (FDA) currently approves of nicotine replacement therapy (NRT) via gum, lozenge, patches, nasal spray, and inhaler as well as drugs bupropion^{ccxxxi,1687} and varenicline^{ccxxxi,1688} to help people stop smoking.¹⁶⁸⁹ Cigarette smoking is the leading preventable cause of disease and death in the United States, contributing to over 480,000 deaths each year. Smoking damages nearly every organ and increases the risk of cancer, heart disease, stroke, lung disease, and other serious conditions. Secondhand smoke also causes thousands of deaths annually. Quitting smoking at any age improves health and lowers the risk of early death.¹⁶⁹⁰

A 2021 review synthesized findings from nearly a hundred studies on smoking cessation interventions to evaluate their relative effectiveness and implementation challenges. This review found that combination therapy, the integration of nicotine replacement therapy (NRT), bupropion, and/or varenicline with behavioral counseling, achieved the highest success rates. After one year of combination therapy up to 24% of individuals remained

^{ccxxxi} The BRFSS defines a current smoker as someone who has smoked at least 100 cigarettes in their lifetime and who currently smokes either every day or some days.

^{ccxxxi} Bupropion is an antidepressant primarily used to treat depression and can also help people stop smoking.

^{ccxxxi} Varenicline is a drug that helps people quit smoking by preventing nicotine from affecting the body.

abstinent, compared to 7–16% who received behavioral therapy alone and 3–5% who quit unassisted. A 2021 meta-analysis cited in the review reported that varenicline combined with NRT was the most effective pharmacologic strategy. The review highlighted that cessation success varies with genetic, socioeconomic, and psychosocial factors, and that tailored interventions that are sensitive to gender, culture, and age yield better outcomes than one-size-fits-all approaches.¹⁶⁹¹

A 2024 Cochrane meta-analysis reviewed 319 randomized controlled trials with over 157,000 participants to compare the effectiveness and safety of smoking cessation medications and nicotine delivery systems. The study found that seven interventions demonstrated clear and clinically meaningful benefits in helping people quit smoking: varenicline, cytisine,^{ccxxxiv} bupropion, nicotine patches, fast-acting NRTs such as gum or lozenges, combination NRT (patch plus a fast-acting form), and nicotine-containing e-cigarettes. Among these, varenicline, cytisine, combination NRT, and nicotine e-cigarettes had the most consistent results across studies, indicating they are the most reliable options for smoking cessation. In contrast, nortriptyline and nicotine tapering showed possible but uncertain benefit, and non-nicotine e-cigarettes had inconclusive effects. Head-to-head analyses showed that varenicline, nicotine e-cigarettes, cytisine, and combination NRT were generally more effective than bupropion, nortriptyline, or single-form NRTs. The study also found that pharmacotherapies were slightly more effective in individuals with comorbid health conditions or those who were hospitalized, underscoring their broad utility across populations. Overall, the findings confirm that multiple pharmacologic and nicotine-based treatments meaningfully increase quit rates, with varenicline, cytisine, and combination NRT consistently the most effective interventions.¹⁶⁹²

For example, the Massachusetts Medicaid Tobacco Cessation Program provided all FDA-approved cessation medications and counseling at minimal or no cost, with broad provider access and extensive outreach. From 2007–2009, roughly 75,000 MassHealth smokers participated, leading to a reduction in smoking prevalence from 38% to 28% and significant decreases in hospitalizations for heart disease. The program also demonstrated strong economic value, with every \$1 spent yielding \$3.12 in cardiovascular-related medical savings.¹⁶⁹³

While the ACA similarly requires coverage of evidence-based tobacco cessation services and at least one product in each FDA-approved category without cost sharing, Massachusetts law goes further by mandating coverage of all generic FDA-approved products, not just one per product type. Both state and federal law allow reasonable utilization management techniques, but Massachusetts emphasizes that at least one product must always be available without prior authorization and explicitly applies the requirement to both prescription and over-the-counter products. In practice, this means Massachusetts law provides broader, more complete coverage than the federal preventive service standard.¹⁶⁹⁴

Estimated Marginal Cost of the Mandate

For this mandate, only the RDC is considered, as the incremental coverage of all generics under Massachusetts law versus one generic under federal law is not expected to meaningfully increase utilization or marginal costs.

^{ccxxxiv} Cytisine is unavailable in the United States as of the time of writing this report.

Universal Postpartum Home Visiting Services

This mandate, part of Chapter 186 of the Acts of 2024, requires coverage for universal postpartum home visiting services without cost sharing, such as copays, coinsurance, or deductibles.^{ccxxxv} “Universal postpartum home visiting services” are evidence-based voluntary home or community-based services for birthing people and caregivers with newborns, including, but not limited to screenings for unmet health needs including reproductive health services; maternal and infant nutritional needs; and emotional health supports, including PPD supports.¹⁶⁹⁵ Pursuant to DOI guidance, the DPH will establish and administer a statewide system of home visiting programs, but in the meantime, carriers should utilize existing networks of home health care providers.¹⁶⁹⁶

Effect of the Mandate on Health

The postpartum period begins after birth and is up to one year after pregnancy, with four main timing windows:

- Day of delivery
- 1 – 6 days postpartum
- 7 – 42 days postpartum
- 43 – 365 days postpartum¹⁶⁹⁷

Many physical, social, psychological changes occur during this period.¹⁶⁹⁸ The postpartum period is critical for recovery from birth and identifying and mitigating pregnancy-related health risks that can have lifelong impacts.¹⁶⁹⁹ Between 2017 and 2019 in the United States, the majority (53%) of pregnancy-related deaths for the birthing person occurred during the postpartum period, especially in the first six weeks after birth.¹⁷⁰⁰ Of these pregnancy-related deaths, 84.2% were determined to be preventable through patient, community, provider, facility, and/or system factors.¹⁷⁰¹ Researchers report higher rates of pregnancy-related deaths and complications among Black and American Indian/Alaska Native birthing people.¹⁷⁰² ACOG reports that as of 2022, nationally one third of maternal deaths, and nearly one in seven severe maternal morbidity (SMM),^{ccxxxvi,1703} occur in the postpartum period.^{ccxxxvii,1704} In 2022, there were over 68,000 births in the Commonwealth.¹⁷⁰⁵ Using data as recent as 2020, in Massachusetts, about 400 birthing people are affected by SMM, with disproportionately high rates among Black birthing people.¹⁷⁰⁶

Postpartum hospital discharge without complications or comorbidities occurs within 24 – 48 hours of delivery, with a single follow-up visit about six weeks later. As of 2018, an estimated 40% of birthing people nationally did not attend any follow-up visit^{1707,1708} because of logistical, financial, or social factors.^{ccxxxviii,1709,1710} ACOG recommends ongoing

^{ccxxxv} Unless required by the Internal Revenue Code to maintain tax-exempt status for the applicable plan.

^{ccxxxvi} SMM includes unexpected outcomes of labor and delivery that can result in significant short- or long-term health consequences. Birth-related examples include hemorrhages, amniotic fluid embolisms, cardiovascular conditions, hypertensive disorders, and/or infections.

^{ccxxxvii} The postpartum period is defined as between seven days and one year after birth.

^{ccxxxviii} Factors include patient (personal traits, genetic pre-dispositions, lack of knowledge of warning signs), community (availability of supports), provider (misdiagnoses, ineffective treatment), facility and/or systems factors (reimbursement models, lack of appointment availability, poor coordination of care).

support, with at least one visit three weeks postpartum, and a comprehensive visit^{ccxxxix} no later than twelve weeks after birth.¹⁷¹¹

To address postpartum needs, the Administration for Children and Families (ACF) defines home visiting as “a service delivery strategy that aims to support the healthy development and well-being of children and families.”¹⁷¹² Many home visiting models exist, but typically models include three main intervention activities conducted through one-on-one interactions:

- Assessing family needs
- Educating and supporting parents
- Referring families to needed services in the community¹⁷¹³

Traditionally, home visiting programs in the United States have served high-risk families, such as the Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV), established under the ACA in 2010.¹⁷¹⁴ Universal home visiting models serve all families regardless of risk, income, age, or other criteria and can reach a broader range of families than programs with need- or eligibility-based enrollment.¹⁷¹⁵ Universal programs can identify needs that might otherwise go undetected and can reduce stigma typically associated with participation in home visiting programs.¹⁷¹⁶

