SENATE DOCKET, NO. 1958 FILED ON: 1/20/2023

SENATE . . . . . No. 1405

The Commonwealth of Massachusetts

PRESENTED BY:

Joan B. Lovely

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

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

An Act relative to newborn screenings for congenital cytomegalovirus.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	
Joan B. Lovely	*Second Essex*	
Sal N. DiDomenico	*Middlesex and Suffolk*	*2/8/2023*
Ryan C. Fattman	*Worcester and Hampden*	*3/20/2023*
Patrick M. O'Connor	*First Plymouth and Norfolk*	*3/20/2023*
Joanne M. Comerford	*Hampshire, Franklin and Worcester*	*3/20/2023*
James B. Eldridge	*Middlesex and Worcester*	*3/20/2023*
Michael O. Moore	*Second Worcester*	*3/20/2023*
Anne M. Gobi	*Worcester and Hampshire*	*4/7/2023*
Brendan P. Crighton	*Third Essex*	*4/7/2023*
Jason M. Lewis	*Fifth Middlesex*	*4/7/2023*
John F. Keenan	*Norfolk and Plymouth*	*4/26/2023*
Bruce E. Tarr	*First Essex and Middlesex*	*7/24/2023*
Kristin E. Kassner	*2nd Essex*	*11/15/2023*
Robyn K. Kennedy	*First Worcester*	*12/20/2023*

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SENATE . . . . . No. 1405

By Ms. Lovely, a petition (accompanied by bill, Senate, No. 1405) of Joan B. Lovely and Sal N. DiDomenico for legislation relative to newborn screenings for congenital cytomegalovirus. Public Health.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE SENATE, NO. *1471* OF 2021-2022.]

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Third General Court
(2023-2024)

An Act relative to newborn screenings for congenital cytomegalovirus.

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

SECTION 1. Chapter 111 of the General Laws, as appearing in the 2020 Official Edition, is hereby further amended by inserting after Section 70H the following section:-

Section 70I: Congenital cytomegalovirus; public information program; annual report

(a) The commissioner of the department shall establish, promote, and maintain a public information program regarding congenital cytomegalovirus, hereinafter referred to as cCMV. Such program shall be conducted throughout the commonwealth, and under said program, a hospital or birthing facility as defined in section 70E or any healthcare provider, physician assistant, nurse or midwife who renders prenatal or postnatal care shall give expectant or new parents or guardians information provided by the department under subsection (b). Such

information shall be made available at the first prenatal appointment or at a preconception visit if applicable, whichever is earliest.

(b) The department shall make available to any healthcare provider, physician assistant, nurse or midwife who renders 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 that has been vetted by an appropriate group of medical experts as determined by the department in conjunction with the advisory committee as established in section 110J of said Chapter 111; provided, however, that the written information provided shall include preventative measures that can be taken throughout pregnancy, and (ii) contact or other referral information for additional educational and support resources. The department may also make such information available to any other person who seeks information about cCMV infections.

SECTION 2. Said chapter 111 is hereby further amended by inserting after section 110C the following sections:-

Section 110D: Required Newborn Screening for Congenital Cytomegalovirus

For the purposes of this section, the following words shall, unless the context clearly requires otherwise, have the following meanings:-

“Birthing facility”, an inpatient or ambulatory health care facility licensed by the department of public health that provides birthing and newborn care services.

"Congenital Cytomegalovirus (hereinafter referred to as cCMV) screening", the identification of a newborn who may have congenital CMV infection or has cCMV confirmed through the use of a saliva or urine test.

"Department", the department of public health.

"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.

The department, in consultation with the perinatal advisory committee, shall develop regulations for all hospitals and birthing facilities requiring cCMV screening within one year of the passage of this legislation. These regulations shall consider evidence-based guidance.

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 department may approve another test to conduct cCMV screening; provided, however, that the test shall be, at the discretion of the department, at least as accurate, widely available and cost-effective as a saliva or urine PCR test. A screening shall 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; provided, however, that the screening shall not be performed 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 educational materials outlined in section 70I(b) shall be provided to the parent or guardian of the infant at the time of cCMV screening.

A hospital that provides birthing and newborn services or a birthing facility shall adopt protocols for cCMV screening using a saliva or urine PCR test or another test approved by the department under this section for all newborns prior to discharge, and not to exceed 21 days from the date of birth, based on the department's regulations, on or before January 1, 2025.

The cost of providing the newborn cCMV screening shall 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 shall be paid by the Commonwealth.

A hospital or birthing facility shall report annually to the department data including, but not limited to, the number of cCMV tests administered and the outcomes of said tests. The hospital or birthing facility shall inform, orally and in writing, a parent or guardian of the newborn infant the result of the cCMV screening test regardless of its outcome. This information shall also be provided in writing to the newborn infant's primary care physician and to the department through its electronic birth certificate system or such mechanism as specified by the department.

The department shall review the protocols required under this section and the implementation of these protocols as part of its birthing facility licensure review processes.

The department shall promulgate regulations to implement the cCMV screening program.

Nothing in this statute shall preclude newborns born at home from obtaining said cCMV screening.

Section 110E: Advisory Committee for CMV Screening Program

There is hereby established an advisory committee for the purpose of implementing the provisions of Section 110I. The advisory committee shall consist of the following members to be appointed by the commissioner of the department: a representative of the hospital industry; a primary care pediatrician or family practitioner; an otolaryngologist; a neonatologist; an infectious disease specialist; a clinician representing newborn nurseries; an audiologist; an ophthalmologist; an obstetrician-gynecologist; a representative of the commonwealth's early intervention program; 2 parents and/or guardians of a child impacted by cCMV; 2 medical professionals; a developer of preventative and/or therapeutic interventions for cCMV; a teacher of the deaf; and a representative of the department.

The advisory committee shall advise the department regarding the validity and cost of proposed cCMV regulations and/or cCMV screening, and shall recommend standards for performing and interpreting screening tests based on the most current technological methods, for documenting test results and follow-up, and for facilitating interaction between professionals and agencies that participate in follow-up care. Members of the advisory committee shall serve without compensation. The advisory committee shall be provided support services by the department.