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THE GENERAL ASSEMBLY OF PENNSYLVANIA

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SENATE BILL

No. 1202 Session of  
2022

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INTRODUCED BY BROOKS, SCHWANK, COSTA, J. WARD, STEFANO, COLLETT  
AND PITTMAN, MAY 16, 2022

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REFERRED TO HEALTH AND HUMAN SERVICES, MAY 16, 2022

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AN ACT

1 Providing for access to pasteurized donor human milk, for duties  
2 of Department of Health and for pasteurized donor human milk  
3 coverage.

4 This act may be referred to as Owen's Law.

5 The General Assembly of the Commonwealth of Pennsylvania  
6 hereby enacts as follows:

7 Section 1. Short title.

8 This act shall be known and may be cited as the Keystone  
9 Access to Pasteurized Donor Human Milk Act.

10 Section 2. Declaration of purpose.

11 The General Assembly finds and declares as follows:

12 (1) In the United States, one in nine infants are born  
13 prematurely, which is one of the highest rates among  
14 developed countries.

15 (2) Up to 70% of mothers who have infants in neonatal  
16 intensive care units are unable to provide enough breast milk  
17 to meet all of their infants' needs, despite adequate  
18 lactation support and effort.

1           (3) Donor human milk provides a lifesaving health  
2 benefit for high-risk infants as a supplement or bridge when  
3 determined to be medically necessary.

4           (4) Donor human milk is evidence-based nutritional  
5 medicine that is essential to the health of medically fragile  
6 infants in both inpatient and outpatient settings due to its  
7 anti-inflammatory and immunological components.

8           (5) A human milk diet for medically compromised infants  
9 provides powerful, unparalleled protection against serious  
10 health complications that can lead to longer hospital stays,  
11 multiple medical and surgical procedures, readmissions,  
12 lifelong disability or even death, while also increasing  
13 rates of exclusive maternal breastfeeding.

14           (6) Pasteurized donor human milk dramatically reduces  
15 the risk of necrotizing enterocolitis, which is the most  
16 prevalent gastrointestinal emergency among preterm infants.

17           (7) Necrotizing enterocolitis has a 24% mortality rate  
18 overall and surgical necrotizing enterocolitis has a 40%  
19 mortality rate.

20           (8) Necrotizing enterocolitis is a devastating  
21 complication that may result in the partial or complete  
22 destruction of the intestinal lining and may lead to short-  
23 term and lifelong health consequences, including premature  
24 death.

25           (9) The use of pasteurized donor human milk has been  
26 shown to decrease the overall incidence of necrotizing  
27 enterocolitis by up to 80% and the rate of surgical  
28 necrotizing enterocolitis by more than 90%.

29           (10) A National Academy of Medicine study identified  
30 preterm birth as a leading cause of neonatal morbidity and

1 disability, resulting in an annual total cost in the United  
2 States of at least \$26,000,000,000.

3 (11) Infants with a wide range of congenital or acquired  
4 conditions can benefit from the use of medically prescribed  
5 pasteurized donor human milk as a component of treatment when  
6 their mothers' own milk is unavailable or cannot meet all of  
7 their needs.

8 (12) Neonatal abstinence syndrome has tripled in the  
9 last 10 years, including a seven-fold increase in neonatal  
10 intensive care unit stays for drug exposed infants who suffer  
11 from feeding intolerance and many other side effects.

12 (13) The incidence of neonatal abstinence syndrome among  
13 infants insured by medical assistance has increased five-fold  
14 in recent years and is equivalent to diagnosing one newborn  
15 with neonatal abstinence syndrome every 25 minutes.

16 (14) The use of pasteurized donor human milk to meet the  
17 nutritional needs of infants with neonatal abstinence  
18 syndrome reduces their symptoms and decreases the need for  
19 additional medical intervention and treatment.

20 (15) Cost is the main access barrier to pasteurized  
21 donor human milk for outpatient infants, who would benefit  
22 from insurance coverage with reimbursement for donor milk,  
23 which includes its related costs for screening, testing and  
24 processing.

25 (16) The availability of and access to pasteurized donor  
26 human milk is impacted by significant, ongoing racial and  
27 economic disparities.

28 (17) Insurance coverage with reimbursement for  
29 prescribed and medically necessary pasteurized donor human  
30 milk for inpatient and outpatient infants is necessary to

1 improve health outcomes and reduce the costs for medical  
2 treatment in this Commonwealth.

3 (18) This act has the following purposes:

4 (i) Promoting the health of medically fragile  
5 infants through access to evidence-based pasteurized  
6 donor human milk when medically prescribed and necessary.

7 (ii) Substantially reducing the incidence of  
8 necrotizing enterocolitis in infants with risk factors  
9 for the disease.

