HOUSE AMENDED

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL No. 709 Session of 2021

INTRODUCED BY TOMLINSON, MARTIN, MENSCH, FONTANA, DİSANTO, STEFANO, SABATINA, KEARNEY, AUMENT, COSTA, SANTARSIERO, COLLETT, L. WILLIAMS, TARTAGLIONE, HAYWOOD AND COMITTA, MAY 25, 2021

AS AMENDED ON SECOND CONSIDERATION, HOUSE OF REPRESENTATIVES, JUNE 14, 2022

AN ACT

Providing for cytomegalovirus education and newborn screening. 1 2 The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows: 3 Section 1. Short title. 4 5 This act shall be known and may be cited as the CMV Education 6 and Newborn Screening Act. Section 2. Definitions. 7 8 The following words and phrases when used in this act shall 9 have the meanings given to them in this section unless the context clearly indicates otherwise: 10 11 "Birthing facility." An inpatient or ambulatory health care 12 facility licensed by the department that provides birthing and 13 newborn care services. "Certified-nurse midwife." An individual licensed by 14 15 the State Board of Medicine to practice midwifery under section

35 of the act of December 20, 1985 (P.L.457, No.112), known as
 the Medical Practice Act of 1985.

3 "CMV." Cytomegalovirus.

4 "Department." The Department of Health of the Commonwealth.

5 "Direct entry midwife." An independent practitioner educated <--</p>
6 in the discipline of midwifery through self-study,

7 apprenticeship, a midwifery school or a college or university-

8 based program distinct from the discipline of nursing. The term-

9 includes certified professional midwives, traditional midwives,

10 Amish, Mennonite or Plain midwives and other specific cultural-

11 or spiritual community-based midwives not licensed by the State-

12 Board of Medicine as a certified-nurse midwife.

Health care practitioner." The term shall have the same meaning as defined in section 103 of the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.

16 "Newborn child." A child under 21 days of age.

"UNLICENSED MIDWIFE." THE TERM SHALL HAVE THE SAME MEANING <--
AS DEFINED IN SECTION 2 OF THE ACT OF SEPTEMBER 9, 1965
(P.L.497, NO.251), KNOWN AS THE NEWBORN CHILD TESTING ACT.
Section 3. Informational publications by department.

(a) General rule.--The department shall make the following available on the department's publicly accessible Internet website:

(1) Up-to-date, evidence-based information about CMV
that has been reviewed by medical experts and national CMV
organizations. The information provided shall include the
following:

28 (i) Th

(i) The incidence of CMV.

29 (ii) The transmission of CMV to pregnant women and
30 women who may become pregnant.

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1 (iii) Birth defects caused by congenital CMV. 2 (iv) Methods of diagnosing congenital CMV. 3 (V) Available preventive measures. 4 (vi) Treatment options. 5 Any other information the department deems (vii) 6 necessary. 7 Contact information regarding support programs and (2) 8 services, including the following: 9 Information hotlines specific to CMV. (i) 10 (ii) Relevant resource centers or clearinghouses. National and local CMV organizations. 11 (iii) 12 Educational and support programs. (iv) 13 (b) Form.--The information provided in accordance with this 14 act shall conform to the applicable standard or standards 15 provided in the enhanced "National Standards for Culturally and 16 Linguistically Appropriate Services in Health and Health Care," as adopted by the United States Department of Health and Human 17 18 Services and published in the Federal Register on September 24, 19 2013. 20 Section 4. Dissemination of information on CMV. 21 Requirement.--A certified-nurse midwife, direct-entry-(a) <---22 midwife or A health care practitioner OR AN UNLICENSED MIDWIFE <---23 that assumes responsibility for the prenatal care of a pregnant 24 woman or a woman who may become pregnant shall provide the <---25 educational information regarding CMV made available by the 26 department under section 3. 27 (b) Compliance.--Delivery of information prepared by the 28 department in accordance with section 3 shall constitute 29 compliance with this section.

30 Section 5. CMV newborn screening.

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1 (a) General rule. Except as provided for in subsection <--</p>
2 (c), the department shall require a birthing facility or a
3 certified nurse midwife, direct entry midwife or health care
4 practitioner that assumes care of a newborn child to screen the
5 newborn child for CMV before the newborn child is 21 days of age
6 if:

7 (1) the newborn child fails the initial newborn hearing8 screening under the act of November 30, 2001 (P.L.849, 9 No.89), known as the Infant Hearing Education, Assessment, 10 Reporting and Referral (IHEARR) Act; or

11 (2) the parent or guardian of a newborn child requests
12 that the newborn child be screened for CMV.