The Commonwealth has a long history of providing pregnancy-related home visits, with the first documented as early as 1901.¹⁷¹⁷ The Commonwealth’s universal home visiting program, Welcome Family, provides a one-time nurse home visit to all families with newborns up to eight weeks old in 18 communities^{ccxi,1718} who have elevated socioeconomic, health, and psychosocial risks.¹⁷¹⁹ The 90-minute visit can take place at home, a mutually agreed location, or via telehealth and occurs ideally between two to four weeks postpartum.¹⁷²⁰ Nurses assess maternal and infant health, nutrition, emotional well-being, substance use, and intimate partner violence and provide brief interventions, education, and referrals.¹⁷²¹ Welcome Family has been associated with higher uptake of EI services and greater participation in ongoing home visiting, though more research is needed to determine its long-term impact on parenting, child development, and health outcomes.¹⁷²²

WHO recommends home visits during the first week after birth to promote maternal well-being and support newborn care.¹⁷²³ Preliminary research shows home visits may lower PPD scores, increase exclusive breastfeeding rates, and lower infant health care utilization.¹⁷²⁴ A study of a home visiting program similar to Welcome Family in North Carolina found that a brief and universal home visiting program can be cost beneficial and have a positive impact on infant and family well-being.¹⁷²⁵ However, evidence on home visiting effectiveness remains mixed. The ACF reports

^{ccxxxix} A comprehensive visit should evaluate physical, social, and psychological well-being. Domains include mood and emotional well-being via screening; guidance and follow-up for existing conditions; infant care and feeding via assessing comfort and confidence with caring for a newborn and breastfeeding and assessing material needs; sexuality, contraception, and birth spacing; sleep and fatigue; physical recovery from birth; chronic disease management; and health maintenance, including vaccinations and well-woman screening.

^{ccxi} Communities include Boston, Brockton, Chelsea, Everett, Fall River, Fitchburg, Holyoke, Lawrence, Lowell, Lynn, New Bedford, North Adams, Pittsfield, Revere, Southbridge, Springfield, Webster, and Worcester.

home visiting has only modest benefits for families on average.¹⁷²⁶ A meta-analysis comparing 60 home visit programs found no significant difference in breastfeeding rates, PPD, adherence to contraception, and adherence to well visits for children between those in the home visit group and those not receiving home visits.¹⁷²⁷ Another study reported that although individual families may benefit from home visiting programs, population-level impacts remain unproven.¹⁷²⁸ Other research suggests inconclusive evidence about the effect, if any, of home visits on decreasing rates of maternal and neonatal mortality.¹⁷²⁹ Additional research is needed to determine whether home visiting significantly reduces these risks and which models lead to better outcomes.

Estimated Marginal Cost of the Mandate

Most carrier survey responses indicated that postpartum home health visits would generally be covered even in the absence of the mandate. However, the mandate established a new category, a universal postpartum home visit program, that was not previously billed to carriers. Chapter 186, which took effect on August 23, 2024, is therefore not reflected in the Massachusetts APCD used for this report. To estimate the mandate's cost, BerryDunn analyzed claims for the sample population's birth rate and incorporated published research. The mandate requires the Department of Public Health (DPH) to develop a universal postpartum home visiting program. This cost estimate assumes that DPH will model the statewide program on the existing Welcome Family program, which has been operated by DPH since 2013.¹⁷³⁰

Assumptions and Analysis

The marginal direct cost is based on assumptions for the applicable patient pool annually, expected utilization rate, and cost per visit. The applicable patient pool for this estimate is the number of births within the fully insured and GIC population annually. Based on the APCD for 2023, there were 23,065 births in Massachusetts within this cohort.

The program's utilization rate is based on data from the Welcome Family program's initial implementation between 2013 and 2016. The 2016 Lessons Learned report provides the most relevant estimates for the Massachusetts population and suggests similar challenges may arise when the program is expanded to new hospitals and communities. The report documented a completed visit rate of 8.64%¹⁷³¹ across eligible births. This analysis assumes that these home visits will be in addition to the 1.3% of births in 2023 that already received home health visits, according to the APCD. A review of providers serving these patients indicates that the existing claims were primarily driven by health needs rather than preventive public health measures.

The Welcome Family program in Massachusetts published a 2018 report that stated per visit cost was \$130.49 in 2016.¹⁷³² When the cost is trended forward to 2023, the per visit cost is estimated to be \$177.09.

Table 29. Incremental Cost of Universal Postpartum Home Visiting Services Mandate

2023 MEASURES	ESTIMATED IMPACT
[a] FI & GIC Births in Massachusetts per Year	23,065
[b] Utilization Assumption	8.6%

[c] Per Visit Cost Assumption	\$ 177.09
Contribution of Total Annual Claims = [a] x [b] x [c]	\$ 353,011
Sample Members	1,576,663
Paid PMPM	\$ 0.02

From these assumptions, the marginal cost of the mandate is \$0.02 PMPM with a total PMPM cost, after administrative loading, of \$0.02 PMPM.

Table 30. Universal Postpartum Home Visiting Services Mandate Contribution to Premium

MEASURES	SAMPLE AMOUNT
Sample Average Members	1,576,663
Paid PMPM	\$ 0.02
Paid PMPM With Admin	\$ 0.02
Allowed PMPM	\$ 0.02
UPPER BOUND IMPACT	
Insured Population	2,150,129
Contribution to Total Annual Claims	\$ 481,408
Contribution to Total Annual Premium	\$ 543,897
Percent of Total Premium	0.003%

Constraints on Analysis

This marginal cost estimate does not account for capacity constraints of the existing Welcome Family program or the time required to develop additional service providers. Currently, the program operates five locations serving six communities. According to the 2018 report, each location was expected to serve up to 459 families per year, suggesting a total capacity of approximately 2,295 families annually. This estimate assumes that roughly 2,000 families within the commercial fully insured and GIC markets will be served; however, given the higher needs of individuals on public health insurance, capacity constraints may prevent the claims experience to emerge as estimated in this report.

5.0 Required Direct Cost (RDC)

Below is a comparison of RDCs to marginal costs. RDCs are the costs of services explicitly described in a mandated benefit law, used by all fully insured and GIC 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 or required by a different state or federal law. RDCs include marginal costs and direct costs that would have been covered absent the mandate.

For older mandates (Sections 1.0-3.0), BerryDunn was able to review administrative claims data to inform the RDC estimates. However, for more recently enacted mandates (Section 4.0), administrative claims data are not yet available, introducing a high degree of uncertainty into the RDC estimates. In addition, DOI bulletins, carrier implementation materials, and documentation of insurer interpretations and operational practices are often not yet issued or accessible. The absence of this information constrains the ability to evaluate realized utilization, quantify cost impacts, and assess administrative burden. As a result, RDC estimates for newer mandates are less precise and more heavily dependent on assumptions. Additionally, when data constraints were too great to develop any reasonable estimate, the RDC is blank and shaded darker grey in **Table 37**.

Table 37. Summary of Estimated Costs for Massachusetts Mandated Benefits as of 2023^{ccxli}

Mandate	Marginal Cost Population (in Millions)	Marginal Cost						RDC Population (in Millions)	Required Direct Cost (RDC)					
		Paid PMPM	Paid PMPM with Admin	Allowed PMPM	Paid\$ (in Millions)	Prem\$ (in Millions)	% of Total Premium		Paid PMPM	Paid PMPM with Admin	Allowed PMPM	Paid\$ (in Millions)	Prem\$ (in Millions)	% of Total Premium
Unduplicated Total All Mandates					\$142.7	\$159.0	0.93%					\$3,671.4	\$4,147.1	24.16%
Massachusetts State Mandates with Potential Direct Marginal Cost														
ABA Services for Down Syndrome	2.2	\$0.01	\$0.01	\$0.01	\$ 0.2	\$ 0.2	0.00%	2.2	\$0.01	\$0.01	\$0.01	\$ 0.2	\$ 0.2	0.00%
Abortion	1.8	\$0.05	\$0.05		\$ 1.0	\$ 1.2	0.01%	1.8	\$1.19	\$1.34	\$1.36	\$ 25.5	\$ 28.8	0.17%
ATS and CSS	2.2	\$0.39	\$0.44	\$0.44	\$ 10.0	\$11.3	0.07%	2.2	\$1.07	\$1.20	\$0.20	\$ 27.5	\$ 31.1	0.18%
Annual Mental Health Wellness Examinations	2.2	\$0.17	\$0.20	\$0.24	\$ 4.5	\$ 5.1	0.03%	2.2	\$0.24	\$0.27	\$0.32	\$ 6.1	\$ 6.9	0.04%
Cleft Palate and Cleft Lip	1.5	\$0.02	\$0.02		\$ 0.3	\$ 0.4	0.00%	2.2	\$0.08	\$0.09	\$0.08	\$ 2.0	\$ 2.3	0.01%
Contraceptive Services	2.2	\$0.03	\$0.04	\$0.03	\$ 0.9	\$ 1.0	0.01%	2.2	\$3.48	\$3.93	\$3.64	\$ 89.8	\$ 101.4	0.59%
Emergency Services Programs	2.2	\$0.03	\$0.03	\$0.03	\$ 0.7	\$ 0.8	0.00%	2.2	\$0.16	\$0.19	\$0.18	\$ 4.3	\$ 4.8	0.03%
Fertility Preservation Services	2.2	\$0.02	\$0.02	\$0.02	\$ 0.5	\$ 0.6	0.00%	2.2	\$0.15	\$0.17	\$0.15	\$ 3.8	\$ 4.3	0.03%
Hearing Aids for Children	1.5	\$0.10	\$0.11	\$0.11	\$ 1.9	\$ 2.1	0.01%	2.2	\$0.33	\$0.37	\$0.42	\$ 8.4	\$ 9.5	0.06%

^{ccxli} Table 37 excludes 1) Midwifery Care and Out-of-Hospital Birth Options, 2) PANDAS/PANS, 3) Pharmaceutical Access, Costs, and Transparency, and 4) COVID Tests, Vaccines and Treatment.

