MANDATED BENEFIT REVIEW OF H.B. 2338 AND S.B. 1471

SUBMITTED TO THE 192ND GENERAL COURT:

AN ACT RELATIVE TO NEWBORN SCREENING FOR CONGENITAL CYTOMEGALOVIRUS

MARCH 2023

Prepared for Massachusetts Center for Health Information and Analysis

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Mandated Benefit Review of House Bill (H.B.) 2338 and Senate Bill (S.B.) 1471 Submitted to the 192nd General Court

An Act Relative to Newborn Screening for Congenital Cytomegalovirus

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1.1 History of the Bill

The Massachusetts Legislature's Committee on Health Care Financing referred 192nd General Court House Bill (H.B.) 2338 and Senate Bill (S.B.) 1461, both titled, "An Act Relative to Newborn Screening for Congenital Cytomegalovirus,"[1] to the Massachusetts Center for Health Information and Analysis (CHIA) for review.[i] Chapter 3 §38C requires CHIA to review the medical of treatments or services included in each mandated benefit bill referred to the agency by a legislative committee should it become law. CHIA must also estimate each bill's fiscal impact, including changes to premiums and administrative expenses.

This report references the Senate and House bills together and hereafter as "the bill." This report is not intended to determine whether the bill would constitute a health insurance benefit mandate for purposes of Commonwealth of Massachusetts (Commonwealth) defrayal under the Affordable Care Act (ACA), nor is it intended to assist with Commonwealth defrayal calculations if it is determined to be a health insurance mandate requiring Commonwealth defrayal.

1.2 What Does the Bill Propose?

As submitted to the 192nd General Court of the Commonwealth of Massachusetts, and refiled in the 193rd General Court, Massachusetts General Law (MGL), the bill requires health insurers to cover the costs for enrollees receiving a required universal screening for congenital cytomegalovirus (cCMV) at all Massachusetts hospitals and birthing facilities.

The bill specifies the following provisions:

- A screening is required to be performed within 21 days from the newborn infant's date of birth, and before the newborn infant is discharged from the birthing facility to the care of the parent or guardian.
    - "Newborn" refers to any liveborn infant who has not yet attained the age of 21 days from a birth occurring in the Commonwealth, or from a birth occurring prior to transfer to a hospital in the Commonwealth.
    - An exemption from screening is permitted if the parent or guardian of the newborn infant objects to the screening based on a sincerely held religious belief of the parent or guardian.
- The cCMV screening should be performed using a saliva polymerase chain reaction (PCR) test unless one is unavailable, in which case a urine PCR test may be used. If positive, a saliva PCR test requires a subsequent confirmatory urine PCR test. The Department of Public Health (DPH) may approve another test

[i] At the time of this report, the bills are refiled with the 193rd General Court under docket numbers H.D. 3273 and S.D. 1958.

to conduct cCMV screening; provided, however, that the test will be, at the discretion of DPH, at least as accurate, widely available, and cost-effective as a saliva or urine PCR test.

- The cost of providing the newborn cCMV screening is required to be a covered benefit reimbursable by all health insurers, except for supplemental policies that only provide coverage for specific diseases, hospital indemnity, Medicare supplement, or other supplemental policies. In the absence of a third-party payer, the charges for the newborn cCMV screening will be paid for by the Commonwealth.
- A hospital or birthing facility will report annually to DPH data including, but not limited to, the number of cCMV tests administered and the outcomes of these tests. The hospital or birthing facility will inform a parent or guardian, orally and in writing, the result of the newborn infant's cCMV screening test regardless of its outcome. This information will also be provided in writing to the newborn infant's primary care physician and to the DPH through its electronic birth certificate system or such mechanism as specified by the DPH.
- Nothing in this statute precludes newborns born at home from obtaining the cCMV screening.

The bill also directs the DPH to establish an advisory committee to implement the provisions of Section 110I. The advisory committee will advise the DPH regarding the validity and cost of proposed cCMV regulations and/or cCMV screening. The committee will also recommend standards for performing and interpreting screening tests based on the most current technological methods for documenting test results and follow up and facilitate interaction between professionals and agencies that participate in follow-up care.

The bill also directs the DPH to develop a public awareness program and encourages providers to engage in patient education about cCMV:

(a) The Commissioner of the DPH will establish, promote, and maintain a public information program regarding cCMV.

(b) The DPH will make available to any healthcare provider, physician assistant, nurse, or midwife who provides prenatal or postnatal care or offers fertility counseling or care to a parent or guardian the following: (i) Up-to-date evidence-based written information about cCMV and universal cCMV screening.

This study by BerryDunn focuses on the provisions of the bill pertaining to insurance coverage of the screening test, the efficacy of universal screening in achieving the intended purpose of the sponsors, and the impact on commercial insurance premiums. The study does not address costs to the Commonwealth associated with the advisory committee and education/awareness programming. The analysis also does not address potential long-term savings or costs to the Commonwealth in education, social services, or other public-sector expenses associated with changes in disability status and functional ability over the lifespan of an individual with cCMV.

1.3 Medical Efficacy of the Bill

cCMV is the most common infectious cause of birth defects in the United States.[2] cCMV is acquired by a developing fetus in utero.[3] About one out of 200 babies is born with cCMV nationally and in Massachusetts.[4] Approximately 10% of infants with this infection will demonstrate signs at birth (i.e., be symptomatic), exhibiting two or more features with central nervous system involvement. Another 10 – 15% of infants with cCMV infection will be asymptomatic (without clinically apparent disease) at birth but will develop sensorineural hearing loss (SNHL)—which may not be detected at birth—and some infants may develop other long-term cCMV-related challenges. The remaining 75 – 80% will remain asymptomatic and are unlikely to develop significant related health conditions.

cCMV meets many of the epidemiology-defined criteria for screening: It is an important health problem with accurate, reliable screening tests and suitable treatments and interventions.[5] Some neonatal screening strategies and diagnostic methods allow the identification of those at risk of developing further complications and can adequately detect cCMV. Although universal screening would bolster the ability to detect asymptomatic cCMV-positive infants; the potential expanded use and benefit of pharmaceutical and nonpharmaceutical interventions for those asymptomatic cCMV-positive infants remains unclear.

cCMV screening programs raise concerns about both underdiagnosis (when infants are screened only when they fail their newborn hearing test, also referred to as "targeted screening") and potential overdiagnosis (when testing all newborns, also referred to as "universal screening").[6,7] Advocates highlight the developmental advantages of early cCMV detection. Interventions might include antiviral drugs or nonpharmaceutical therapies, such as speech-language therapy, hearing aids, cochlear implants, and sign language instruction. Others, however, note shortcomings in available testing platforms and raise concerns about overdiagnosis and overtreatment. Approximately 80% of children with cCMV remain healthy and never have any problems related to the infection. Follow-up testing and monitoring of these infants may bring unnecessary costs and interventions, along with undue concern for parents of otherwise typically developing infants.[8]

The proposed universal screening program offers an opportunity for high target effectiveness; it will catch a substantial proportion (nearly all) of Massachusetts cCMV-infected infants, allowing earlier treatment for those who may not have been detected via a newborn hearing test process. However, it may also present lower target efficiency than available targeted screening. With universal screening, many Massachusetts' infants who test positive will require follow-up testing; universal screening will also require monitoring a significant number of infants to identify those infected with cCMV who are at risk for developing adverse health impacts. Studies suggest that some form of newborn cCMV screening is warranted, although whether the screening should be mandatory as targeted or universal remains under debate.

1.4 Current Coverage

BerryDunn surveyed nine insurance carriers in the Commonwealth, and six responded. All of the carriers who responded currently cover screening for cCMV with no restrictions or symptom requirements. However, providers are not consistently ordering cCMV testing at birth. Therefore, although carriers reported that they do not anticipate changes under the proposed bill, utilization of testing will increase if the bill becomes law.

1.5 Cost of Implementing the Bill

Requiring coverage for this benefit by fully insured health plans would result in an average annual increase, over five years, to the typical member's monthly health insurance premium of between $0.14 to $0.18 per member per month (PMPM), or between 0.023% to 0.030% of premium. The impact on premiums is driven by the requirement of universal cCMV screening of infants.

1.6 Plans Affected by the Proposed Benefit Mandate

The bill amends statutes that regulate health insurance carriers in the Commonwealth. It includes the following sections, each of which addresses statutes regarding a particular type of health insurance policy when issued or renewed in the Commonwealth:[9]

- Chapter 32A – Plans Operated by the Group Insurance Commission (GIC) for the Benefit of Public Employees
- Chapter 175 – Commercial Health Insurance Companies
- Chapter 176A – Hospital Service Corporations
- Chapter 176B – Medical Service Corporations
- Chapter 176G – Health Maintenance Organizations (HMOs)

The bill, as written, amends Chapter 118E of the General Laws. However, estimating the bill's impact to MassHealth membership is outside the scope of this report.

1.7 Plans Not Affected by the Proposed Benefit Mandate

Self-insured plans (i.e., where the employer or policyholder retains the risk for medical expenses and uses a third-party administrator or insurer to provide only administrative functions), except for those provided by the GIC, are not subject to state-level health insurance mandates. State mandates do not apply to Medicare and Medicare Advantage plans or other federally funded plans, including TRICARE (covering military personnel and dependents), the Veterans Administration, and the Federal Employees Health Benefit Plan, the benefits for which are determined by, or under the rules set by, the federal government.

This report is not intended to determine whether the bill would constitute a health insurance benefit mandate for purposes of Commonwealth defrayal under the ACA, nor is it intended to assist with Commonwealth defrayal calculations if it is determined to be a health insurance mandate requiring Commonwealth defrayal.