13 (A) REQUIREMENT.--THE DEPARTMENT SHALL REQUIRE A BIRTHING <---14 FACILITY, A CERTIFIED-NURSE MIDWIFE, A HEALTH CARE PRACTITIONER OR AN UNLICENSED MIDWIFE THAT ASSUMES CARE OF A NEWBORN CHILD TO 15 16 OFFER THE PARENT OR GUARDIAN OF THE NEWBORN CHILD SCREENING FOR CMV, OR A REFERRAL FOR SCREENING FOR CMV, BEFORE THE NEWBORN 17 18 CHILD IS 21 DAYS OF AGE IF THE NEWBORN CHILD FAILS THE INITIAL 19 NEWBORN HEARING SCREENING UNDER THE ACT OF NOVEMBER 30, 2001 (P.L.849, NO.89), KNOWN AS THE INFANT HEARING EDUCATION, 20 ASSESSMENT, REPORTING AND REFERRAL (IHEARR) ACT. 21

22 (B) CONSENT REQUIRED.--BEFORE A CMV SCREENING IS PERFORMED 23 ON A NEWBORN CHILD, A PARENT OR GUARDIAN OF THE NEWBORN CHILD 24 SHALL PROVIDE WRITTEN CONSENT TO A BIRTHING FACILITY, A 25 CERTIFIED-NURSE MIDWIFE, A HEALTH CARE PRACTITIONER OR AN 26 UNLICENSED MIDWIFE THAT ASSUMES CARE OF THE NEWBORN CHILD. THE 27 PARENT OR GUARDIAN SHALL PROVIDE THE WRITTEN CONSENT ON A FORM 28 DEVELOPED BY THE BIRTHING FACILITY, CERTIFIED-NURSE MIDWIFE, 29 HEALTH CARE PRACTITIONER OR UNLICENSED MIDWIFE. THE BIRTHING FACILITY, CERTIFIED-NURSE MIDWIFE, HEALTH CARE PRACTITIONER OR 30

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UNLICENSED MIDWIFE SHALL INCLUDE THE WRITTEN CONSENT UNDER THIS
 SUBSECTION IN THE MEDICAL RECORDS OF THE NEWBORN CHILD AND
 SUBMIT A REPORT ON THE MEDICAL RECORDS TO THE DEPARTMENT IN A
 MANNER SPECIFIED BY THE DEPARTMENT.

5 OBJECTION. -- A CMV SCREENING MAY NOT BE PERFORMED ON A (C) NEWBORN CHILD IF THE PARENT OR GUARDIAN OF THE NEWBORN CHILD 6 7 OBJECTS TO THE CMV SCREENING FOR ANY REASON. A BIRTHING 8 FACILITY, A CERTIFIED-NURSE MIDWIFE, A HEALTH CARE PRACTITIONER OR AN UNLICENSED MIDWIFE THAT ASSUMES CARE OF A NEWBORN CHILD 9 SHALL DOCUMENT AN OBJECTION UNDER THIS SUBSECTION IN WRITING AND 10 INCLUDE THE OBJECTION IN THE MEDICAL RECORDS OF THE NEWBORN 11 12 CHILD AND SUBMIT A REPORT ON THE MEDICAL RECORDS TO THE 13 DEPARTMENT IN A MANNER SPECIFIED BY THE DEPARTMENT.

14 (b) (D) Screening.--A CMV screening shall be performed using <-15 the following:</pre>

16 (1) polymerase chain reaction (PCR) on saliva or urine;
17 (2) follow-up urine test to a positive PCR saliva test
18 for confirmation; or

19 (3) testing approved on or before the effective date of20 this section by:

21

(i) the department; or

(ii) the Centers for Disease Control and Prevention.
(c) Exception. A screening under subsection (a) may not be <--
performed if a parent or guardian of the newborn child dissents
on the grounds that the screening conflicts with a religious

26 belief or practice.

(E) ELECTION.--NOTHING IN THIS SECTION SHALL BE CONSTRUED TO <--
28 PROHIBIT A PARENT OR GUARDIAN OF A NEWBORN CHILD FROM ELECTING
29 TO HAVE THE NEWBORN CHILD SCREENED FOR CMV.

30 Section 6. Regulations.

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The WITHIN TWO YEARS OF THE EFFECTIVE DATE OF THIS SECTION, <--1 THE department shall promulgate regulations necessary to 2 3 effectuate the provisions of this act. 4 Section 7. Effective date. 5 This act shall take effect in 90 days IMMEDIATELY.

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