Mandate	Marginal Cost Population (in Millions)	Marginal Cost						RDC Population (in Millions)	Required Direct Cost (RDC)					
		Paid PMPM	Paid PMPM with Admin	Allowed PMPM	Paid\$ (in Millions)	Prem\$ (in Millions)	% of Total Premium		Paid PMPM	Paid PMPM with Admin	Allowed PMPM	Paid\$ (in Millions)	Prem\$ (in Millions)	% of Total Premium
Infertility Treatment ^{ccxlii}	1.2	\$ 7.58	\$8.59	\$7.75	\$113.0	\$125.4	0.73%	1.8	\$6.51	\$7.36	\$7.05	\$ 139.7	\$ 157.7	0.92%
Low Protein Food Products	1.5	\$ 0.04	\$0.05	\$0.04	\$ 0.8	\$ 0.9	0.01%	2.2	\$0.10	\$0.11	\$0.10	\$ 2.6	\$ 2.9	0.02%
Medically Necessary Breast Cancer Screenings and Exams	2.2	\$ 0.19	\$0.22		\$ 5.0	\$ 5.7	0.03%							
Nonprescription Enteral Formulas	1.5	\$ 0.03	\$0.04	\$0.03	\$ 0.6	\$ 0.7	0.00%	2.2	\$ 0.09	\$ 0.10	\$ 0.10	\$ 2.4	\$ 2.7	0.02%
Oral Cancer Therapy	2.2	\$ 0.07	\$0.08		\$ 1.9	\$ 2.1	0.01%	2.2	\$10.46	\$11.81	\$10.63	\$ 269.8	\$ 304.8	1.78%
Telehealth	2.2	\$ 0.04	\$0.04	\$0.05	\$ 1.0	\$ 1.1	0.01%							
Universal Postpartum Home Visiting Services	2.2	\$ 0.02	\$0.02	\$0.02	\$ 0.5	\$ 0.5	0.00%	2.2	\$ 0.02	\$ 0.02	\$ 0.02	\$ 0.5	\$ 0.5	0.00%
Mandates Judged to Have Zero or Unmeasurable Marginal Cost														
Abuse-Deterrent Opioids								2.2	\$ 0.08	\$ 0.09	\$ 0.10	\$ 2.2	\$ 2.4	0.01%
Autism Spectrum Disorders								2.2	\$ 5.94	\$ 6.71	\$ 6.48	\$ 153.3	\$ 173.2	1.01%
Behavioral Health Care								2.2	\$43.67	\$49.33	\$52.77	\$1126.8	\$1272.8	7.41%
BMT for Treatment of Breast Cancer														
Cardiac Rehabilitation								2.2	\$ 0.17	\$ 0.19	\$ 0.19	\$ 4.3	\$ 4.8	0.03%
CNMs								0.8	\$ 0.33	\$ 0.38	\$ 0.38	\$ 3.1	\$ 3.5	0.02%

^{ccxlii} RDC infertility treatment estimates exclude GIC pharmacy claims, which are not available in the APCD. Pharmacy costs comprise a substantial share of total infertility treatment expenses.

Mandate	Marginal Cost Population (in Millions)	Marginal Cost					RDC Population (in Millions)	Required Direct Cost (RDC)						
		Paid PMPM	Paid PMPM with Admin	Allowed PMPM	Paid\$ (in Millions)	Prem\$ (in Millions)		% of Total Premium	Paid PMPM	Paid PMPM with Admin	Allowed PMPM	Paid\$ (in Millions)	Prem\$ (in Millions)	% of Total Premium
CRNAs								2.2	\$ 0.84	\$ 0.95	\$ 0.94	\$ 21.7	\$ 24.5	0.14%
Chiropractic Services								0.4	\$ 1.06	\$ 1.20	\$ 2.10	\$ 5.5	\$ 6.3	0.04%
Chiropractors								0.8	\$ 1.74	\$ 1.96	\$ 2.83	\$ 16.3	\$ 18.4	0.11%
Clinical Trials (to Treat Cancer)								2.2	\$ 0.14	\$ 0.16	\$ 0.17	\$ 3.6	\$ 4.1	0.02%
Collaborative Care								2.2	\$ 0.11	\$ 0.12	\$ 0.12	\$ 2.8	\$ 3.2	0.02%
Cytologic Screening								2.2	\$ 0.96	\$ 1.09	\$ 1.04	\$ 24.8	\$ 28.0	0.16%
Dentists								0.8	\$ 0.45	\$ 0.51	\$ 0.57	\$ 4.2	\$ 4.8	0.03%
Diabetes-Related Services and Supplies								2.2	\$11.47	\$12.95	\$13.27	\$ 295.9	\$ 334.2	1.95%
Early Intervention Services								2.2	\$ 1.00	\$ 1.13	\$ 1.10	\$ 25.8	\$ 29.1	0.17%
Hearing Screening for Newborns								2.2	\$ 0.02	\$ 0.02	\$ 0.02	\$ 0.5	\$ 0.6	0.00%
HIV-Associated Lipodystrophy Treatment								2.2	\$ 0.01	\$ 0.01	\$ 0.01	\$ 0.3	\$ 0.4	0.00%
Home Health Care								2.2	\$15.85	\$17.91	\$17.28	\$ 409.0	\$ 462.0	2.69%
HRT								2.2	\$ 0.90	\$ 1.02	\$ 1.26	\$ 23.3	\$ 26.4	0.15%
Hospice Care								2.2	\$ 1.38	\$ 1.56	\$ 1.59	\$ 35.6	\$ 40.2	0.23%
Human Donor Milk (DHM)														
HLA Testing								2.2	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.0	\$ 0.0	0.00%

Mandate	Marginal Cost Population (in Millions)	Marginal Cost					RDC Population (in Millions)	Required Direct Cost (RDC)					
		Paid PMPM	Paid PMPM with Admin	Allowed PMPM	Paid\$ (in Millions)	Prem\$ (in Millions)		% of Total Premium	Paid PMPM	Paid PMPM with Admin	Allowed PMPM	Paid\$ (in Millions)	Prem\$ (in Millions)
Hypodermic Syringes or Needles							2.2	\$ 0.03	\$ 0.03	\$ 0.06	\$ 0.8	\$ 0.9	0.01%
Lead Poisoning Screening							2.2	\$ 0.04	\$ 0.04	\$ 0.04	\$ 1.0	\$ 1.1	0.01%
Mammography							2.2	\$ 4.65	\$ 5.25	\$ 4.83	\$ 120.0	\$ 135.5	0.79%
Maternity Care (Including Minimum Maternity Stay)							2.2	\$13.06	\$14.75	\$14.58	\$ 337.0	\$ 380.7	2.22%
MHAT, CBAT, and ICBAT													
Nurse Practitioners							2.2	\$ 7.68	\$ 8.67	\$ 9.66	\$ 198.1	\$ 223.7	1.30%
Off-Label Uses of Prescription Drugs to Treat Cancer													
Off-Label Uses of Prescription Drugs to Treat HIV/AIDS													
Optometrists							0.8	\$ 1.00	\$ 1.13	\$ 1.43	\$ 9.4	\$ 10.6	0.06%
Physician Assistants							2.2	\$ 2.71	\$ 3.06	\$ 3.61	\$ 69.9	\$ 79.0	0.46%
Podiatrists							2.2	\$ 0.73	\$ 0.82	\$ 1.10	\$ 18.8	\$ 21.3	0.12%
Postpartum Depression Screenings													
Prescription Eye Drops							2.2	\$ 0.37	\$ 0.41	\$ 0.55	\$ 9.4	\$ 10.6	0.06%
Preventive Care for Children Up to Age Six							2.2	\$14.36	\$16.22	\$16.73	\$ 370.5	\$ 418.5	2.44%
Prosthetic Devices							2.2	\$ 0.27	\$ 0.31	\$ 0.30	\$ 7.0	\$ 8.0	0.05%
Scalp Hair Prostheses for Cancer Patients							2.2	\$ 0.01	\$ 0.01	\$ 0.01	\$ 0.3	\$ 0.3	0.00%