Endnotes

[1] The 192nd General Court of the Commonwealth of Massachusetts. "House Bill 2338 and Senate Bill 1471: An Act Relative to Newborn Screenings for Congenital Cytomegalovirus." Accessed December 16, 2022. **https://malegislature.gov/Bills/192/H2338** and **https://malegislature.gov/Bills/192/S1471**.

[2] Centers for Disease Control and Prevention. "Congenital CMV and Hearing Loss." Accessed January 6, 2023. **https://www.cdc.gov/cmv/hearing-loss.html**.

[3] Centers for Disease Control and Prevention. "About Cytomegalovirus (CMV)." Accessed January 4, 2023. **https://www.cdc.gov/cmv/overview.html**.

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[6] Pesch MH, Danziger P, Friedman Ross L, AND Matheny Antommaria AH. June 2022. "An Ethical Analysis of Newborn Congenital Cytomegalovirus Screening." *Pediatrics* 149(6): e2021055368. Accessed January 9, 2023. **https://publications.aap.org/pediatrics/article-abstract/149/6/e2021055368/188128/An-Ethical-Analysis-of-Newborn-Congenital?redirectedFrom=fulltext**.

[7] Lazzarotto T, Blázquez-Gamero D, Delforge ML, Foulon I, Luck S, Modrow S, et al. 2020. "Congenital Cytomegalovirus Infection: A Narrative Review of the Issues in Screening and Management From a Panel of European Experts." *Front Pediatr* 8:13. Accessed January 6, 2023. **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7006044/**.

[8] *Op. cit. Pesch MH, Danziger P, Friedman Ross L, AND Matheny Antommaria AH. "An Ethical Analysis of Newborn Congenital Cytomegalovirus Screening." Pediatrics.*

[9] Although Chapter 176A is not included in the bill's current language, the sponsor confirmed the bill's intent is to include it. Chapter 118E (MassHealth) is included in the bill but estimating the bill's impact for MassHealth is not within the scope of this report.

2.0 Medical Efficacy Assessment

Massachusetts General Law (MGL) Chapter 3 §38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with reviewing the medical efficacy of proposed mandated health insurance benefits. Medical efficacy reviews summarize current literature on the effectiveness and use of the treatment or service and describe the potential impact of a mandated benefit on the quality of patient care and health status of the population.

The medical efficacy assessment relied on the following sources of data:

- Published scholarly literature, reports, and population-based data, which are cited throughout this report
- Survey of commercial carriers in the Commonwealth of Massachusetts to gather descriptions of current coverage
- Massachusetts All-Payer Claims Database (APCD)

This study by BerryDunn focuses on the provisions of the bill pertaining to insurance coverage of the screening test, the efficacy of the screening in achieving the intended purpose of the sponsors, and impact on commercial insurance premiums. The study does not address costs to the state associated with the advisory committee and education/awareness programming. The analysis also does not address potential long-term savings or costs to the state in education, social services, or other public-sector expenses associated with changes in disability status and functional ability over the lifespan of an individual with cCMV.

This report includes the following sections:

2.0: Medical Efficacy Assessment

- Section 2.1: What Is Congenital Cytomegalovirus (cCMV), and How Is It Transmitted?
- Section 2.2: Signs and Symptoms
- Section 2.3: Other States' Screening Coverage
- Section 2.4: Medical Efficacy

3.0: Conclusion

2.1 What Is CMV, and How Is It Transmitted?

cCMV, acquired by a developing fetus in utero, is the most common infectious cause of birth defects in the United States.[1,2] When infected with CMV during pregnancy, the virus in a pregnant person's blood can cross through the placenta and infect the developing fetus.[3]

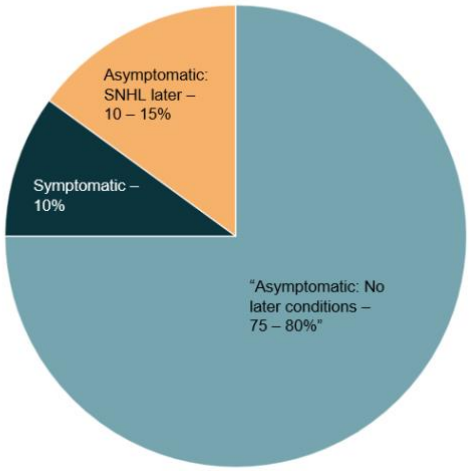
About one out of 200 babies is born with cCMV nationally and in Massachusetts. Of these babies, one out of five will have long-term health problems.[4] cCMV educational and hygienic measures may reduce the risk of exposure and prevent primary maternal infection.[5] The U.S. Centers for Disease Control and Prevention (CDC) suggests prevention measures during pregnancy, such as frequent hand-washing, avoiding sharing food, and preventing contact with a child's saliva.[6] Nonetheless, recent studies identified gaps in knowledge about CMV among women,

finding only 9% are aware of CMV and its implications. [7,8] This suggests the potential benefit of education and awareness efforts as specified in the bill.

2.2 Signs and Symptoms[9]

Approximately 10% of infants with cCMV infection will be symptomatic and demonstrate signs at birth, exhibiting two or more features with central nervous system involvement, while others may develop problems later during infancy or childhood [10] (Figure 1). About a third of infants born with symptomatic cCMV infection will develop sensorineural hearing loss (SNHL) and may develop other longer-term health problems. Another 10 – 15% of infants with cCMV infection will be asymptomatic (without clinically apparent disease) at birth but will develop SNHL and are at risk for developing other long-term neurodevelopmental complications and disability. cCMV infection accounts for about 10 – 25% of all childhood SNHL.[11] However, 75 – 80% of infants born with cCMV infection will remain asymptomatic and unlikely to develop significant related health conditions.

Figure 1. Symptomatic Expression of Infants Born With cCMV Infection[ii]



Some newborns may experience hearing loss that may or may not be detected by a newborn hearing test. Hearing loss may be present at birth or develop later, even in babies who have passed the newborn hearing test.[12] And hearing loss might progress from mild to severe during the first two years of life—a critical period for language learning.[13] Over time, hearing loss can affect a child's ability to develop language and social skills. [14]

cCMV infection is diagnosed by detection of CMV DNA in the saliva, urine, or blood (testing methods discussed in further detail in Section 2.4.2) within 21 days after birth. Congenital cCMV infection cannot be diagnosed using samples collected more than three weeks after birth because testing after this time cannot distinguish between congenital infection and an infection acquired during or after delivery.[15]

[ii] The following symptoms could be present at birth or develop later: rash, jaundice (yellowing of the skin or whites of the eyes, hearing loss, microcephaly (small head), low birth weight, hepatosplenomegaly (enlarged liver and spleen), seizures, retinitis (damaged eye retina), vision loss, intellectual disability, and lack of coordination or weakness.

2.3 Other States' Screening Coverage

Several states have mandated that birthing facilities conduct targeted screenings for newborns who fail their newborn hearing test; Minnesota is the first and, thus far, only state to enact a universal newborn cCMV screening requirement[16] (Table 1). Minnesota's authorizing legislation passed in 2021; in 2022, the state's Newborn Screening Advisory Committee and the commissioner of health endorsed adding universal cCMV to the state's newborn screening program. Minnesota has not yet implemented this, as the state's health department is charged with determining and validating the laboratory method, developing follow-up protocols, and working with external partners to establish clinical guidelines.[17] Indiana now also joins Massachusetts in proposing a legislative mandate for universal newborn screening. The New York State Department of Health was recently awarded a contract from the federal National Institute of Child Health and Human Development (NICHD) to provisionally add cCMV to the newborn screening panel and to test all infants for infection (with parent opt-out available).[18] New York plans to start the testing program in mid-2023. No statutory or regulatory provisions exist for universal screening in New York, and state funds are not allocated for this screening program.

Table 1. displays existing legislative mandates among the states.[19]

Table 1. State Legislative Mandates as of July 2022

STATE	UNIVERSAL SCREENING	TARGETED SCREENING: AFTER FAILED HEARING TEST	EDUCATION
Colorado			X
Connecticut		X	
Hawaii			X
Idaho			X
Illinois		X	X
Iowa		X	X
Kentucky		X	X
Maine		X	X
Minnesota	X		X
Nebraska			X
New York		X	X
Oregon			X
Pennsylvania		X	X
Tennessee			X
Texas			X
Utah		X	X
Virginia		X	

2.4 Medical Efficacy

Advocates of the proposed universal screening assert several benefits.[20] First, universal screening of newborns for cCMV may increase detection of symptomatic infections.[21] Early and immediate detection of cCMV following birth allows for early and expedient interventions, including the administration of antiviral medications that could prevent further progression of hearing loss and other cCMV complications. Timely diagnosis and early intervention for SNHL improves long-term language outcomes and reduces the functional impairments that stem from hearing loss. [22]

As noted in Section 2.1, infants with symptomatic cCMV infections account for only about 10% of all cCMV-infected infants—and many of these infants are likely to have been identified due to their symptom presentation. A universal screening program, beyond a marginal increase in identification of these symptomatic infants, would also identify a larger number of asymptomatic cCMV-infected infants at birth. Recent studies of universal cCMV screening address the need to explore the efficacy, including the cost-effectiveness, of identifying asymptomatic cCMV-infected infants.[23]

A 2022 *Pediatrics* paper reviews the debate regarding the methods and merits of cCMV newborn screening, including which infants to screen, which tests to use, and whether the benefits of early detection and intervention outweigh the risks.[24] Several previous studies have laid the foundation for these questions.[25,26,27,28,29]

2.4.1 Screening

cCMV is not currently included in Massachusetts' required routine newborn screening. Universal screening, as designated in the bill, would require cCMV screening of all infants, regardless of symptoms.