10 (iii) Improving medical outcomes for infants with  
11 serious health conditions where access to donor milk will  
12 aid in their recovery.

13 (iv) Reducing the symptomology of neonatal  
14 abstinence syndrome for drug exposed infants to decrease  
15 the need for extensive medical intervention and  
16 treatment.

17 (v) Improving public awareness of the availability  
18 of pasteurized donor human milk and educating families  
19 about this life-saving medicine.

20 (vi) Requiring insurance coverage with reimbursement  
21 for medically necessary pasteurized donor human milk.

22 (vii) Improving short-term and long-term health  
23 outcomes for the smallest and most fragile residents of  
24 this Commonwealth by providing access to donor milk not  
25 only to reduce health care costs, but most importantly,  
26 to save lives.

27 Section 3. Definitions.

28 The following words and phrases when used in this act shall  
29 have the meanings given to them in this section unless the  
30 context clearly indicates otherwise:

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

2 "Health care provider." A person, corporation, facility,  
3 institution or other entity licensed, certified or approved by  
4 the Commonwealth to provide health care or professional medical  
5 services.

6 "Inpatient infant." An infant who is younger than 12 months  
7 of age based on the infant's corrected gestational age, who is  
8 receiving care in an inpatient setting where pasteurized donor  
9 human milk has been determined to be medically necessary and who  
10 exhibits any of the following health conditions:

11 (1) An infant birth weight less than 1800 grams.

12 (2) An infant gestational age equal to or less than 34  
13 weeks.

14 (3) Infant hypoglycemia.

15 (4) A high risk for development of necrotizing  
16 enterocolitis, bronchopulmonary dysplasia or retinopathy of  
17 prematurity.

18 (5) A congenital or acquired gastrointestinal condition  
19 with long-term feeding or malabsorption complications.

20 (6) Congenital heart disease requiring surgery in the  
21 first year of life.

22 (7) Has had or will have an organ or bone marrow  
23 transplant.

24 (8) Sepsis.

25 (9) Congenital hypotonia associated with feeding or  
26 malabsorption complications.

27 (10) Renal disease requiring dialysis in the first year  
28 of life.

29 (11) Craniofacial anomalies.

30 (12) An immunologic deficiency.

1 (13) Neonatal abstinence syndrome.

2 (14) Any other serious congenital or acquired condition.

3 "Licensed milk bank." A milk bank licensed in this  
4 Commonwealth under the act of February 12, 2020 (P.L.13, No.7),  
5 known as the Keystone Mother's Milk Bank Act.

6 "Necrotizing enterocolitis" or "NEC." A life-threatening  
7 condition that most often occurs in a premature infant, but also  
8 occurs in a term infant or near term infant, and that causes  
9 intestinal inflammation characterized by variable injury or  
10 damage to the intestinal tract resulting in the potential death  
11 of intestinal tissue.

12 "Neonatal abstinence syndrome" or "NAS." A withdrawal  
13 syndrome of an infant that occurs when an infant is born after  
14 exposure to drugs, including opioids in utero, and that is  
15 associated with multiple side effects, including tremors,  
16 vomiting, poor feeding, poor weight gain and high-pitched  
17 crying, which may lead to increased length of hospital stays and  
18 additional health care costs depending on severity.

19 "Outpatient infant." An infant who is younger than 12 months  
20 of age based on the infant's corrected gestational age, who is  
21 receiving care in an outpatient setting where pasteurized donor  
22 human milk has been determined to be medically necessary and who  
23 exhibits any of the following health conditions:

24 (1) A congenital or acquired gastrointestinal condition  
25 with long-term feeding or malabsorption complications.

26 (2) Congenital heart disease requiring surgery in the  
27 first year of life.

28 (3) Has had or will have an organ or bone marrow  
29 transplant.

30 (4) A history of sepsis.

1 (5) Congenital hypotonia associated with feeding or  
2 malabsorption complications.

3 (6) Renal disease requiring dialysis in the first year  
4 of life.

5 (7) Craniofacial anomalies.

6 (8) An immunologic deficiency.

7 (9) Any other serious congenital or acquired condition.

8 "Pasteurized donor human milk" or "PDHM." Human milk derived  
9 from a donor as defined in section 3 of the Keystone Mother's  
10 Milk Bank Act, which is donated to a licensed milk bank for  
11 processing and distribution.

12 Section 4. Access to pasteurized donor human milk.

13 A health care provider shall ensure that an inpatient infant  
14 or outpatient infant under the health care provider's care  
15 receives medically necessary PDHM when any of the following  
16 apply:

17 (1) The infant's mother is medically or physically  
18 unable to produce maternal breast milk.