Mandate	Marginal Cost Population (in Millions)	Marginal Cost					RDC Population (in Millions)	Required Direct Cost (RDC)				
		Paid PMPM	Paid PMPM with Admin	Allowed PMPM	Paid\$ (in Millions)	Prem\$ (in Millions)		Paid PMPM	Paid PMPM with Admin	Allowed PMPM	Paid\$ (in Millions)	Prem\$ (in Millions)
Speech, Hearing, and Language Disorders							2.2	\$ 0.89	\$ 1.00	\$ 1.19	\$ 22.9	\$ 25.8
Substance Abuse Treatment Prior Authorization							2.2	\$19.10	\$21.57	\$20.65	\$ 492.8	\$ 556.6
Tobacco Cessation							2.2	\$ 0.19	\$ 0.21	\$ 0.25	\$ 4.8	\$ 5.4

6.0 Discussion and Conclusions

The marginal cost of benefits that carriers report they would not otherwise provide without mandate laws, or that actuarial analysis indicates have a measurable cost, is estimated at \$159 million. [Table 31](#) summarizes these impacts, presenting them as a share of premium, on a PMPM basis, and as total spending in the fully insured market.

While these estimates quantify the direct financial impact, measuring the full cost of mandates goes beyond the scope of this report. The accompanying efficacy reports offer valuable context by highlighting the health and social benefits associated with mandated services and providing insights that complement the financial analysis.

In addition to the direct costs, benefit mandates can also lead to indirect effects that fall outside the scope of this study. Some of these effects may increase overall spending, e.g., additional births associated with fertility treatment coverage, while others may reduce spending, such as avoided hospitalizations resulting from diabetes care.

These estimates highlight the direct financial impact of mandates, while also acknowledging the broader benefits and considerations that extend beyond cost.

Table 31. Summary of Estimated Costs for Massachusetts Mandated Benefits as of 2023 Dollars in Millions^{ccxliii} (000,000s)

MANDATE	MARGINAL CLAIMS ESTIMATE	MARGINAL PREMIUM IMPACT	PERCENT OF PREMIUM
Unduplicated Total All Mandates	\$ 142.73	\$ 158.99	0.93%
Massachusetts State Mandates with Potential Direct Marginal Cost			
Infertility Services	\$ 113.04	\$ 125.43	0.73%
Acute Treatment and Clinical Stabilization Services	\$ 9.98	\$ 11.31	0.07%
Medically Necessary Breast Cancer Screenings and Exams	\$ 5.02	\$ 5.67	0.03%
Annual Mental Health Wellness Examinations	\$ 4.47	\$ 5.05	0.03%
Oral Cancer Therapy	\$ 1.85	\$ 2.10	0.01%
Hearing Aids for Children	\$ 1.85	\$ 2.10	0.01%
Abortion	\$ 1.04	\$ 1.17	0.01%
Telehealth	\$ 0.99	\$ 1.11	0.01%
Contraceptive Services	\$ 0.88	\$ 1.00	0.01%
Low Protein Food Products	\$ 0.78	\$ 0.87	0.01%
Emergency Services Programs	\$ 0.73	\$ 0.82	0.00%
Nonprescription Enteral Formulas	\$ 0.61	\$ 0.68	0.00%
Fertility Preservation Services	\$ 0.52	\$ 0.59	0.00%
Universal Postpartum Home Visiting Services	\$ 0.48	\$ 0.54	0.00%
Cleft Palate and Cleft Lip	\$ 0.32	\$ 0.36	0.00%
ABA Services for Down Syndrome	\$ 0.16	\$ 0.18	0.00%
Mandates Judged to Have Zero or Unmeasurable Marginal Cost			
Abuse-Deterrent Opioids	\$ -	\$ -	0.00%
Autism Spectrum Disorders	\$ -	\$ -	0.00%
Behavioral Health Care	\$ -	\$ -	0.00%
Bone Marrow Transplants for Treatment of Breast Cancer	\$ -	\$ -	0.00%
Cardiac Rehabilitation	\$ -	\$ -	0.00%

^{ccxliii} Table 38 excludes 1) Midwifery Care and Out-of-Hospital Birth Options, 2) PANDAS/PANS, 3) Pharmaceutical Access, Costs, and Transparency, and 4) COVID Tests, Vaccines and Treatment.

MANDATE	MARGINAL CLAIMS ESTIMATE	MARGINAL PREMIUM IMPACT	PERCENT OF PREMIUM
Certified Nurse Midwives	\$ -	\$ -	0.00%
Certified Registered Nurse Anesthetists	\$ -	\$ -	0.00%
Chiropractic Services	\$ -	\$ -	0.00%
Chiropractors	\$ -	\$ -	0.00%
Clinical Trials (to Treat Cancer)	\$ -	\$ -	0.00%
Collaborative Care	\$ -	\$ -	0.00%
Cytologic Screening	\$ -	\$ -	0.00%
Dentists	\$ -	\$ -	0.00%
Diabetes-Related Services and Supplies	\$ -	\$ -	0.00%
Early Intervention Services	\$ -	\$ -	0.00%
Hearing Screening for Newborns	\$ -	\$ -	0.00%
HIV-Associated Lipodystrophy Treatment	\$ -	\$ -	0.00%
Home Health Care	\$ -	\$ -	0.00%
HRT	\$ -	\$ -	0.00%
Hospice Care	\$ -	\$ -	0.00%
Human Donor Milk (DHM)	\$ -	\$ -	0.00%
HLA Testing	\$ -	\$ -	0.00%
Hypodermic Syringes or Needles	\$ -	\$ -	0.00%
Lead Poisoning Screening	\$ -	\$ -	0.00%
Mammography	\$ -	\$ -	0.00%
Maternity Health Care (Including Minimum Maternity Stay)	\$ -	\$ -	0.00%
Mental Health Acute Treatment, CBAT, ICBAT	\$ -	\$ -	0.00%
Nurse Practitioners	\$ -	\$ -	0.00%
Off-Label Uses of Prescription Drugs to Treat Cancer	\$ -	\$ -	0.00%
Off-Label Uses of Prescription Drugs to Treat HIV/AIDS	\$ -	\$ -	0.00%
Optometrists	\$ -	\$ -	0.00%
Physician Assistants	\$ -	\$ -	0.00%
Podiatrists	\$ -	\$ -	0.00%

MANDATE	MARGINAL CLAIMS ESTIMATE		MARGINAL PREMIUM IMPACT		PERCENT OF PREMIUM
Postpartum Depression Screening	\$	-	\$	-	0.00%
Prescription Eye Drops	\$	-	\$	-	0.00%
Preventive Care for Children Up to Age 6	\$	-	\$	-	0.00%
Prosthetic Devices	\$	-	\$	-	0.00%
Scalp Hair Protheses for Cancer Patients	\$	-	\$	-	0.00%
Speech, Hearing, and Language Disorders	\$	-	\$	-	0.00%
Substance Abuse Treatment Prior Authorization	\$	-	\$	-	0.00%
Tobacco Cessation	\$	-	\$	-	0.00%

This report was prepared by BerryDunn's Health Analytics Practice Group.

Appendix A: Summary of Health Insurance Benefit Mandates

Table 32. Summary of Health Insurance Benefit Mandates^{ccxlii}

MANDATE	STATUTE	SUMMARY	IN 2021 REPORT
ABA Services for Down Syndrome	Chapter 388 of the Acts of 2024. Statutory sections being amended: M.G.L. c. 32A § 25A; c. 118E § 10H1/2; c. 175 § 47AA1/2; c. 176A § 8DD1/2; c. 176B §. 4DD1/2; c. 176G § 4V1/2	Mandates coverage for ST, OT, PT, and ABA for individuals with a Down syndrome diagnosis.	No
Abortion	M.G.L. c. 32A § 17C; c. 175 § 47F; c. 176A § 8H; c. 176B §. 4H; c. 176G § 4I	Mandates coverage of abortion, as defined in section 12K of Chapter 112, abortion-related care, prenatal care, childbirth, and postpartum care to the same extent as provided for medical conditions not related to pregnancy. At the request of the employer, church or church-affiliated organizations may be exempt from providing this coverage.	No
Abuse-Deterrent Opioids	M.G.L. c. 175 § 47EE; c. 176A § 8GG; c. 176B § 4GG; c. 176G § 4Y; c. 32A § 17L	Mandates coverage for ADO drug products listed on the formulary provided by the Massachusetts Drug Formulary Commission 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. For carriers to achieve compliance with this section, there may not be an increase in patient cost sharing.	Yes
Acute Treatment and Clinical Stabilization Services	M.G.L. c. 175 § 47GG; c. 176A § 8II; c. 176B § 4II; c. 176G § 4AA; c. 32A § 17N	Mandates coverage for medically necessary ATS and medically necessary CSS for up to a total of 14 days without the requirement to obtain preauthorization prior to obtaining these services, provided that the facility provides the carrier with both notification of admission and the initial treatment plan within 48 hours of admission; that the utilization review procedures may be initiated on Day 7; and any policy, contract, agreement, plan, or certificate of insurance issued, delivered, or renewed within the Commonwealth provides coverage for a SUD evaluation ordered pursuant to section 51	Yes

^{ccxlii} Table 39 excludes Midwifery Care and Out-of-Hospital Birth Options, and COVID Tests, Vaccines and Treatment.