Massachusetts law designates requirements for "[b]lood screening of newborns for treatable diseases and disorders" under state public health regulatory authority in 105 CMR 270.00.[30] The program includes required screening for 32 disorders, with the potential to screen for 67 conditions. For these tests, the hospital or birthing center collects a few drops of blood, via a heel stick, and sends a dried blood spot (DBS) sample to a state-designated laboratory, which uses the single DBS sample to test for all of the designated conditions.

Currently in Massachusetts, some hospitals use targeted screening for infants who fail the newborn hearing screen or present with other risk factors. [31] Other hospitals do not have a policy. A survey of Massachusetts birth hospitals, as reported by the Massachusetts cCMV Coalition, shows less than half of hospitals have specific policies for targeted cCMV screening for babies who fail their newborn hearing screen.

However, as noted, about 90% of infants born with cCMV are asymptomatic at birth. Most infants born with asymptomatic cCMV will have neurodevelopmental outcomes in the typical range.[32] But cCMV-related hearing loss often develops or advances in early childhood and may not be detected within the newborn stage.

cCMV cannot be diagnosed retroactively. If testing is not done within the first 21 days after birth, it is impossible to accurately determine if an infant was born with cCMV and if subsequent hearing loss or other disabilities result from the infection.

Current cCMV newborn screening protocols often limit cCMV screening to infants who fail their newborn hearing screen.[33] Such testing focuses particularly on early detection of SNHL, with the potential for early treatment. However, most (93%) infants with cCMV do not fail their newborn hearing test.[34] A frequently cited study reports that the hearing test failed to identify 43% of infants with cCMV-related hearing loss in the neonatal period and cCMV infants at risk for late onset SNHL.[35] In other words, a policy of targeted screening of only those infants who fail the

newborn hearing screening will not detect the actual number of cCMV cases. A targeted screening approach will fail to identify infants with cCMV and those at risk for cCMV-related hearing loss.

Universal screening has not been in practice yet in any U.S. state. (Although Minnesota is now the first state to authorize the initiation of universal newborn screening, the program is not yet in effect.) Generally, cCMV-infected neonates are identified only because of a suspected maternal infection during pregnancy or symptoms and signs associated with cCMV at birth. A 2022 multicenter study confirmed that, without universal neonatal screening, some infected infants at risk to develop related neurological complications may not be recognized at birth.[36]

In theory, universal screening would identify all infants with cCMV, including those with asymptomatic disease and those who will develop hearing loss in infancy. Such screening, however, will also identify the more than 80% of infants with cCMV that will never develop disabling long-term complications.[37]

2.4.2 Screening Method: Considerations

The bill specifies that "the cCMV screening shall be performed using a saliva PCR test, unless one is unavailable, in which case a urine PCR test may be used. If positive, a saliva PCR test would require a confirmatory urine PCR test." In addition, the DPH may approve another test that it determines to be "at least as accurate, widely available and cost-effective as a saliva or urine PCR test."

The bill sponsors, Senator Joan B. Lovely and Representative Kay Khan, further clarified the provision pertaining to DPH approval of other testing methods. They note this language in the bill "would cover any other current or future test that is comparable to saliva +/- urine PCR in sensitivity and specificity (both at least 95%)."[38]

Each available testing method for newborn screening for cCMV has advantages and challenges.[39] Specimens for cCMV testing need to be collected within 21 days from the date of birth to distinguish between congenital and acquired postnatal infection.[40] Saliva is the preferred sample for PCR testing, with greater than 95% sensitivity for the identification of cCMV; however, a positive result may require confirmation with urine testing because of potential contamination of saliva with CMV in human milk.[41] Saliva specimens must be collected at least 30 minutes after breastmilk consumption to avoid CMV shedding in breastmilk.[42,43,44] The saliva testing method also requires a new testing infrastructure, which would include associated costs.[45]

Any positive result from saliva should be confirmed with a subsequent urine test.[46] Urine is challenging to collect in the days after birth because of low urine output in newborns.[47] The *Pediatrics* 2022 review notes that the United States currently lacks commercially available capacity for automated testing of large numbers of urine or saliva cCMV PCR tests.[48]

DBS collection is a standard practice in screening newborns for various genetic and metabolic diseases; hospitals already collect infant DBS samples for the state's newborn screening testing panel. Readily available infrastructure exists to rapidly incorporate DBS screening into standard clinical care, potentially reducing the overall cost of such programs.[49] However, the DBS tests have previously been reported to have lower sensitivity (ability to detect cCMV), with a reported sensitivity between 38.3% and 76.8%.[50,51] A more recent (2021) study assessing the sensitivity of DBS testing for detection of cCMV reports a sensitivity of 85.7%—substantially higher than was reported in past studies.[52] This relatively high sensitivity of the DBS method suggests its improving utility for universal cCMV screening.

2.4.3 Follow-Up and Treatment Options

cCMV screening and follow-up of a positive cCMV screening result will likely involve several steps, including the following:[53,54]

- Confirmatory urine CMV testing, blood tests.
- Assessment by a pediatrician or by an infectious diseases doctor.
- Discussion of screening results in more detail, followed by further testing:
    - Physical exam and assessment of whether infant has any signs or symptoms of cCMV
    - Other laboratory investigations
    - Diagnostic audiology (detailed hearing test)
    - Head ultrasound
    - Ophthalmologic assessment
- Other follow-up as indicated.

Possible outcomes and treatments, following confirmation of a positive result, include the following:[55,56]

cCMV Infection with Signs or Symptoms (Symptomatic)

- About 10 – 15% of infants with cCMV infection demonstrate signs or symptoms at birth. These infants are at a higher risk for hearing loss and developmental problems that require ongoing monitoring. Interventions might include antiviral drugs or nonpharmaceutical therapies, such as speech-language therapy, hearing aids, cochlear implants, and sign language instruction.
- Symptomatic cCMV with central nervous system involvement—when symptoms are evident within the first month of an infant's life—may benefit from treatment with antiviral medications (primarily valganciclovir) beginning in the first month of life.[57] Such treatment may improve hearing and developmental outcomes.[58] However, valganciclovir can have serious side effects.[59] Targeted treatment of cCMV limits treatment with valganciclovir for the most severely affected infants, with caution against overuse of the medication.[60,61,62] Evidence is limited, and consensus lacking, about valganciclovir's effectiveness to treat infants with mildly symptomatic or asymptomatic cCMV with isolated hearing loss alone.[63,64]

cCMV Infection with No Signs or Symptoms in First Month (Asymptomatic)

- Developmental conditions are slightly more likely to emerge in babies born with asymptomatic cCMV than in those without. In particular, babies with asymptomatic cCMV have about a 10% chance of developing permanent hearing loss in early childhood. Infants with cCMV-related hearing loss will gain advantages from early interventions and ongoing access to audiology services.
- 80% of children with cCMV remain healthy and never experience problems related to the infection. Ongoing follow-up and monitoring, based on their positive test result, may create excess concern among parents

and, along with it, excess testing or other restrictions associated with vulnerable child syndrome.[65] As well, frequent testing adds healthcare costs that would not be incurred for an otherwise typically developing child.

2.4.4 Screening Efficacy: A Summary View

cCMV meets many of the criteria for screening; it is an important health problem with accurate, reliable screening tests and suitable treatments and interventions.[66] Several neonatal screening strategies and diagnostic methods allow the identification of those at risk of related developing complications and can adequately detect cCMV. Universal screening would bolster the ability to detect asymptomatic cCMV-positive infants. But the potential expanded use and benefit of pharmaceutical and nonpharmaceutical interventions for those asymptomatic cCMV-positive infants remains unclear; important questions about screening remain unanswered.[67]

The June 2022 issue of *Pediatrics* provides various perspectives about cCMV screening, noting that cCMV screening programs raise unique ethical dilemmas of both under- and overdiagnosis.[68] One perspective highlights the developmental advantages of early cCMV detection, supporting a broad approach to treatment beyond antiviral medication alone. A second view notes shortcomings in available testing platforms and raises concerns about overdiagnosis and overtreatment. The final commentary challenges the risks of undue parental anxiety and vulnerable child syndrome as a barrier to screening, instead considering cCMV screening as a controlled opportunity to understand and support the experiences of affected children and their families.

Error! Reference source not found. reviews advantages and disadvantages of the proposed universal screening approach -- moving from targeted cCMV testing (only when newborns show deficits in their newborn hearing test) to a universal cCMV screening -- and compares the proposed use of saliva and/or urine PCR method to the DBS testing method.

TABLE 3: CONSIDERATIONS IN PROPOSED UNIVERSAL SCREENING APPROACH

ADVANTAGES	*CHALLENGES*
Universal versus Targeted Screening	
High target effectiveness: ▪ Universal screening program will catch a substantial proportion (nearly all) of cCMV-infected infants, allowing earlier treatment for those who may not have been detected via a newborn hearing test process.	**Lower target efficiency:** ▪ Universal screening program for a large number (nearly all) Massachusetts' infants will require follow-up of a significant number of infants to identify the small proportion of cCMV-infected infants at risk for developing adverse health impacts.
Saliva/urine versus DBS testing method	
▪ Saliva carries a high viral load with low occurrence of false positives in testing.[69] ▪ Sensitivity of test: Saliva and urine are highly effective in identifying infants with cCMV infection. ▪ Saliva/urine is more sensitive than the DBS method, which is less sensitive and may produce false negative results.	▪ Potential specimen interference: saliva sample must not be collected within 30 minutes of breastfeeding. ▪ Requires retesting/confirmation testing. ▪ Saliva and urine testing require additional sample and handling procedures; Saliva/urine method is not now a routine newborn screening process, while DBS testing may be done via routine newborn blood sample.

