

HOUSE No. 2338

The Commonwealth of Massachusetts

PRESENTED BY:

Kay Khan

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: | DATE ADDED: |
|------------------------------------|-----------------------|------------------|
| <i>Kay Khan</i> | <i>11th Middlesex</i> | <i>2/18/2021</i> |
| <i>Jack Patrick Lewis</i> | <i>7th Middlesex</i> | <i>2/19/2021</i> |
| <i>Paul J. Donato</i> | <i>35th Middlesex</i> | <i>2/22/2021</i> |
| <i>Tami L. Gouveia</i> | <i>14th Middlesex</i> | <i>2/22/2021</i> |
| <i>Edward F. Copping</i> | <i>10th Suffolk</i> | <i>2/22/2021</i> |
| <i>Patricia A. Duffy</i> | <i>5th Hampden</i> | <i>2/23/2021</i> |
| <i>Brian W. Murray</i> | <i>10th Worcester</i> | <i>2/23/2021</i> |
| <i>Lindsay N. Sabadosa</i> | <i>1st Hampshire</i> | <i>2/24/2021</i> |
| <i>Adrian C. Madaro</i> | <i>1st Suffolk</i> | <i>2/24/2021</i> |
| <i>Paul W. Mark</i> | <i>2nd Berkshire</i> | <i>2/25/2021</i> |
| <i>David Henry Argosky LeBoeuf</i> | <i>17th Worcester</i> | <i>2/26/2021</i> |
| <i>Kate Lipper-Garabedian</i> | <i>32nd Middlesex</i> | <i>2/26/2021</i> |
| <i>David Biele</i> | <i>4th Suffolk</i> | <i>3/3/2021</i> |
| <i>Bradley H. Jones, Jr.</i> | <i>20th Middlesex</i> | <i>3/9/2021</i> |
| <i>Joan B. Lovely</i> | <i>Second Essex</i> | <i>3/1/2021</i> |
| <i>Jacob R. Oliveira</i> | <i>7th Hampden</i> | <i>3/3/2021</i> |
| <i>Angelo J. Puppolo, Jr.</i> | <i>12th Hampden</i> | <i>3/5/2021</i> |
| <i>Joseph D. McKenna</i> | <i>18th Worcester</i> | <i>3/9/2021</i> |

| | | |
|---------------------------|-----------------------|------------------|
| <i>Paul K. Frost</i> | <i>7th Worcester</i> | <i>3/9/2021</i> |
| <i>Peter Capano</i> | <i>11th Essex</i> | <i>3/11/2021</i> |
| <i>Hannah Kane</i> | <i>11th Worcester</i> | <i>3/11/2021</i> |
| <i>Paul F. Tucker</i> | <i>7th Essex</i> | <i>3/15/2021</i> |
| <i>Jay D. Livingstone</i> | <i>8th Suffolk</i> | <i>3/29/2021</i> |
| <i>Mary S. Keefe</i> | <i>15th Worcester</i> | <i>4/1/2021</i> |
| <i>Brian M. Ashe</i> | <i>2nd Hampden</i> | <i>4/26/2021</i> |
| <i>Natalie M. Higgins</i> | <i>4th Worcester</i> | <i>4/29/2021</i> |
| <i>Steven C. Owens</i> | <i>29th Middlesex</i> | <i>5/7/2021</i> |
| <i>Sally P. Kerans</i> | <i>13th Essex</i> | <i>5/7/2021</i> |
| <i>Thomas M. Stanley</i> | <i>9th Middlesex</i> | <i>6/23/2021</i> |
| <i>Sean Garballey</i> | <i>23rd Middlesex</i> | <i>8/2/2021</i> |

HOUSE No. 2338

By Ms. Khan of Newton, a petition (accompanied by bill, House, No. 2338) of Kay Khan and others relative to newborn screenings for congenital cytomegalovirus. Public Health.

The Commonwealth of Massachusetts

**In the One Hundred and Ninety-Second General Court
(2021-2022)**

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:

1 Chapter 111 of the General Laws is hereby amended by inserting after section 110H the
2 following sections:-

3 Section 110I: Required Newborn Screening for Congenital Cytomegalovirus

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

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

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

11 “Department”, the department of public health.

12 “Newborn,” any liveborn infant who has not yet attained the age of 21 days from a birth
13 occurring in the commonwealth or from a birth prior to transfer to a hospital in the
14 commonwealth.

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

18 The cCMV screening shall be performed using a saliva PCR test unless one is
19 unavailable in which case a urine PCR test may be used. If positive, a saliva PCR test would
20 require a confirmatory urine PCR test. The department may approve another test to conduct
21 cCMV screening; provided, however, that the test shall be, at the discretion of the department, at
22 least as accurate, widely available and cost-effective as a saliva or urine PCR test. A screening
23 shall be performed within 21 days from the date of birth and before the newborn infant is
24 discharged from the birthing facility to the care of the parent or guardian; provided, however,
25 that the screening shall not be performed if the parent or guardian of the newborn infant objects
26 to the screening based upon a sincerely held religious belief of the parent or guardian. The
27 cCMV educational materials outlined in section 70I(b) shall be provided to the parent or
28 guardian of the infant at the time of cCMV screening.

29 A hospital that provides birthing and newborn services or a birthing facility shall adopt
30 protocols for cCMV screening using a saliva or urine PCR test or another test approved by the
31 department under this section for all newborns prior to discharge, and not to exceed 21 days from
32 the date of birth, based on the department’s regulations, on or before January 1, 2023.

33 The cost of providing the newborn cCMV screening shall be a covered benefit
34 reimbursable by all health insurers, except for supplemental policies that only provide coverage
35 for specific diseases, hospital indemnity, Medicare supplement or other supplemental policies. In
36 the absence of a third-party payer, the charges for the newborn cCMV screening shall be paid by
37 the Commonwealth.

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

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

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

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

50 Section 110J: Advisory Committee for CMV Screening Program

51 There is hereby established an advisory committee for the purpose of implementing the
52 provisions of Section 110I. The advisory committee shall consist of the following members to be
53 appointed by the commissioner of the department: a representative of the hospital industry; a

54 primary care pediatrician or family practitioner; an otolaryngologist; a neonatologist; an
55 infectious disease specialist; a clinician representing newborn nurseries; an audiologist; an
56 ophthalmologist; an obstetrician-gynecologist; a representative of the commonwealth's early
57 intervention program; 2 parents and/or guardians of a child impacted by cCMV; 2 medical
58 professionals; a developer of preventative and/or therapeutic interventions for cCMV; a teacher
59 of the deaf; and a representative of the department.

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

67 Chapter 111 of the General Laws is hereby further amended by inserting after Section
68 70H the following section:-

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

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

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

78 (b) The department shall make available to any healthcare provider, physician assistant,
79 nurse or midwife who renders prenatal or postnatal care or offers fertility counseling or care to a
80 parent or guardian the following: (i) up-to-date evidence-based, written information about cCMV
81 and universal cCMV screening that has been vetted by an appropriate group of medical experts
82 as determined by the department in conjunction with the advisory committee as established in
83 section 110J of said Chapter 111; provided, however, that the written information provided shall
84 include preventative measures that can be taken throughout pregnancy, and (ii) contact or other
85 referral information for additional educational and support resources. The department may also
86 make such information available to any other person who seeks information about cCMV
87 infections.