MANDATE	STATUTE	SUMMARY	IN 2021 REPORT
		½ of chapter 11 without the requirement to obtain prior authorization. The treating clinician in consultation with the patient will determine medical necessity and provide documentation in the patient's medical record.	
Annual Mental Health Wellness Examinations	M.G.L. c. 32A §32; c. 175 § 47TT; c. 176A §8UU; c. 176B §4UU; c. 176G §4MM	Mandates coverage for an annual mental health wellness examination without cost sharing performed by a licensed mental health professional or PCP. This examination may be provided as part of an annual preventive visit with a PCP.	No
Autism Spectrum Disorders	M.G.L. c. 175 § 47AA; c. 176A § 8DD; c. 176B § 4DD; c. 176G § 4V; c. 32A § 25	Mandates coverage for the diagnosis and treatment of ASDs, to the same extent as coverage for physical conditions when provided or ordered by a licensed physician or licensed psychologist who determined the care to be medically necessary. The services included in the treatment of ASDs under this mandate include habilitative or rehabilitative care, pharmacy care, psychiatric care, psychological care, and therapeutic care.	Yes
Behavioral Health Care	M.G.L. c. 175 § 47B; c. 176A § 8A; c. 176B § 4A; c. 176G § 4M; c. 32A § 22	Mandates coverage of the diagnosis and treatment of specified biologically based mental disorders including schizophrenia, bipolar disorder, OCD, 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. Additionally, this mandate requires the coverage of the diagnosis and treatment of rape-related mental or emotional disorders, as well as the diagnosis and treatment of non-biologically based mental, behavioral, or emotional disorders for children and adolescents under the age of 19.	Yes
Bone Marrow Transplants for Treatment of Breast Cancer	M.G.L. c. 175 § 47R; c. 176A § 8O; c. 176B § 4O; c. 176G § 4F; c. 32A § 17D	Mandates coverage for BMTs for individuals diagnosed with breast cancer that has progressed to metastatic disease, provided they meet criteria provided by DPH.	Yes
Cardiac Rehabilitation	M.G.L. c. 175 § 47D; c. 176A § 8G; c. 176B § 4F; c. 176G § 4	Mandates the coverage of cardiac rehabilitation, which is defined as multidisciplinary, medically necessary treatment of individuals with documented cardiovascular disease.	Yes

MANDATE	STATUTE	SUMMARY	IN 2021 REPORT
Certified Nurse Midwives	M.G.L. c. 175 § 47E; c. 176B § 4G; also c. 176B § 7	Mandates that services provided by CNMs are reimbursed if the same services provided by any other practitioner would be reimbursed, provided the services are being performed within the lawful scope of practice for CNMs. Additionally, c. 176B § 7 provides that no MSC "...discriminate in any way against participating nurse midwives in the furnishing of midwifery service to its subscribers and covered dependents."	Yes
Certified Registered Nurse Anesthetists	M.G.L. c. 175 § 47Q; c. 176A § 8S; c. 176B § 4T; c. 176G § 4	Mandates that services provided by CRNAs are reimbursed if the same services provided by any other practitioner would be reimbursed, provided the services are being performed within the lawful scope of practice for CRNAs.	Yes
Chiropractic Services	M.G.L. c. 176B § 4L	Mandates the coverage of chiropractic services.	Yes
Chiropractors	M.G.L. c. 175 § 108D; c. 176B § 7	Mandates the coverage of chiropractic services performed by a physician or chiropractor.	Yes
Cleft Palate and Cleft Lip	M.G.L. c. 175 § 47BB; c. 176A § 8EE; c. 176B § 4EE; c. 176G § 4W; c. 32A § 17J	Mandates coverage for the cost of treating cleft lip and cleft palate for children under 18, including medical, dental, oral and facial surgery, surgical management and follow-up care by oral and plastic surgeons, orthodontic treatment and management, preventive and restorative dentistry to ensure good health and adequate dental structures for orthodontic treatment or prosthetic management therapy, ST, audiology, and nutrition services.	Yes
Clinical Trials (to Treat Cancer)	M.G.L. c. 175 § 110L; c. 176A § 8X; c. 176B § 4X; c. 176G § 4P	Mandates coverage of 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
Collaborative Care	M.G.L. c. 175 § 47QQ; c. 176A § 8RR; c. 176B § 4RR; c. 176G § 4JJ; c. 32A § 22A	Mandates coverage of mental health or SUD treatment services that are delivered through the psychiatric CoCM.	No
Contraceptive Services/Contrac eptive Coverage – ACCESS	M.G.L. c. 32A § 28; c. 175 § 47W; c. 176A § 8W; c. 176B § 4W; c. 176G § 4O	Mandates coverage for outpatient contraceptive services (consultations, exams, procedures, etc.) and prescription contraceptive drugs and devices to the same extent as other	Some provisions were not in the prior report.

MANDATE	STATUTE	SUMMARY	IN 2021 REPORT
		outpatient services and other prescription drugs and devices not related to contraception.	
Cytologic Screening	M.G.L. c. 175 §§ 47G and 110(L); c. 176A § 8J; 176B § 4I; c. 176G § 4	Mandates coverage for cytologic screening (Pap smear) annually for women 18 years and older.	Yes
Dentists	M.G.L. c. 175 § 108B; c. 176B § 4	Mandates that dentists be considered physicians for purposes of reimbursement for the services they are licensed to perform.	Yes
Diabetes-Related Services and Supplies	M.G.L. c. 175 § 47N; c. 176A § 8P; c. 176B § 4S; c. 176G § 4H; c. 32A § 17G	Mandates coverage for medically necessary items for the treatment of diabetes that fall within a category of benefits and services for which coverage is otherwise afforded and that have been prescribed by a health care professional, which includes (but is not limited to) blood glucose monitors, monitoring strips, lancets, insulin, syringes, lab tests, urine and lipid profiles, and special shoes.	Yes
Early Intervention Services	M.G.L. c. 175 § 47C; c. 176A § 8B; c. 176B § 4C; c. 176G § 4	Mandates coverage for early intervention services from birth to age three for children with or at risk for specific developmental delays including chromosomal abnormalities, neurological conditions, metabolic disorders, visual impairments, permanent hearing loss, and delayed cognitive, physical, communicative, social, or emotional development.	Yes
Emergency Services Programs	M.G.L. c. 32A § 31; c. 175 § 47RR; c. 176A § 8TT; c. 176B § 4TT; c. 176G § 4LL	Mandates coverage on a nondiscriminatory basis for all medically necessary ESPs. These programs, managed under contract with the Massachusetts Behavioral Health Partnership, provide community-based emergency psychiatric services, including 24/7 mobile crisis intervention for youth and adults, emergency service provider community-based locations, and adult community crisis stabilization services.	No
Fertility Preservation Services	Chapter 140 of the Acts of 2024. Statutory sections being amended: M.G.L. c. 32A § 17T; c. 175 § 47VV; c. 176A § 8WW; c. 176B § 4WW; c. 176G § 4OO	Mandates coverage for fertility preservation services, including, but not limited to, procurement, cryopreservation, and storage of gametes, embryos, or other reproductive tissue, for individuals who have a diagnosed medical or genetic condition that may directly or indirectly cause impairment of fertility by affecting reproductive organs or processes.	No