3.0 Conclusion

Targeted cCMV screening programs raise concerns about underdiagnosis because they only test infants who fail their newborn hearing test, while universal cCMV screening programs raise concerns about potential overdiagnosis due to testing of all newborns.[70] Advocates highlight the developmental advantages of early cCMV detection, supporting a broad approach to treatment beyond antiviral medication alone. Interventions might include antiviral drugs for infants symptomatic at birth and nonpharmaceutical therapies, such as speech-language therapy, hearing aids, cochlear implants, and sign language instruction. However, a universal screening program raises concerns about overdiagnosis and overtreatment. About 80% of children with cCMV remain healthy and never experience any problems related to the infection. Follow-up testing and monitoring of these infants may result in unnecessary costs and interventions, along with undue concern for parents of otherwise typically developing infants.[71]

The proposed universal screening program offers an opportunity for high target effectiveness; it will catch a substantial proportion (nearly all) of Massachusetts' cCMV-infected infants, allowing earlier treatment for those who may not have been detected via a newborn hearing test process. However, it may also present lower target efficiency than available targeted approaches. With universal screening, a large number of Massachusetts' infants who test positive will require follow-up testing; universal screening will also require monitoring a significant number of infants to identify those infected with cCMV who are at risk for developing adverse health impacts.

Costs associated with cCMV infection include the costs of managing/treating cCMV-related conditions for infants born with varying levels of symptomatic or asymptomatic infections. Hearing loss, as noted, is the most common complication of cCMV. However, most excess medical costs for children with symptomatic cCMV are incurred among those who had neurological complications and/or prematurity—conditions likely to have been diagnosed outside of cCMV screening.

Studies suggest that some form of newborn cCMV screening programs is warranted, but whether that screening should be mandatory as targeted or universal remains under debate. Targeted screening appears cost-effective and requires testing fewer newborns. Universal screening, however, offers better opportunities for early comprehensive care and potentially larger net savings when considering the possibility of averted losses in patient and caregiver productivity as well as reduced wages, over the lifespan of the child—although determining this impact is beyond the scope of this report.

Universal newborn screening will require additional healthcare resources for diagnosis, treatment, and ongoing surveillance of asymptomatic infants through at least six years of age.[72] Existing studies may not have accounted for these costs nor the potential for excess testing and services. Salivary PCR testing will require additional costs for processing and staff infrastructure, which have not been included in estimates in the literature.

Overall, both targeted or universal screening show benefits in outcomes as well as varying costs and cost-effectiveness. Recent findings that endorse the cost-effectiveness of universal cCMV screening rely on the inclusion of productivity and education costs and potential savings over an individual's lifespan. These costs and potential savings will be incurred across economic sectors, but not directly by the healthcare system. For that reason, BerryDunn's analysis of the mandate's cost impact on private health insurance premiums does not include the productivity and other upside gains as cost offsets.

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AN ACT RELATIVE TO NEWBORN SCREENING FOR CONGENITAL CYTOMEGALOVIRUS

ACTUARIAL ASSESSMENT

1.0 Executive Summary

The Massachusetts Legislature's Committee on Health Care Financing referred 192nd General Court House Bill (H.B.) 2338 and Senate Bill (S.B.) 1471, both titled "An Act Relative to Newborn Screening for Congenital Cytomegalovirus," to the Massachusetts Center for Health Information and Analysis (CHIA) for review.[3] This report references H.B. 2338 and S.B. 1471 together and hereafter as "the bill." The bill requires health insurers to cover the costs for enrollees receiving a required universal screening for congenital cytomegalovirus (cCMV) at all Massachusetts hospitals or birthing facilities.

Chapter 3 §38C requires CHIA to review the medical efficacy of treatments or services included in each mandated benefit bill referred to the agency by a legislative committee should it become law. CHIA must also estimate each bill's fiscal impact, including changes to premiums and administrative expenses. This report provides the fiscal analysis.

This report is not intended to determine whether the bill would constitute a health insurance benefit mandate for purposes of Commonwealth of Massachusetts (Commonwealth) defrayal under the Affordable Care Act (ACA), nor is it intended to assist with Commonwealth defrayal calculations if it is determined to be a health insurance mandate requiring Commonwealth defrayal.

The bill requires health insurers to cover the costs for newborn enrollees receiving a required universal screening for cCMV at all Massachusetts birthing facilities. The bill also specifies that the cCMV screening shall be performed using a saliva polymerase chain reaction (PCR) test, unless one is unavailable, in which case a urine PCR test may be used. If positive, a saliva PCR test would require a confirmatory urine PCR test.

1.1 Current Insurance Coverage

BerryDunn surveyed nine insurance carriers in the Commonwealth, and six responded. All of the carriers currently cover screening for cCMV with no restrictions or requirements of symptoms. However, providers are not consistently ordering cCMV testing at birth. Therefore, although carriers reported they do not anticipate changes under the proposed bill, utilization of testing will increase should the bill become law.

1.2 Analysis

BerryDunn estimated the impact of the bill on insurance premiums by 1) assessing the incremental cost of moving from a targeted to a universal screening approach for cCMV and 2) measuring the expenses related to follow-up services for infants identified with cCMV infection, and the increased carrier expenses associated with these services.

1.3 Summary Results

The estimated impact of the proposed requirement on medical expense and premiums appears below and is primarily due to anticipated increased testing if the bill passes. The analysis provides estimates for low-, mid-, and high-level scenarios, with the high-level scenarios using the most conservative assumptions.

[3] At the time of this report, the bills are filed with the 193rd General Court under docket numbers H.D. 3273 and S.D. 1958.

In the first year, the incremental insurance cost ranges from $0.12 to $0.15 per member per month (PMPM).

Table ES-1 displays the summary results for a five-year period. This analysis estimates that the bill, if enacted as drafted for the General Court, would increase fully insured premiums by as much as 0.03% on average over the next five years; a more likely increase is approximately 0.027%—equivalent to an average annual expenditure of $4.3 million over the 2024 – 2028 period. The impact on premiums is driven largely by the provision that requires health insurers to cover the costs for all infants to receive a required universal screening for cCMV at all Massachusetts hospitals and birthing facilities.

Table ES-1. Summary Results

	2024	2025	2026	2027	2028	WEIGHTED AVERAGE	FIVE-YEAR TOTAL
Average Members (000s)	2,242	2,262	2,266	2,269	2,271		
Medical Expense Low ($000s)	$2,805	$3,006	$3,222	$3,453	$3,700	$3,237	$16,186
Medical Expense Mid ($000s)	$3,192	$3,428	$3,682	$3,953	$4,243	$3,699	$18,497
Medical Expense High ($000s)	$3,579	$3,850	$4,141	$4,452	$4,786	$4,162	$20,809
Premium Low ($000s)	$3,267	$3,502	$3,753	$4,022	$4,309	$3,770	$18,852
Premium Mid ($000s)	$3,718	$3,993	$4,288	$4,604	$4,942	$4,309	$21,544
Premium High ($000s)	$4,168	$4,484	$4,823	$5,186	$5,575	$4,847	$24,236
PMPM Low	$0.12	$0.13	$0.14	$0.15	$0.16	$0.14	$0.14
PMPM Mid	$0.14	$0.15	$0.16	$0.17	$0.18	$0.16	$0.16
PMPM High	$0.15	$0.17	$0.18	$0.19	$0.20	$0.18	$0.18
Estimated Monthly Premium	$562	$577	$593	$609	$625	$593	$593
Premium % Rise Low	0.022%	0.022%	0.023%	0.024%	0.025%	0.023%	0.023%
Premium % Rise Mid	0.025%	0.025%	0.027%	0.028%	0.029%	0.027%	0.027%
Premium % Rise High	0.028%	0.029%	0.030%	0.031%	0.033%	0.030%	0.030%

2.0 Introduction

Bills submitted to the 192nd General Court of the Commonwealth of Massachusetts, H.B. 2338 and S.B. 1471.[4] require health insurers to cover the costs for enrollees receiving a required universal screening for cCMV at all Massachusetts hospitals and birthing facilities.

This review estimates the impact on insurance premiums and administrative expenses of the following bill provisions:

- A screening will be performed within 21 days from the date of birth and before the newborn infant is discharged from the birthing facility to the care of the parent or guardian
    - "Newborn," any liveborn infant who has not yet attained the age of 21 days from a birth occurring in the commonwealth or from a birth prior to transfer to a hospital in the commonwealth.
    - An exemption will be permitted if the parent or guardian of the newborn infant objects to the screening based upon a sincerely held religious belief of the parent or guardian.
- The cCMV screening will be performed using a saliva PCR test, unless one is unavailable, in which case a urine PCR test may be used. If positive, a saliva PCR test would require a subsequent confirmatory urine PCR test.
- The Department of Public Health (DPH) may approve another test to conduct cCMV screening, provided, however, that the test will be, at the discretion of the Department, at least as accurate, widely available, and cost-effective as a saliva or urine PCR test.
- The cost of providing the newborn cCMV screening will be a covered benefit reimbursable by all health insurers, except for supplemental policies that only provide coverage for specific diseases, hospital indemnity, Medicare supplement, or other supplemental policies. In the absence of a third-party payer, the charges for the newborn cCMV screening will be paid for by the Commonwealth.

Section 3.0 of this analysis outlines the provisions and interpretations of the bill. Section 4.0 summarizes the methodology used for the estimate. Section 5.0 discusses important considerations in translating the bill's language into estimates of its incremental impact on healthcare costs, and steps through the calculations. Section 6.0 discusses results.

[4] At the time of this report, the bills are filed with the 193rd General Court under docket numbers H.D. 3273 and S.D. 1958.