19 (2) The infant's mother is medically or physically  
20 unable to produce maternal breast milk in sufficient  
21 quantities to meet the infant's needs.

22 (3) The infant's mother's maternal breast milk is  
23 contraindicated.

24 Section 5. Duties of department.

25 (a) Public information campaign.--The department, in  
26 collaboration with the Department of Human Services, shall  
27 conduct a public information campaign to inform parents and  
28 health care providers of the availability of PDHM in this  
29 Commonwealth to treat inpatient infants and outpatient infants,  
30 including the availability of health insurance coverage with

1 reimbursement in accordance with section 6.

2 (b) Educational materials.--In conducting the public  
3 information campaign under subsection (a), the department, in  
4 collaboration with the Department of Human Services, shall  
5 develop culturally and linguistically appropriate educational  
6 materials regarding PDHM, including the availability of PDHM,  
7 the importance of the use of PDHM in medically necessary  
8 circumstances to prevent NEC and treat NAS and the requirements  
9 of this act. The department shall make the educational materials  
10 under this subsection publicly accessible at no cost and shall  
11 develop the educational materials for specific audiences,  
12 including parents, medical assistance recipients and health care  
13 providers.

14 Section 6. Pasteurized donor human milk coverage.

15 (a) Coverage.--A health insurance policy or government  
16 program covered under this section shall provide coverage with  
17 reimbursement for PDHM prescribed for an inpatient infant or  
18 outpatient infant when any of the following apply:

19 (1) The infant's mother is medically or physically  
20 unable to produce maternal breast milk.

21 (2) The infant's mother is medically or physically  
22 unable to produce maternal breast milk in sufficient  
23 quantities to meet the infant's needs.

24 (3) The infant's mother's maternal breast milk is  
25 contraindicated.

26 (b) Copayments, deductibles and coinsurance.--The coverage  
27 with reimbursement provided under this section shall be subject  
28 to copayment, deductible and coinsurance provisions and any  
29 other general exclusions or limitations of a health insurance  
30 policy or government program to the same extent as other medical



1 services covered by the policy or program are subject to these  
2 provisions.

3 (c) Reimbursement.--A health insurance policy or government  
4 program covered under this section shall provide reimbursement  
5 for PDHM separately from the health care provider payment for  
6 inpatient services.

7 (d) Construction.--Nothing in this section shall be  
8 construed to limit benefits otherwise available to an individual  
9 under a health insurance policy or government program.

10 (e) Applicability.--

11 (1) This section shall apply to any individual or group  
12 health insurance policy, contract or plan that provides  
13 medical or health care coverage on an expense-incurred  
14 service or prepaid basis, that is offered, issued or renewed  
15 in this Commonwealth on or after the effective date of this  
16 section and that is offered by or governed under any of the  
17 following:

18 (i) The act of May 17, 1921 (P.L.682, No.284), known  
19 as The Insurance Company Law of 1921.

20 (ii) Subdivision (f) of Article IV of the act of  
21 June 13, 1967 (P.L.31, No.21), known as the Human  
22 Services Code.

23 (iii) The act of December 29, 1972 (P.L.1701,  
24 No.364), known as the Health Maintenance Organization  
25 Act.

26 (iv) The act of May 18, 1976 (P.L.123, No.54), known  
27 as the Individual Accident and Sickness Insurance Minimum  
28 Standards Act.

29 (v) A nonprofit corporation subject to 40 Pa.C.S.  
30 Ch. 61 (relating to hospital plan corporations) or 63

1 (relating to professional health services plan  
2 corporations).

3 (2) This section shall not apply to any of the following  
4 policies:

5 (i) An accident only policy.

6 (ii) A credit only policy.

7 (iii) A long-term care or disability income policy.

8 (iv) A specified disease policy.

9 (v) A Medicare supplement policy.

10 (vi) A Civilian Health and Medical Program of the  
11 Uniformed Services (CHAMPUS) supplement policy.

12 (vii) A fixed indemnity policy.

13 (viii) A dental only policy.

14 (ix) A vision only policy.

15 (x) A workers' compensation policy.

16 (xi) An automobile medical payment policy.

17 (xii) A hospital indemnity policy.

18 (xiii) Another similar policy providing for limited  
19 benefits.

20 Section 7. Applicability of policies.

21 For a health insurance policy for which a form or rate is  
22 required to be filed with the Insurance Department or the  
23 Federal Government, section 6 shall apply to a policy for which  
24 a form or rate is first filed on or after the effective date of  
25 this section. For a health insurance policy for which a form or  
26 rate is not required to be filed with the Insurance Department  
27 or the Federal Government, section 6 shall apply to a policy  
28 issued or renewed on or after 90 days after the effective date  
29 of this section.

30 Section 8. Effective date.

1        This act shall take effect in 60 days.