MANDATE	STATUTE	SUMMARY	IN 2021 REPORT
Hearing Aids for Children	M.G.L. c. 175 § 47X; c. 176A § 8Y; c. 176B § 4EE; c. 176G § 4N; c. 32A § 23	Mandates coverage for the cost of one hearing aid per hearing-impaired ear up to \$2,000 for each hearing aid every 36 months regardless of etiology, for any child 21 years of age or younger. 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	M.G.L. c. 175 § 47C; c. 111 § 67F; c. 176A § 8B; c. 176B § 4C; c. 176G §§ 4, 4K; c. 32A § 17F	Mandates coverage for newborn hearing screening tests before the infant is discharged from the hospital or birthing center.	Yes
HIV-Associated Lipodystrophy Treatment	M.G.L. c. 32A § 17O, c. 118 § 10J, 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.	Yes
Home Health Care	M.G.L. c. 175 § 110(K); c. 176A § 8I; c. 176G § 4C	Mandates coverage for home care services, which are defined as services provided by a home health agency in a patient's residence when deemed medically necessary.	Yes
Hormone Replacement Therapy (HRT)	M.G.L. c. 175 § 47W; c. 176A § 8W; c. 176B § 4W; c. 176G § 4O	Mandates that policies cover outpatient services or outpatient prescription drugs or devices to provide hormone replacement therapy for peri- and post-menopausal women.	Yes
Hospice Care	M.G.L. 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 Donor Milk (DHM)	Chapter 186 of the Acts of 2024. Statutory sections being amended: M.G.L. c. 32A § 17V; c. 175 § 47XX; c. 176A § 8YY; c. 176B § 4YY; c. 176G § 4QQ	Mandates the coverage of medically necessary pasteurized DHM and DHM-derived products, provided the milk comes from a certified human milk bank, a licensed medical practitioner issues a written order, and the infant is under six months old, undergoing inpatient treatment for conditions that place them at high risk for NEC, and unable to receive maternal breast milk due to medical reasons.	No
Human Leukocyte Antigen Testing	M.G.L. c. 175 § 47V; c. 176A § 8V; c. 176B § 4V;	Mandates coverage for the cost of HLA testing or histocompatibility locus antigen testing necessary to establish BMT donor suitability.	Yes

MANDATE	STATUTE	SUMMARY	IN 2021 REPORT
	c. 176G § 4Q; c. 32A § 17H		
Hypodermic Syringes or Needles	M.G.L. c. 175 § 47Y; c. 176A § 8CC; c. 176B § 4CC; c. 176G § 4U	Mandates coverage for medically necessary hypodermic syringes or needles.	Yes
Infertility Treatment	M.G.L. c. 175 § 47H; c. 176A § 8K; c. 176B § 4J; c. 176G § 4	Mandates that policies providing pregnancy-related benefits to provide, to the same extent benefits are provided for other pregnancy-related procedures, coverage for medically necessary expenses for the diagnosis and treatment of infertility.	Yes
Lead Poisoning Screening	M.G.L. c. 175 § 47C; c. 176A § 8B; c. 176B § 4C; c. 176G § 4	Mandates coverage for screening for lead poisoning for all children under age six and others deemed at risk.	Yes
Low Protein Food Products	M.G.L. c. 175 § 47I; c. 176A § 8L; c. 176B § 4K; c. 176G § 4D; c. 32A § 17A	Mandates coverage for low protein food products for which a physician has issued a written order that are medically necessary for the treatment of inherited diseases of amino acids and organic acids.	Yes
Mammography	M.G.L. c. 175 §§ 47G and 110(L); c. 176A § 8J; 176B § 4I; c. 176G § 4	Mandates coverage for one "baseline" mammogram between ages 35 and 40 and annual mammograms for individuals 40 years of age and older.	Yes
Maternity Health Care (Including Minimum Maternity Stay)	M.G.L. c. 175 § 47F; c. 176A § 8H; c. 176B § 4H; c. 176G §§ 4, 4I; c. 32A § 17C	Mandates coverage for prenatal care, childbirth, and postpartum care to the same extent as medical conditions not related to pregnancy with required coverage for a minimum 48 hours of inpatient care following a vaginal delivery and a minimum of 96 hours of inpatient care following a caesarean section.	Yes
Medically Necessary Breast Screenings and Exams for Equity and Early Detection	Chapter 231 of the Acts of 2024. Statutory sections being amended: M.G.L. c. 175 § 47ZZ; c. 32A § 34; c. 118E § 10W; c. 176A § 8AAA; c. 176B § 4AAA; c. 176G § 4SS(this does not seem correct, there is no section 4RR)	Mandates carriers that provide coverage for mammograms (any non-legacy plan) also provide coverage for diagnostic examinations for breast cancer, DBT screening, and medically necessary and appropriate screening with breast MRI or screening breast ultrasound without cost sharing.	No
Mental Health Acute Treatment, Community-Based Acute Treatment, and	M.G.L. c. 32A § 17S; c. 175 § 47SS; c. 176A § 8SS; c. 176B § 4SS; c. 176G § 4KK	Mandates coverage for medically necessary mental health acute treatment, community-based acute treatment, and intensive community-based acute treatment, without requiring preauthorization. Requires the	No

MANDATE	STATUTE	SUMMARY	IN 2021 REPORT
Intensive Community-Based Treatment		provider to provide an initial treatment plan within 72 hours of admission.	
Nonprescription Enteral Formulas	M.G.L. c. 175 § 47I; c. 176A § 8L; c. 176B § 4K; c. 176G § 4D; c. 32A § 17A	Mandates coverage for medically necessary nonprescription enteral formulas for home use to treat malabsorption caused by Crohn's disease, ulcerative colitis, gastroesophageal reflux, GI motility, chronic intestinal pseudo-obstruction, and inherited diseases of amino acids and organic acids.	Yes
Nurse Practitioners	M.G.L. c. 175 § 47Q; c. 176A § 8S; c. 176B § 4T; c. 176G § 4; c. 176R	Mandates reimbursement of services provided by NPs when the same services would be 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
Off-Label Uses of Prescription Drugs to Treat Cancer	M.G.L. c. 175 §§ 47K, 47L; c. 176A § 8N; c. 176B § 4N; c. 176G § 4E	Mandates 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 requires carriers to provide coverage of prescription drugs prescribed off-label consistent with the panel's recommendations.	Yes
Off-Label Uses of Prescription Drugs to Treat HIV/AIDS	M.G.L. c. 175 §§ 47O, 47P; c. 176A § 8Q; c. 176B § 4P; c. 176G § 4G	Mandates the Commissioner of Insurance to establish a panel of experts to review off-label uses of prescription drugs for the treatment of HIV/AIDS for medical appropriateness and requires carriers to provide coverage for prescription drugs for off-label use consistent with the panel's recommendations.	Yes
Optometrists	M.G.L. c. 175 § 108(8)(D); c. 175 § 110(F); 176B § 4	Mandates coverage for optometry services when performed by physicians or optometrists and when within the lawful scope of practice of optometrists.	Yes
Oral Cancer Therapy	M.G.L. c. 175 § 47DD; c. 176A § 8FF; c. 176B § 4FF; c. 176G § 4X; c. 32A § 17K	Mandates coverage for orally administered cancer chemotherapy treatment medications used to kill or slow the growth of cancerous cells on a basis not less favorable than other routes of administration for cancer medications.	Yes
PANDAS/PANS Treatment	M.G.L. c. 175 § 47NN; c. 176A § 8OO; c. 176B § 4OO; c. 176G § 4GG; c. 32A § 17R	Mandates coverage for treatment for PANDAS/PANS that includes, but is not limited to, the use of IVIG therapy.	No

MANDATE	STATUTE	SUMMARY	IN 2021 REPORT
Pharmaceutical Access, Costs, and Transparency	Chapter 342 of the Acts of 2024	Mandates carriers to choose one generic and one brand name drug to treat diabetes, asthma, and the two most prevalent heart conditions among its enrollees. Generic drugs must not be subject to cost sharing. Brand name drugs and insulin must not be subject to deductible or co-insurance and copays shall not exceed \$25 per 30-day supply.	No
Physician Assistants	M.G.L. c. 176S	Mandates reimbursement for services provided by PAs when services are reimbursed when performed by any other practitioner and are within the lawful scope of practice of PAs. Additionally, PAs may be designated as a PCP if the carrier requires designation of one.	Yes
Podiatrists	M.G.L. c. 175 § 110(I); c. 176B § 4; c. 176G § 1	Mandates reimbursement for services provided by podiatrists when services are reimbursed when performed by physicians or podiatrists and are within the lawful scope of practice of podiatry.	Yes
Postpartum Depression Screenings	Chapter 186 of the Acts of 2024. Statutory sections being amended: M.G.L. c. 32A § 17U; c. 175 § 47WW; c. 176A § 8XX; c. 176B § 4XX; c. 176G § 4PP	Mandates coverage for screenings for PPD and MDD.	No
Prescription Eye Drops	M.G.L. c.175 §47PP, c.176A §8QQ, c.176B §4QQ, c.176G §4II	Mandates coverage for refills of PEDs in accordance with the Medicare Part D guidelines on early refills of topical ophthalmic products when the prescribing health care practitioner indicates on the original prescription that additional quantities of the PEDs are needed; the refill requested does not exceed the number of additional quantities indicated on the original prescription; and the PEDs prescribed are covered under the policy or contract of the insured.	Yes
Preventive Care for Children Up to Age 6	M.G.L. 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	M.G.L. c. 175 § 47Z; c. 176A § 8AA; c. 176B §	Mandates coverage for prosthetic devices and repairs under the same terms and conditions	Yes