3.0 Interpretation of the Bill

3.1 Coverage for cCMV Screening and Specification of Methods

As submitted to the General Court of the Commonwealth of Massachusetts, the bill requires health insurers to cover the costs for enrollees receiving a required universal screening for cCMV at all Massachusetts birthing facilities. The bill also specifies that the cCMV screening shall be performed using a saliva PCR test, unless one is unavailable, in which case a urine PCR test may be used. If positive, a saliva PCR test would require a subsequent confirmatory urine PCR test.

3.2 Plans Affected by the Proposed Mandate

The bill amends statutes that regulate commercial healthcare carriers in the Commonwealth. It includes the following sections, each of which addresses statutes dealing with a particular type of health insurance policy when issued or renewed in the Commonwealth:[1]

- Chapter 32A – Plans Operated by the Group Insurance Commission (GIC) for the Benefit of Public Employees
- Chapter 175 – Commercial Health Insurance Companies
- Chapter 176A – Hospital Service Corporations
- Chapter 176B – Medical Service Corporations
- Chapter 176G – Health Maintenance Organizations (HMOs)

Self-insured plans, except for those managed by the GIC, are not subject to state-level health insurance benefit mandates. State mandates do not apply to Medicare or Medicare Advantage plans, the benefits of which are qualified by Medicare. This analysis excludes members over 64 years of age who have fully insured commercial plans, and this analysis does not address any potential effect on Medicare supplement plans, even to the extent they are regulated by state law.

3.3 Covered Services

BerryDunn surveyed nine insurance carriers in the Commonwealth, and six responded. All of the carriers currently cover screening for cCMV with no restrictions or requirements of symptoms. However, providers are not consistently ordering cCMV testing at birth. Therefore, although carriers reported that they did not anticipate changes under the proposed bill, utilization of testing will increase should the bill become law.

3.4 Existing Laws Affecting the Cost of the Bill

cCMV is not currently included in Massachusetts' required routine newborn screening and is not conducted as a universal screening test. Massachusetts law designates requirements for "[b]lood screening of newborns for treatable diseases and disorders" under its public health regulatory authority in 105 CMR 270.00.[2] The program includes required screening for 32 disorders and the potential to screen for 67 conditions. For these tests, the hospital or birthing center collects a few small drops of blood, via a heel stick, and sends a dried blood spot (DBS) sample to a state-designated laboratory, which uses the single DBS sample to test for all the designated conditions.

Currently in Massachusetts, some hospitals use targeted cCMV screening for infants who fail the newborn hearing screen or present with other risk factors.[3] Other hospitals do not have a policy; a survey of Massachusetts hospitals with obstetrical services reports that less than half of hospitals have any targeted cCMV screening policy for babies who fail their newborn hearing screen.

4.0 Methodology

4.1 Overview

As submitted to the 192nd General Court of the Commonwealth of Massachusetts, and refiled in the 193rd General Court, the bill requires health insurance carriers to cover the costs for enrollees receiving a required universal screening for cCMV at all Massachusetts birthing facilities. The bill also specifies that the cCMV screening shall be performed using a saliva PCR test, unless one is unavailable, in which case a urine PCR test may be used. If positive, a saliva PCR test would require a confirmatory urine PCR test.

The carriers report that they currently cover the cost of cCMV screening, regardless of the presence of symptoms, and carriers currently incur such costs on a case-by-case basis. The costs of the proposed mandate would result from a policy change to universal testing, requiring coverage of the test for all infants. Universal testing is currently not the practice at Massachusetts hospitals and birthing centers. The proposed bill includes the establishment of an advisory committee that will advise the DPH on cCMV screening. This analysis assumes that the committee endorses the bill's specifications for universal screening.

The proposed legislation requires a carrier's cCMV screening for all infants with fully insured coverage born in Massachusetts. The assessment of the impact of the increase in cCMV test utilization requires estimating the number of births and the cost per screening. Section 6 of this report discusses the cost impact should the bill become law.

BerryDunn estimated the impact of the bill on insurance premiums by assessing the incremental cost of universal screening for cCMV and the resulting increased carrier expenses related to identification of additional infants with cCMV and related follow-up services. The incremental cost of universal screening is estimated using claims data from the Massachusetts All-Payer Claims Database (APCD) to determine the cost for the screening and from published reports and population data to determine the number of births and screenings in the fully insured market. The incremental cost of follow-up services for newly identified cCMV-positive infants is estimated by using APCD claims data to determine follow-up service costs and published reports to determine the number of infants requiring follow-up services.

The combination of these components, and accounting for carrier retention, results in an estimate of the bill's incremental effect on premiums, which is projected over the five years beginning with January 1, 2024, as the implementation date should the bill become law.

4.2 Data Sources

The primary data sources used in the analysis are as follows:

- Input from legislative sponsors, providing information about the intended effect of the bill
- Survey of commercial carriers in the Commonwealth, gathering descriptions of current coverage
- Massachusetts APCD

- Published scholarly literature, reports, and population data, cited as appropriate

4.3 Steps in the Analysis

This section summarizes the analytic steps used to estimate the impact of the bill on premiums. Figure 1 depicts the analytic steps as a logic model.

1. **Calculate the screening costs for the population**

   A. Used Massachusetts vital statistics to determine the number of infants born in 2019 (most current reporting year).

   B. Adjusted by percentage of infants covered by commercial insurance.

   C. Adjusted total commercially insured infants, which include both self-insured and fully insured infants, by percentage of fully insured coverage to determine number of infants with fully insured coverage who will be screened.

   D. Used literature and the APCD to estimate the cost per screening.

   E. Multiplied the total number of infants (1C) by estimated cost per screening (1D).

   F. Used literature to estimate the number of infants who would test cCMV positive.

   G. Multiplied the estimated cost per screening by the number of cCMV-positive infants to estimate costs for a second screening), which will confirm the infant population testing cCMV positive.

   H. Summed results from 1E and 1G to estimate total screening test costs.

2. **Calculate follow-up costs for asymptomatic cCMV-infected population**

   A. Used literature to identify the percentage of cCMV-positive infants who will be asymptomatic at birth.

   B. Multiplied the total number of cCMV-positive infants (1F) by the asymptomatic birth rates from the literature to estimate the number of asymptomatic cCMV-positive infants.

   C. Used literature and the APCD to estimate the cost of providing follow-up services for asymptomatic cCMV-positive infants.

   D. Projected the cost of the follow-up services over the projection period, considering that new infants will be identified each year.

   E. Multiplied the cost of providing follow-up services (2D) by the number of asymptomatic cCMV-positive infants (2B) to estimate the total cost to provide follow-up and monitoring for infants identified as CMV-infected who are asymptomatic at birth.

3. **Calculate the impact of the projected claim costs on insurance premiums.**

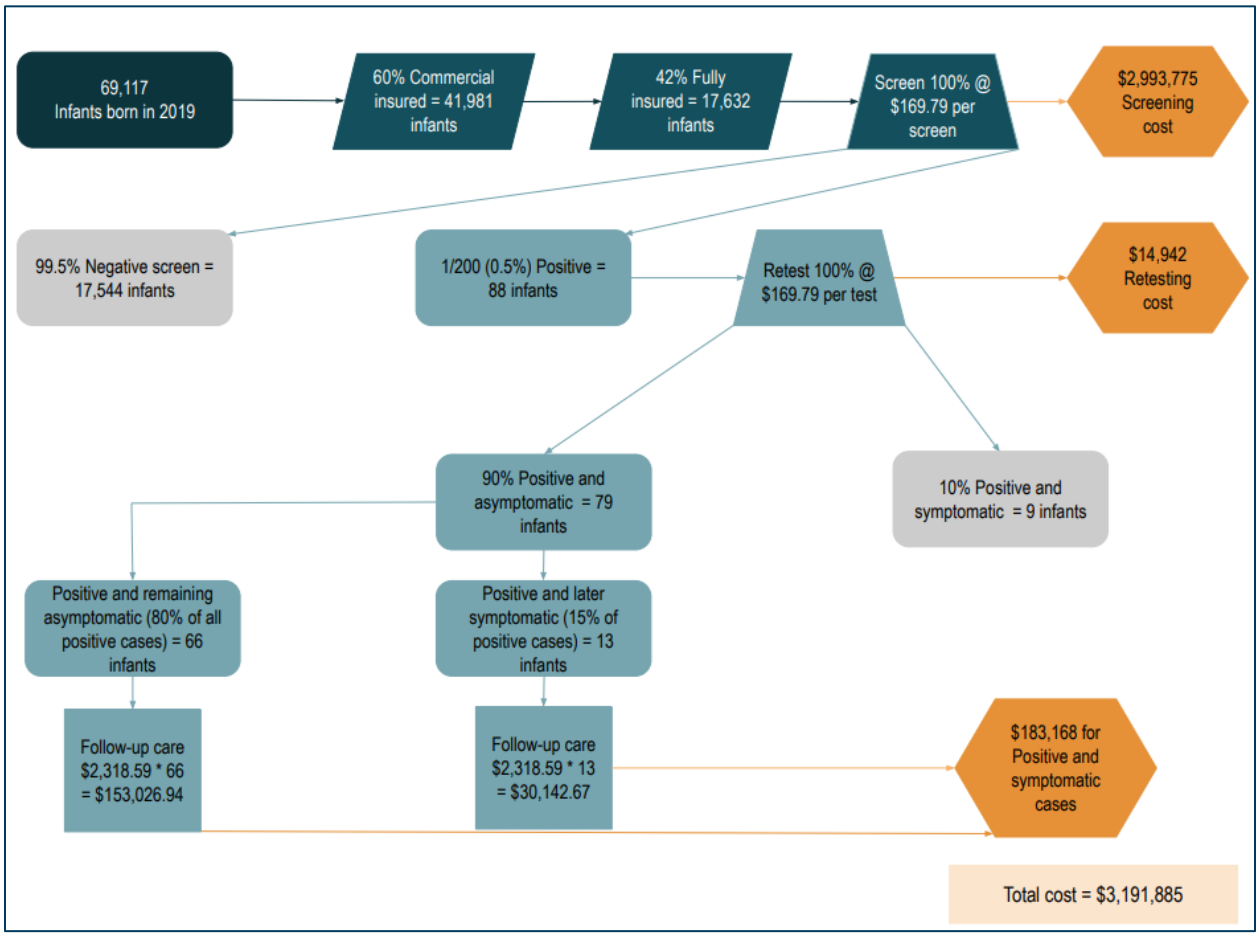
   A. Added the incremental cost calculated in Steps 1H and 2E to determine the total incremental claims impact.

B. Estimated the fully insured Commonwealth population under age 65 projected for the next five years (2024 – 2028).

C. Multiplied the PMPM incremental net cost of the mandate by the projected population estimate to calculate the total estimated marginal claims cost of the bill.

D. Estimated insurer retention (administrative costs, taxes, and profit) and applied the estimate to the final incremental claims cost calculated in Step 3C.

Figure 1. Steps in Analysis Using 2024 Mid-Scenario Numbers*



4.4 Assumptions and Limitations

The incremental cost of the bill stems from universal screening for cCMV and from incremental follow-up costs due to the identification of additional infants with cCMV. This cost was estimated using APCD claims data to determine the cost for the screening and from published reports and population data to determine the number of births and screenings in the fully insured market. The incremental cost of follow-up services for newly identified cCMV-positive infants is estimated using claims data from the APCD to determine the cost for follow-up services and from published reports, which also supports estimates of the number of infants requiring follow-up services.

However, based on MA APCD data, very few infants in Massachusetts are currently tested for cCMV, so the actual cost per screening is uncertain and based largely on the literature. BerryDunn assumed a range of costs per screening in calculating the marginal cost estimate. Similarly, the cost per follow-up service is uncertain, and BerryDunn assumed a range in cost per service to calculate the marginal cost.

The bill allows for a religious exemption to cCMV screening. The number of exemptions is difficult to predict, but it would likely be a small number. One small carrier indicated that cCMV testing at birth is included in bundled payments. These births were included in the universal screening calculations, and the low end of the cost range would account for these uncertainties.

Follow-up costs from asymptomatic cCMV-positive infants can last up to age six.[4] Absent universal screening, these infants would initiate treatment when symptoms begin and are identified. Currently, in the absence of universal infant cCMV screening, some children in the post neonatal period up to age six may have onset symptoms (and initiate treatment for those symptoms) that are cCMV-related but not identified as such. These services have costs already being incurred, but these costs remain uncertain. In the current analysis, BerryDunn included all follow-up costs through the projection period for all infants identified with cCMV infection. This approach likely includes a marginal amount of already existing costs; the low end of the cost range accounts for this uncertainly.

BerryDunn assumes that most symptomatic infants at birth are currently identified and diagnosed with cCMV infection in the absence of the universal screening mandate. In that case, those symptomatic infants are receiving the follow-up services and pharmaceutical antiviral treatment for their infection, and the bill's mandate will not change those costs in the system. However, some infants with symptoms at birth may not have been tested for cCMV, and they may not currently be receiving antiviral and other treatments available for newborn cCMV infection. Universal testing would identify these infants, adding antiviral treatment costs. The estimated cost for these additional few infants is not material, and the high end of the cost range would account for this uncertainty.

COVID-19 has impacted the number of commercial fully insured members in 2020. Fully insured membership declined due to decreased enrollment in employer-sponsored insurance (ESI). The impact that COVID-19 and economic trends will have on employment and, therefore, ESI in the 2024 – 2028 projection period is uncertain.

Appendix A addresses these limitations further.

5.0 Analysis

This section describes the calculations outlined in the previous section in more detail. The analysis includes a best estimate middle-cost scenario, a low-cost scenario, and a high-cost scenario using more conservative assumptions. The analysis section proceeds as follows:

- Section 5.1 describes the steps used to calculate the PMPM expenses associated with universal screening for cCMV.
- Section 5.2 describes the steps used to calculate the PMPM cost associated with follow-up costs for infants testing positive for cCMV but with no symptoms.
- Section 5.3 describes potential costs associated with antiviral therapy for infants with symptoms, but not previously screened or identified.
- Section 5.4 aggregates the marginal PMPM costs.
- Section 5.5 projects the fully insured population age 0 to 64 in the Commonwealth over the years 2024 to 2028 in the analysis period.
- Section 5.6 calculates the total estimated marginal cost of the bill.
- Section 5.7 adjusts these projections for carrier retention to arrive at an estimate of the bill's effect on premiums for fully insured plans.

5.1 Coverage for cCMV Screening of Newborns

The proposed legislation requires insurers to cover the costs for enrollees receiving required universal cCMV screening at all Massachusetts birthing facilities. The bill also specifies that the cCMV screening shall be performed using a saliva PCR test, unless one is unavailable, in which case a urine PCR test may be used. If positive, a saliva PCR test would require a subsequent confirmatory urine PCR test. The DPH reported 41,981 births for the commercially insured population in 2019.[5] Of the commercial population, 42% of covered members were fully insured. (See Appendix A for discussion of excluding those members in the commercial self-insured population.) BerryDunn estimates approximately 17,632 infants born in the fully insured population.

41,981 births x 42% = 17,632 infants in the fully insured population

About one out of 200 babies in the United States is born with cCMV.[6] When babies test positive, they are rescreened to confirm results, resulting in 88 (=17,632 / 200) additional screenings. Adding the number of additional screenings to the number of births results in the total number of incremental screenings. The bill allows for a religious exemption to cCMV screening. This number is difficult to predict but likely small. In addition, a small number of infants born with symptoms currently receive cCMV testing, but the number is not material. The low end of the cost range accounts for both of these uncertainties. Table 1 displays the number of births and number of incremental cCMV screenings.

Table 1. Number of Fully Insured Births and Incremental Screenings

NUMBER OF BIRTHS	RESCREENS	INCREMENTAL SCREENING
17,632	88	17,720

Next, using the paid claim amounts and the number of screening tests in the Massachusetts APCD, BerryDunn calculated the cost per screening test for cCMV. The amount varies and is between $120 and $150 per screening. A review of literature showed that cost estimates also vary. A 2022 micro-costing study estimated the cost at $138 per infant screened.[7] BerryDunn assumed the cost is $120 per test in the low scenario, $135 in the mid scenario, and $150 in the high scenario.

The cost per screening test has been trending downward in the APCD. BerryDunn multiplied the cost per test by the long-term average national projection for cost increases to physician and clinical services—reported at 5.9%[8] over the projection period—to estimate the cost per test over the projection period. Table 2 displays these results.

Table 2. Projected Cost per cCMV Screening Test

	2020	2024	2025	2026	2027	2028
Low Scenario	$120	$151	$160	$169	$179	$190
Mid Scenario	$135	$170	$180	$190	$202	$214
High Scenario	$150	$189	$200	$212	$224	$237

BerryDunn multiplied the number of incremental screening tests from Table 1 by the cost per test from Table 2 to calculate the total incremental claims cost of universal screening for cCMV. Table 3 displays these results.

Table 3. Projected Total Claims Cost for Universal cCMV Screening

	2020	2024	2025	2026	2027	2028
Low Scenario	$2,126,400	$2,674,415	$2,832,206	$2,999,306	$3,176,265	$3,363,664
Mid Scenario	$2,392,200	$3,008,717	$3,186,231	$3,374,219	$3,573,298	$3,784,122
High Scenario	$2,658,000	$3,343,019	$3,540,257	$3,749,132	$3,970,331	$4,204,580

BerryDunn next divided the incremental claims cost from Table 3 by the corresponding member months, estimated as part of the population estimate described in Appendix A, to calculate the PMPM cost shown in Table 4.

Table 4. Projected PMPM Cost for Universal cCMV Screening

	2022	2024	2025	2026	2027	2028
Low Scenario	$0.08	$0.10	$0.10	$0.11	$0.12	$0.12
Mid Scenario	$0.10	$0.11	$0.12	$0.12	$0.13	$0.14
High Scenario	$0.11	$0.12	$0.13	$0.14	$0.15	$0.15

5.2 Follow-Up Costs for Infants Testing Positive for cCMV With No Symptoms

This section explains the calculations for marginal costs incurred by asymptomatic cCMV-infected infants at birth. Under universal testing, these infants will incur follow-up services not currently performed or in insurance carrier costs.

As discussed in the prior section, there were approximately 17,632 infants born in the fully insured population, with 88 infants (0.5%) testing positive for cCMV. Approximately 10% of infants with cCMV infection will be symptomatic at birth, exhibiting two or more features with central nervous system involvement.[9] These infants are likely screened for cCMV and already incur treatment and follow-up costs. Approximately 10 – 15% of infants with cCMV infection will be asymptomatic (without clinically apparent disease) at birth but will develop symptoms later and are at risk for developing long-term neurodevelopmental complications and disability. Finally, 75 – 80% of infants born with cCMV infection will remain asymptomatic and unlikely to develop significant related health conditions. Conservatively, BerryDunn assumed that 15% of infants who test positive would later be symptomatic and that 75% will test positive but never be symptomatic. BerryDunn calculated the number of infants in the three categories. Table 5 displays these results.