MANDATE	STATUTE	SUMMARY	IN 2021 REPORT
	4AA; c. 176G § 4S; c. 32A § 17I	that apply to other durable medical equipment. Additionally, the mandate places restrictions on the use of annual or lifetime limits for prosthetic devices.	
Scalp Hair Prostheses for Cancer Patients	M.G.L. c. 175 § 47T; c. 176A § 8T; c. 176B § 4R; c. 176G § 4J; c. 32A § 17E	Mandates coverage for scalp hair prostheses, if coverage is provided for any other prosthesis, worn for hair loss suffered as a result of the treatment of cancer or leukemia, in an amount not to exceed \$350 per year, subject to a written statement from the treating physician that the scalp hair prosthesis is medically necessary.	Yes
Speech, Hearing, and Language Disorders	M.G.L. c. 175 § 47X; c. 176A § 8Y; c. 176B § 4Y; c. 176G § 4N; c. 32A § 23	Mandates coverage for the medically necessary diagnosis and treatment of speech, hearing, and language disorders by individuals licensed as SLPs or audiologists.	Yes
Substance Abuse Treatment Prior Authorization	M.G.L. c. 175 § 47FF; c. 176A § 8HH; c. 176B § 4HH; c. 176G § 4Z; c. 32A § 17M	Mandates that policies may not require a member to obtain a preauthorization for substance abuse treatment if the provider is certified or licensed by the DPH.	Yes
Telehealth	M.G.L. c. 175 § 47MM; c. 176A § 38; 176B § 25; 176G § 33; c. 32A § 30	Mandates coverage for behavioral health services delivered via telehealth. For the purposes of this mandate, "behavioral health services" encompass care for mental health, developmental, or substance use disorders. "Telehealth" includes the use of synchronous or asynchronous audio, video, electronic media, and other telecommunications for health services, such as interactive audio-video, remote monitoring, audio-only phone, and online adaptive interviews. Telehealth services are required to be covered if these services are covered in person and deemed appropriate for telehealth.	No
Tobacco Cessation	M.G.L. c. 175 § 47LL ; c. 176A § 8NN ; c. 176B § 4NN ; c. 176G § 4FF	Mandates coverage for tobacco cessation counseling and products. Coverage of tobacco cessation products under this mandate must not require cost-sharing and includes all generic FDA-approved tobacco cessation products that are prescribed by a health care provider. Carriers must ensure individuals have access to at least one tobacco cessation product without the requirement to obtain prior authorization. Under this mandate, carriers may apply reasonable managed care techniques to determine the frequency, method, treatment, and/or setting for the tobacco cessation product or service.	No

MANDATE	STATUTE	SUMMARY	IN 2021 REPORT
Universal Postpartum Home Visiting Services	Chapter 186 of the Acts of 2024. Statutory sections being amended: M.G.L. c. 32A § 17W; c. 175 § 47YY; c. 176A § 8ZZ; c. 176B § 4ZZ; c. 176G § 4RR	Requires coverage for universal postpartum home visiting services without cost sharing, unless required by the Internal Revenue Code to maintain tax-exempt status for the applicable plan.	No

Appendix B: Estimation of Population Subsets

Membership potentially affected by the proposed mandated change includes Commonwealth residents with fully insured, employer-sponsored health insurance (ESI) issued by a Commonwealth-licensed company (including through the GIC); nonresidents with fully insured ESI issued in the Commonwealth; Commonwealth residents with individual (direct) health insurance coverage; and lives covered by GIC self-insured coverage. Other populations within the self-insured commercial sector are excluded from the state coverage mandate due to federal ERISA protections of self-insured plans. The 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. 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.

CHIA-reported enrollment data formed the basis for membership projections. CHIA publishes a biannual enrollment trends report and supporting databook¹⁷³³, which provide enrollment data for Commonwealth residents by insurance carrier for most carriers, excluding some small carriers. CHIA uses supplemental information beyond the data in the Massachusetts APCD to develop its enrollment trends report and adjust the resident totals from the Massachusetts APCD. For the base year 2020 in the membership projection, the 2020 Massachusetts APCD and published 2020 membership reports available from the Massachusetts DOI^{1734,1735} were used to develop a factor to adjust the CHIA enrollment data for the few small carriers not present in the enrollment report. The adjustment was trended forward to 2024 and applied to CHIA enrollment data.

In 2021, commercial, fully insured membership was 5.6% less than in 2019, with a shift to both uninsured and MassHealth coverage. As part of the public health emergency (PHE), members were not disenrolled from MassHealth coverage even when they no longer passed eligibility criteria. Shortly before the PHE ended, redetermination efforts began in April 2023 and were anticipated to occur over a 12-month period. Many of the individuals subject to redetermination will no longer be eligible for MassHealth coverage. It is anticipated that a portion of individuals losing coverage will be eligible for coverage in individual ACA plans and ESI. MassHealth's monthly caseload reports¹⁷³⁶ indicated that coverage redeterminations were largely completed by June 2024. The Massachusetts Health Connector's monthly reports¹⁷³⁷ showed that membership growth stabilized through December 2024, likely due to disenrolled MassHealth members enrolling in individual plans. CHIA's quarterly enrollment trends report¹⁷³⁸ showed stable total membership in private commercial group insurance, with a shift from fully insured to self-insured plans. Based on this information, BerryDunn estimated the final 2024 membership impacted by the proposed mandate.

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.¹⁷³⁹ Membership was projected from 2025 to 2050, with growth rate estimates by age and gender derived from a Massachusetts population projection from UMass Donahue Institute.¹⁷⁴⁰

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

Appendix C: List of Study Acronyms

AA	Alcoholics Anonymous
AAFP	American Academy of Family Physicians
AAO	American Academy of Ophthalmology
AAP	American Academy of Pediatrics
AAPA	American Academy of Physician Associates
ABA	Applied Behavioral Analysis
ACA	Affordable Care Act
ACCESS	Advancing Contraceptive Coverage and Economic Security in Our State
ACEP	American College of Emergency Physicians
ACCF	American College of Cardiology Foundation
ACF	Administration for Children and Families
ACIP	Advisory Committee on Immunization Practices
ACME	Accreditation Commission for Midwifery Education
ACNM	American College of Nurse-Midwives
ACOG	American College of Obstetricians and Gynecologists
ACR	American College of Radiology
ACS	American Cancer Society
ADDM	Autism and Developmental Disabilities Monitoring
ADL	Activity of Daily Living
ADO	Abuse-Deterrent Opioid
AGS	American Glaucoma Society
AHA	American Heart Association
AHFS-DI	American Hospital Formulary Service-Drug Information
AHIP	America's Health Insurance Plans
AHRQ	Agency for Healthcare Research and Quality
AIDS	Acquired Immunodeficiency Syndrome
ALOS	Average Length of Stay
AMA	American Medical Association
AMI	Any Mental Illness

APA	American Psychiatric Association
APMLE	American Podiatric Medical Licensing Examination
APRN	Advanced Practice Registered Nurse
ART	Assisted Reproductive Technology
ARV	Antiretroviral
ASAM	American Society of Addiction Medicine
ASBrS	American Society of Breast Surgeons
ASC	Ambulatory Surgical Center
ASDs	Autism Spectrum Disorders
ATS	Acute Treatment Services
AVT	Auditory-Verbal Therapy
BCBSMA	Blue Cross/Blue Shield of Massachusetts
BEST	Boston Emergency Services Team
BHCM	Behavioral Health Care Manager
BKD	Beta-Ketothiolase Deficiency
BLL	Blood Lead Level
BLS	Bureau of Labor Statistics
BMI	Body Mass Index
BMT	Bone Marrow Transplant
BSAS	Bureau of Substance Addiction Services
BSN	Bachelor of Science in Nursing
CAH	Critical Access Hospital
CAM	Complementary and Alternative Medicine
CANS	Central Auditory Nervous System
CAPD	Central Auditory Processing Disorder
CBAT	Community-Based Acute Treatment
CBHC	Community Behavioral Health Center
CBT	Cognitive Behavioral Therapy
CBTs	Cord Blood Transplants
CCS	Community Crisis Stabilization