Table 5. Distribution of cCMV-Positive Infants

	% OF INFANTS	NUMBER OF INFANTS
Positive Symptomatic at Birth	10%	9
Positive Not Symptomatic at Birth	90%	79
Positive Later Symptomatic	*15%*	*13*
Positive Never Symptomatic	*75%*	*66*
Total	100%	88

Next, BerryDunn developed the cost of follow-up for each infant. A 2016 study reported the annual cost of follow-up care for infants testing positively for cCMV at $1,238.[10] BerryDunn multiplied these follow-up costs per service by the average national cost increases for physician and clinical services between 2016 and 2020, which were reported at 3%.[11] This average excluded the 2020 impact of COVID-19. Adjusting the follow-up costs from the study to 2020 results in a total of $1,393 per infant. BerryDunn's review of the follow-up services in the APCD, however, suggested a higher per-infant cost for cCMV-related follow-up services. BerryDunn used the cost per service by carrier in the APCD to develop a cost range.

Initial tests incurred in the infants' first year account for most follow-up costs. The costs also include two audiologist follow-up visits per year in subsequent years. Over the projection period, the cost of audiologist follow-up visits would ramp up. The ramp up is due to the cost of the annual follow up visits from prior cohorts which is added to the cost of new cCMV-positive infant cohorts. Since follow-up care continues through age 6, the ramp up will continue through the projection period. Table 6 presents the impact of this ramp up on the annual cost amounts.

Table 6. Projected Cost per Infant for cCMV Follow-Up Services

	2020	2024	2025	2026	2027	2028
Low Scenario	$1,311	$1,311	$1,656	$2,000	$2,345	$2,689
Mid Scenario	$1,843	$1,843	$2,301	$2,758	$3,215	$3,672
High Scenario	$2,375	$2,375	$2,945	$3,515	$4,085	$4,655

The values in Table 6 are not adjusted for yearly increases in the cost of services. BerryDunn multiplied the cost per infant in Table 6 by the long-term average national projection for cost increases for physician and clinical services, which are reported at 5.9%[12] over the projection period, to estimate the cost per test over the projection period.

Table 7. Projected Cost per Infant for Inflation-Adjusted cCMV Follow-Up Services

	2024	2025	2026	2027	2028
Low Scenario	$1,649	$2,205	$2,821	$3,502	$4,254
Mid Scenario	$2,319	$3,064	$3,890	$4,802	$5,809
High Scenario	$2,987	$3,923	$4,958	$6,102	$7,364

BerryDunn multiplied the 79 infants with no symptoms at birth, from Table 5, by the costs per infant from Table 7 to calculate the total incremental claims cost of follow-up care for infants with cCMV but with no symptoms at birth. Table 8 displays these results. This approach is slightly conservative because 13 of the 79 infants who were not symptomatic at birth will become symptomatic. The current cost paid by the carriers would include the follow-up care once a child becomes symptomatic. With very few infants, and only two follow-up visits per year included in the current covered cost, the impact of including these costs is not material and only slightly increases the estimate.

Table 8. Projected Marginal Cost for cCMV Follow-Up Services

	2024	2025	2026	2027	2028
Low Scenario	$130,301	$174,228	$222,885	$276,676	$336,039
Mid Scenario	$183,168	$242,083	$307,312	$379,395	$458,914
High Scenario	$235,980	$309,879	$391,677	$482,049	$581,721

BerryDunn next divided the incremental claims cost from Table 8 by the corresponding member months to calculate the PMPM cost, as shown in Table 9.

Table 9. Projected Marginal PMPM Cost for cCMV Follow-Up Services

	2024	2025	2026	2027	2028
Low Scenario	$0.00	$0.01	$0.01	$0.01	$0.01
Mid Scenario	$0.01	$0.01	$0.01	$0.01	$0.02
High Scenario	$0.01	$0.01	$0.01	$0.02	$0.02

5.3 Antiviral Treatment Cost for Infants Not Screened with Symptoms

Symptomatic infants are screened for cCMV at birth; if they test positive, they are treated with antiviral therapy. The Massachusetts cCMV Coalition notes that, in the absence of universal screening, "families cannot benefit from early detection and interventions, including the administration of antiviral medications, that could prevent further progression of hearing loss and additional symptoms."[13] However, the Centers for Disease Control and Prevention (CDC) designated antivirals "for babies with signs of congenital CMV infection at birth" and noted that antiviral medications (primarily valganciclovir) "can have serious side effects and has only been studied in babies with signs of congenital CMV infection."[14]

It may be possible that an infant with cCMV symptoms at birth is not tested for cCMV and does not currently receive antiviral treatments available for newborn cCMV infection. Under the proposed bill, universal screening would identify these infants and potentially add incremental costs for antiviral treatment. To quantify the potential impact, BerryDunn used the APCD and compared the number of infants screened for cCMV with a positive diagnosis to the number of infants receiving antiviral treatment. With universal screening, BerryDunn estimates one or two newly identified infants may receive antiviral treatment. The antiviral treatment paid claim cost in the APCD is about $3,500 per infant. The potential incremental cost of $7,000 is not material to this analysis, and the high end of the cost range accounts for this uncertainty.

5.4 Marginal Cost PMPM

The total PMPM marginal cost results from the addition of the estimated PMPM costs associated with universal screening and with follow-up care for cCMV infants with no symptoms (from Tables 4 and 9 and as shown in Table 10).

Table 10. Estimated Marginal PMPM Claims Cost of Mandate

	2024	2025	2026	2027	2028
Low Scenario	$0.10	$0.11	$0.12	$0.13	$0.14
Mid Scenario	$0.12	$0.13	$0.14	$0.15	$0.16
High Scenario	$0.13	$0.14	$0.15	$0.16	$0.18

5.5 Projected Fully Insured Population in the Commonwealth

Table 11 shows the fully insured population in the Commonwealth ages 0 to 64 projected for the next five years. Appendix A describes the sources of these values.

Table 11. Projected Fully Insured Population in the Commonwealth, Ages 0 – 64

YEAR	2024	2025	2026	2027	2028
Total (0 – 64)	2,241,736	2,262,201	2,265,778	2,268,960	2,270,746

5.6 Total Marginal Medical Expense

The analysis assumes the mandate would be effective for policies issued and renewed on or after January 1, 2024. The incremental impact of universal cCMV screening would be immediate, meaning the impact would take effect even before a policy renews, because carriers currently cover the services included in the mandate. Coverage for follow up care would also be immediate but would ramp up over the projection period as described in Section 5.2

Multiplying the total estimated PMPM cost by the projected fully insured membership over the analysis period results in the total cost (medical expense) associated with the proposed requirement, as shown in Table 12.

Table 12. Estimated Marginal Claims Cost

	2024	2025	2026	2027	2028
Low Scenario	$2,804,716	$3,006,433	$3,222,190	$3,452,941	$3,699,704
Mid Scenario	$3,191,885	$3,428,314	$3,681,530	$3,952,692	$4,243,036
High Scenario	$3,578,998	$3,850,136	$4,140,809	$4,452,379	$4,786,301

5.7 Carrier Retention and Increase in Premium

Assuming an average retention rate of 14.1%—based on CHIA's analysis of administrative costs and profit in the Commonwealth[15]—the increase in medical expense was adjusted upward to approximate the total impact on premiums. Table 13 displays the result.

Table 13: Estimate of Increase in Carrier Premium Expense

	2024	2025	2026	2027	2028
Low Scenario	$3,266,660	$3,501,601	$3,752,893	$4,021,649	$4,309,055
Mid Scenario	$3,717,597	$3,992,966	$4,287,888	$4,603,711	$4,941,875
High Scenario	$4,168,469	$4,484,263	$4,822,811	$5,185,698	$5,574,617

6.0 Results

The estimated impact of the proposed requirement on medical expenses and premiums appears in Table 14 below. The analysis includes development of a best estimate mid-level scenario as well as a low-level scenario and a high-level scenario using more conservative assumptions. The impact on premiums is driven by the provisions of the bill that require universal testing for cCMV and the resulting additional follow-up services. Variation between scenarios is attributable to the uncertainty surrounding the cost per screening and follow-up services.

6.1 Five-Year Estimated Impact

For each year in the five-year analysis period, Table 14 displays the projected net impact of the proposed language on medical expenses and premiums using a projection of Commonwealth fully insured membership. Note that the relevant provisions are assumed effective January 1, 2024.[16] Low, mid, and high scenarios vary in the estimated cost per screening for cCMV and the cost per therapy and follow-up. The low scenario would result in $3.8 million per year on average. The high scenario's projected impact is $4.8 million The mid scenario would result in average annual costs of $4.3 million, or an average of 0.027% of premiums.

Finally, the impact of the proposed law on any one individual, employer group, or carrier may vary from the overall results, depending on the current level of benefits each receives or provides and how the benefits will change under the proposed language.

Table 14. Summary Results

	2024	2025	2026	2027	2028	WEIGHTED AVERAGE	FIVE-YEAR TOTAL
Average Members (000s)	2,242	2,262	2,266	2,269	2,271		
Medical Expense Low ($000s)	$2,805	$3,006	$3,222	$3,453	$3,700	$3,237	$16,186
Medical Expense Mid ($000s)	$3,192	$3,428	$3,682	$3,953	$4,243	$3,699	$18,497
Medical Expense High ($000s)	$3,579	$3,850	$4,141	$4,452	$4,786	$4,162	$20,809
Premium Low ($000s)	$3,267	$3,502	$3,753	$4,022	$4,309	$3,770	$18,852
Premium Mid ($000s)	$3,718	$3,993	$4,288	$4,604	$4,942	$4,309	$21,544
Premium High ($000s)	$4,168	$4,484	$4,823	$5,186	$5,575	$4,847	$24,236
PMPM Low	$0.12	$0.13	$0.14	$0.15	$0.16	$0.14	$0.14
PMPM Mid	$0.14	$0.15	$0.16	$0.17	$0.18	$0.16	$0.16
PMPM High	$0.15	$0.17	$0.18	$0.19	$0.20	$0.18	$0.18
Estimated Monthly Premium	$562	$577	$593	$609	$625	$593	$593
Premium % Rise Low	0.022%	0.022%	0.023%	0.024%	0.025%	0.023%	0.023%
Premium % Rise Mid	0.025%	0.025%	0.027%	0.028%	0.029%	0.027%	0.027%
Premium % Rise High	0.028%	0.029%	0.030%	0.031%	0.033%	0.030%	0.030%

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6.2 Impact on GIC

The proposed mandate would apply to self-insured plans operating for state and local employees by the GIC. The benefit offerings of GIC plans are similar to most other commercial plans in Massachusetts. This section describes the results for the GIC.

Findings from BerryDunn's carrier survey indicate that benefit offerings for GIC and other commercial plans in the Commonwealth are similar. For this reason, the cost of the bill for GIC will likely be similar to the cost for other fully insured plans in the Commonwealth.

BerryDunn assumed the proposed legislative change will apply to self-insured plans that the GIC operates for state and local employees, with an effective date of July 1, 2024. The incremental impact of universal cCMV screening would be immediate, meaning the impact would take effect even before a policy renews, because carriers currently cover the services included in the mandate. Coverage for follow up care would also be immediate but would ramp up over the projection period as described in Section 5.2

Table 15 breaks out the GIC's self-insured membership as well as the corresponding incremental medical expense.

Table 15. GIC Summary Results

	2024	2025	2026	2027	2028	WEIGHTED AVERAGE	FIVE-YEAR TOTAL
GIC Self-Insured							
Members (000s)	312	312	311	311	310		
Medical Expense Low ($000s)	$391	$414	$443	$473	$505	$445	$2,226
Medical Expense Mid ($000s)	$445	$473	$506	$541	$579	$509	$2,543
Medical Expense High ($000s)	$499	$531	$569	$610	$654	$572	$2,861

Endnotes

[1] The bill, as currently written, does not include Chapter 176A. However, the sponsors confirmed that the bill's intent is to include Chapter 176A.

[2] Massachusetts Department of Public Health. "105 CMR 270.00: Blood screening of newborns for treatable diseases and disorders." Accessed January 3, 2023. **https://www.mass.gov/regulations/105-CMR-27000-blood-screening-of-newborns-for-treatable-diseases-and-disorders**.

[3] Massachusetts cCMV Coalition. "CMV Fact Sheet." Accessed January 9, 2023. **https://cmvmass.org/factsheet/.**

[4] Gantt, S., Dionne, F., Kozak, F. K., Goshen, O., Goldfarb, D. M., Park, A. H., Boppana, S. B., and Fowler, K. 2016. "Cost-effectiveness of Universal and Targeted Newborn Screening for Congenital Cytomegalovirus Infection." *JAMA Pediatrics* 170(12): 1173 – 1180. **https://doi.org/10.1001/jamapediatrics.2016.2016**.

[5] Massachusetts Department of Public Health. February 2022. "Massachusetts Births 2019, Registry of Vital Records and Statistics." Accessed October 25, 2022. **https://www.mass.gov/doc/2019-birth-report/download**.

[6] Centers for Disease Control and Prevention. "Congenital CMV and Hearing Loss." Accessed January 6, 2023. **https://www.cdc.gov/cmv/hearing-loss.html**.

[7] Gillespie, A.N., Dalziel, K., Webb, E., Wong, J., Jones, C.A., and Sung, V. 2022. "Targeted screening for congenital cytomegalovirus: A micro-costing analysis." *J Paediatr Child Health*. Accessed January 3, 2023. **https://doi.org/10.1111/jpc.16239**.

[8] U.S. Centers for Medicare & Medicaid Services, Office of the Actuary. National Health Expenditure Projections. "Table 6, Hospital Care Expenditures; Aggregate and per Capita Amounts, Percent Distribution and Annual Percent Change by Source of Funds: Calendar Years 2018-2027; Private Insurance." Accessed May 23, 2022. **https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html**.

[9] Megan H. Pesch and Mark R. Schleiss. August 2022. "Emerging Concepts in Congenital Cytomegalovirus." *Pediatrics* 150(2): e2021055896. Accessed January 9, 2023. **https://publications.aap.org/pediatrics/article-abstract/150/2/e2021055896/188582/Emerging-Concepts-in-Congenital-Cytomegalovirus?redirectedFrom=fulltext**.

[10] Gantt, S., Dionne, F., Kozak, F. K., Goshen, O., Goldfarb, D. M., Park, A. H., Boppana, S. B., and Fowler, K. 2016. "Cost-effectiveness of Universal and Targeted Newborn Screening for Congenital Cytomegalovirus Infection." *JAMA Pediatrics* 170(12): 1173 – 1180. **https://doi.org/10.1001/jamapediatrics.2016.2016**.

[11] *Op. cit. U.S. Centers for Medicare & Medicaid Services, Office of the Actuary. National Health Expenditure Projections. Table 6, Hospital Care Expenditures; Aggregate and per Capita Amounts, Percent Distribution and Annual Percent Change by Source of Funds: Calendar Years 2018-2027; Private Insurance.*

[12] *Ibid.*

[13] *Op. cit. Massachusetts cCMV Coalition. CMV Fact Sheet.*

[14] Centers for Disease Control and Prevention. "Babies Born with Congenital Cytomegalovirus (CMV)." Accessed January 13, 2023. **https://www.cdc.gov/cmv/congenital-infection.html**.

[15] Massachusetts Center for Health Information and Analysis. September 2017. *Annual Report on the Massachusetts Health Care System*. Accessed September 14, 2022. **http://www.chiamass.gov/annual-report**.

[16] With an assumed start date of January 1, 2016, dollars were estimated at 70.7% of the annual cost based upon an assumed renewal distribution by month (January through December) by market segment and the Massachusetts market segment composition.

Appendix A: Membership Affected by the Proposed Language

Membership potentially affected by proposed mandated change criteria includes Commonwealth residents with fully insured, employer-sponsored health insurance issued by a Commonwealth-licensed company; nonresidents with fully insured, employer-sponsored insurance issued in the Commonwealth; Commonwealth residents with individual (direct) health insurance coverage; and lives covered by GIC self-insured coverage. Other populations within the self-insured commercial sector are excluded from the state coverage mandate due to federal Employee Retirement Income Security Act (ERISA) protections of self-insured plans.

The unprecedented economic circumstances due to COVID-19 add particular challenges to the estimation of health plan membership. 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. Given the uncertainty, BerryDunn took a simplified approach to the membership projections. These membership projections are not intended for any purpose other than producing the total dollar range in this study. Further, to assess how recent volatility in commercial enrollment levels might affect these cost estimates, please note that the PMPM and percentage of premium estimates are unaffected because they are per-person estimates, and the total dollar estimates will vary by the same percentage as any percentage change in enrollment levels.

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

CHIA publishes monthly enrollment summaries in addition to its biannual enrollment trends report and supporting databook (enrollment-trends-Data Through September 2021 databook[1] and Monthly Enrollment Summary – June 2021[2]), 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.

The DOI-published reports titled Quarterly Report of HMO Membership in Closed Network Health Plans as of December 31, 2018,[3] and Massachusetts DOI Annual Report Membership in Medical Insured Preferred Provider Plans by County as of December 31, 2018.[4] These reports provide fully insured covered members for licensed Commonwealth insurers for members with a primary residence is the Commonwealth. The DOI reporting includes all insurance carriers and was used to supplement the Massachusetts APCD membership for small carriers not in the Massachusetts APCD.

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. When the PHE ends, redetermination efforts will begin, at which time these individuals 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. Although the impact of COVID-19 on the fully insured market over the five-year projected period (2023 – 2027) is uncertain,

BerryDunn has made the following assumptions to estimate membership:

- The federal PHE will end in 2023
- Redetermination will occur over 12 months for MassHealth members[5]
- MassHealth members will be eligible for commercially insured plans

BerryDunn assumes 80% of the commercial membership reductions that occurred during the PHE will return to the commercial market by the end of 2023. BerryDunn further assumes that the remainder of this membership will return to the commercial market by the end of the projection period in December 2027.

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.[6] Membership was projected from 2022 – 2028 using Massachusetts Department of Transportation population growth rate estimates by age and gender.[7]

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 U.S. Census Bureau used for the Commonwealth population. Breakdowns of the GIC self-insured lives by gender and age were based on U.S. Census Bureau distributions.

Appendix A Endnotes

[1] Center for Health Information and Analysis. "Estimates of fully insured and self-insured membership by insurance carrier." Accessed November 15, 2020. **https://www.chiamass.gov/enrollment-in-health-insurance/**.

[2] Ibid.

[3] Massachusetts Division of Insurance. "HMO Group Membership and HMO Individual Membership." Accessed November 12, 2020. **https://www.mass.gov/doc/group-members/download; https://www.mass.gov/doc/individual-members/download**.

[4] Massachusetts Division of Insurance. "Membership 2018." Accessed November 12, 2020. **https://www.mass.gov/doc/2018-ippp-medical-plans/download**.

[5] Blue Cross Blue Shield of Massachusetts Foundation. "The End of the Federal Continuous Coverage Requirement in MassHealth." Accessed September 22, 2022. **https://www.bluecrossmafoundation.org/publication/end-federal-continuous-coverage-requirement-masshealth-key-strategies-reducing-coverage**.

[6] U.S. Census Bureau. "Annual Estimates of the Population for the United States, Regions, States, and Puerto Rico: April 1, 2010 to July 1, 2018." Accessed November 12, 2020. **https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk**.

[7] Massachusetts Department of Transportation. "Socio-Economic Projections for 2020 Regional Transportation Plans." Accessed November 12, 2020. **https://www.mass.gov/lists/socio-economic-projections-for-2020-regional-transportation-plans**.