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
CLI	Charlotte Lozier Institute
CM	Certified Midwife
CME	Continuing Medical Education
CMS	Centers for Medicare & Medicaid Services
CMV	Cytomegalovirus
CNM	Certified Nurse-Midwife
COA	Council on Accreditation of Nurse Anesthesia Educational Programs
CoCM	Psychiatric Collaborative Care Model
COH	Controlled Ovarian Hyperstimulation
COPD	Chronic Obstructive Pulmonary Disease
CPM	Certified Professional Midwife
CPT®	Current Procedural Terminology
CR	Collaborative Reanalysis
CR	Cardiac Rehabilitation
CRNA	Certified Registered Nurse Anesthetist
CSS	Clinical Stabilization Services
CVD	Cardiovascular Disease
CY	Calendar Year
DBT	Digital Breast Tomosynthesis
DC	Doctor of Chiropractic
D.C.	District of Columbia
D&E	Dilation and Evacuation
DEA	Drug Enforcement Agency
DES	Diethylstilbestrol
DFC	Drug Formulary Commission

DHH	Deaf or Hard of Hearing
DHM	Donor Human Milk
DIR	Developmental, Individual Differences, Relationship-Based Approach
DKE	Diabetic Ketoacidosis
DMEPOS	Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
DO	Doctor of Osteopathy
DOI	Massachusetts Division of Insurance
DOR	Diminished Ovarian Reserve
DPA	Diagnostic Pharmaceutical Agents
DPH	Department of Public Health
DPM	Doctor of Podiatric Medicine
DSM	Diagnostic and Statistical Manual of Mental Disorders
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, 5 th edition
DSM-V	Diagnostic and Statistical Manual of Mental Disorders, 5 th edition
DTT	Discrete Trial Training
DTS	Department of Testing Services
DVT	Deep Vein Thrombosis
EC	Emergency Contraceptive
ED	Emergency Department
EHDI	Early Hearing Detection and Intervention
EI	Early Intervention
EIBI	Early Intensive Behavioral Intervention
EHB	Essential Health Benefit
EHE	Ending the HIV Epidemic in the U.S.
EM	Erythema Migrans
EMS	Emergency Medical Services
EN	Enteral Nutrition
EOHHS	Massachusetts Executive Office of Health and Human Services
EPDS	Edinburgh Postnatal Depression Screen
ER	Extended Release

ERISA	Employee Retirement Income Security Act
ESDM	Early Start Denver Model
ESP	Emergency Services Program
FDA	United States Food & Drug Administration
FDAAA	FDA Amendments Act
FDAMA	FDA Modernization Act
FEHB	Federal Employees Health Benefit Plan
FHA	Functional Hypothalamic Amenorrhea
FI	Fully Insured
FPA	Full Practice Authority
GAO	United States General Accounting Office
GAS	Group A Strep
GDM	Gestational Diabetes Mellitus
GI	Gastrointestinal
GIC	Massachusetts Group Insurance Commission
HDC-ABMT	High-Dose Chemotherapy Plus Autologous Bone Marrow Transplant
HDHP	High Deductible Health Plan
HEN	Home Enteral Nutrition
HIOP	High-Intensity Outpatient
HIV	Human Immunodeficiency Virus
HHA	Home Health Agency
HHC	Home Health Care
HHS	United States Department of Health and Human Services
HLA	Human Leukocyte Antigen
HMO	Health Maintenance Organization
HPC	Health Policy Commission
HPV	Human Papillomavirus
HRSA	Health Resources and Services Administration
HRT	Hormone Replacement Therapy
HSCTs	Hematopoietic Stem Cell Transplants

HT	Hormone Therapy
ICBAT	Intensive Community-Based Acute Treatment
ICSI	Intracytoplasmic Sperm Injection
IDEA	Individuals with Disabilities Education Act
IDSA	Infectious Diseases Society of America
ILADS	International Lyme and Associated Diseases Society
INBDE	Integrated National Board Dental Examination
IOP	Intensive Outpatient
IPV	Intimate Partner Violence
IR	Immediate Release
IUD	Intrauterine Device
IUI	Intrauterine Insemination
IV	Intravenous
IVF	In Vitro Fertilization
IVIG	Intravenous Immunoglobulin
JCIH	Joint Commission on Infant Hearing
JCNDE	Joint Commission on National Dental Examinations
KFF	Kaiser Family Foundation
LARC	Long-Acting Reversible Contraception
LBW	Low Birth Weight
LDHIV	HIV-Associated Lipodystrophy
LEA	Local Education Agency
LOS	Length of Stay
LPF	Low Protein Food
MAHP	Massachusetts Association of Health Plans
MAT	Medication-Assisted Treatment
MCHB	Maternal and Child Health Bureau
MCI	Mobile Crisis Intervention
MD	Medical Doctor
MDD	Major Depressive Disorder

MDPH	Massachusetts Department of Public Health
M.G.L.	Massachusetts General Law
MHAT	Mental Health Acute Treatment
MHPAEA	Mental Health Parity and Addiction Equity Act of 2008
MIECHV	Maternal, Infant, and Early Childhood Home Visiting Program
MRI	Magnetic Resonance Imaging
MWS	Million Women Study
NA	Narcotics Anonymous
NADO	Non-Abuse Deterrent Drug
NBEO	National Board of Examiners in Optometry
NCCIH	National Center for Complementary and Integrative Health
NCCN	National Comprehensive Cancer Network
NCSBN	National Council of State Boards of Nursing
NDC	National Drug Code
NEC	Necrotizing Enterocolitis
NFO	Non-Fatal Opioid Overdose
NICU	Neonatal Intensive Care Unit
NIDA	National Institute of Drug Abuse
NIH	National Institutes of Health
NMDP	National Marrow Donor Program
NMPHA	Newborns' and Mothers' Health Protection Act of 1996
NORC	National Opinion Research Center
NP	Nurse Practitioner
NPDD	Nose-Pivoted Drop Delivery Device
NPI	National Provider Identifier
NPPES	National Plan and Provider Enumeration System
NRTI	Nucleoside Reverse Transcriptase Inhibitor
NSDUH	National Survey on Drug Use and Health
N-SSATS	National Survey of Substance Abuse Treatment Services
NQTL	Nonquantitative Treatment Limitation

OD	Doctor of Optometry
OECD	Organizations for Economic Co-operation and Development
ORP	Ordering, Referring, and Prescribing
OT	Occupational Therapy
OD	Opioid Use Disorder
PA	Physician Assistant
PANCE	PA National Certifying Exam
PANS	Pediatric Acute-Onset Neuropsychiatric Syndrome
PANDAS	Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections
PAM	Pain Assessment and Management
PBM	Pharmacy Benefit Manager
PCOS	Polycystic Ovary Syndrome
PCP	Primary Care Provider
PED	Prescription Eye Drop
Phe	Phenylalanine
PHQ-9	Patient Health Questionnaire-9
PI	Protease Inhibitor
PKU	Phenylketonuria
PLDS	Post-Lyme Disease Syndrome
PMPM	Per Member Per Month
PND	Perinatal Depression
POI	Primary Ovarian Insufficiency
PPD	Postpartum Depression
PRAMS	Pregnancy Risk Assessment Monitoring System
PrEP	Pre-Exposure Prophylaxis
PRT	Pivotal Response Training
PT	Physical Therapy
PTLDS	Post-Treatment Lyme Disease Syndrome
PTSD	Post-Traumatic Stress Disorder
RDC	Required Direct Cost

RN	Registered Nurse
RWD	Real-World Data
SAMHSA	Substance Abuse and Mental Health Services Administration
SBI	Society of Breast Imaging
SDOH	Social Determinants of Health
SEER	Surveillance, Epidemiology, and End Results
SI	Self-Insured
SLP	Speech-Language Pathologist
SMI	Serious Mental Illness
SMM	Severe Maternal Morbidity
SNF	Skilled Nursing Facility
SNRIs	Serotonin/Norepinephrine Reuptake Inhibitors
SSRIs	Selective Serotonin Reuptake Inhibitors
ST	Speech Therapy
SUD	Substance Use Disorder
TEACCH	Treatment and Education of Autistic and Related Communication Handicapped Children
TMOD	Treatment and Management of Ocular Disease
TPA	Therapeutic Pharmaceutical Agents
TPE	Therapeutic Plasma Exchange
TSS	Transitional Support Services
USPSTF	United States Preventive Services Task Force
VBI	Verbal Behavior Intervention
VLBW	Very Low Birth Weight
WHI	Women's Health Initiative
WHI Study	WHI Clinical Trial and Observation Study
WHO	World Health Organization
5-FU	5-fluorouraci

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