

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 1202 Session of 2022

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

SENATOR BROOKS, HEALTH AND HUMAN SERVICES, AS AMENDED, JUNE 7, 2022

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 "GOVERNMENT PROGRAM." A PROGRAM OF GOVERNMENT-SPONSORED OR <--  
3 SUBSIDIZED HEALTH CARE COVERAGE, INCLUDING:

4 (1) THE COMMONWEALTH'S MEDICAL ASSISTANCE PROGRAM  
5 ESTABLISHED UNDER THE ACT OF JUNE 13, 1967 (P.L.31, NO.21),  
6 KNOWN AS THE HUMAN SERVICES CODE.

7 (2) THE CHILDREN'S HEALTH INSURANCE PROGRAM UNDER  
8 ARTICLE XXIII-A OF THE ACT OF MAY 17, 1921 (P.L.682, NO.284),  
9 KNOWN AS THE INSURANCE COMPANY LAW OF 1921.

10 "Health care provider." A person, corporation, facility,  
11 institution or other entity licensed, certified or approved by  
12 the Commonwealth to provide health care or professional medical  
13 services.

14 "HEALTH INSURANCE POLICY." A POLICY, SUBSCRIBER CONTRACT, <--  
15 CERTIFICATE OR PLAN ISSUED BY AN INSURER THAT PROVIDES HOSPITAL  
16 OR MEDICAL OR SURGICAL HEALTH CARE COVERAGE. THE TERM DOES NOT  
17 INCLUDE ANY OF THE FOLLOWING:

18 (1) AN ACCIDENT ONLY POLICY.

19 (2) A CREDIT ONLY POLICY.

20 (3) A LONG-TERM CARE OR DISABILITY INCOME POLICY.

21 (4) A SPECIFIED DISEASE POLICY.

22 (5) A MEDICARE SUPPLEMENT POLICY.

23 (6) A FIXED INDEMNITY POLICY.

24 (7) A DENTAL ONLY POLICY.

25 (8) A VISION ONLY POLICY.

26 (9) A WORKERS' COMPENSATION POLICY.

27 (10) AN AUTOMOBILE MEDICAL PAYMENT POLICY.

28 (11) ANY OTHER SIMILAR POLICIES PROVIDING FOR LIMITED  
29 BENEFITS.

30 "Inpatient infant." An infant who is younger than 12 months

1 of age based on the infant's corrected gestational age, who is  
2 receiving care in an inpatient setting ~~where pasteurized donor~~ <--  
3 ~~human milk has been determined to be medically necessary and,~~ <--  
4 who exhibits any of the following health conditions AND FOR WHOM <--  
5 PASTEURIZED DONOR HUMAN MILK IS MEDICALLY NECESSARY:

- 6 (1) An infant birth weight less than 1800 grams.
- 7 (2) An infant gestational age equal to or less than 34  
8 weeks.
- 9 (3) Infant hypoglycemia.
- 10 (4) A high risk for development of necrotizing  
11 enterocolitis, bronchopulmonary dysplasia or retinopathy of  
12 prematurity.
- 13 (5) A congenital or acquired gastrointestinal condition  
14 with long-term feeding or malabsorption complications.
- 15 (6) Congenital heart disease requiring surgery in the  
16 first year of life.
- 17 (7) Has had or will have an organ or bone marrow  
18 transplant.
- 19 (8) Sepsis.
- 20 (9) Congenital hypotonia associated with feeding or  
21 malabsorption complications.
- 22 (10) Renal disease requiring dialysis in the first year  
23 of life.
- 24 (11) Craniofacial anomalies.
- 25 (12) An immunologic deficiency.
- 26 (13) Neonatal abstinence syndrome.
- 27 (14) Any other serious congenital or acquired condition.

28 "INSURER." AN ENTITY THAT OFFERS, ISSUES OR RENEWS AN <--  
29 INDIVIDUAL OR GROUP HEALTH, ACCIDENT OR SICKNESS INSURANCE  
30 POLICY, CONTRACT OR PLAN, AND THAT IS GOVERNED UNDER ANY OF THE

1 FOLLOWING:

2 (1) THE INSURANCE COMPANY LAW OF 1921, INCLUDING SECTION  
3 630 AND ARTICLE XXIV.

4 (2) THE ACT OF DECEMBER 29, 1972 (P.L.1701, NO.364),  
5 KNOWN AS THE HEALTH MAINTENANCE ORGANIZATION ACT.

6 (3) 40 PA.C.S. CH. 61 (RELATING TO HOSPITAL PLAN  
7 CORPORATIONS).

8 (4) 40 PA.C.S. CH. 63 (RELATING TO PROFESSIONAL HEALTH  
9 SERVICES PLAN CORPORATIONS).

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

13 "Necrotizing enterocolitis" or "NEC." A life-threatening  
14 condition that most often occurs in a premature infant, but also  
15 occurs in a term infant or near term infant, and that causes  
16 intestinal inflammation characterized by variable injury or  
17 damage to the intestinal tract resulting in the potential death  
18 of intestinal tissue.

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

26 "Outpatient infant." An infant who is younger than 12 months  
27 of age based on the infant's corrected gestational age, who is  
28 receiving care in an outpatient setting ~~where pasteurized donor~~ <--  
29 ~~human milk has been determined to be medically necessary and,~~ <--  
30 who exhibits any of the following health conditions AND FOR WHOM <--

1 PASTEURIZED DONOR HUMAN MILK IS MEDICALLY NECESSARY:

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

4 (2) Congenital heart disease requiring surgery in the  
5 first year of life.

6 (3) Has had or will have an organ or bone marrow  
7 transplant.

8 (4) A history of sepsis.

9 (5) Congenital hypotonia associated with feeding or  
10 malabsorption complications.

11 (6) Renal disease requiring dialysis in the first year  
12 of life.

13 (7) Craniofacial anomalies.

14 (8) An immunologic deficiency.

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

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

20 ~~Section 4. Access to pasteurized donor human milk.~~ <--

21 ~~A health care provider shall ensure that an inpatient infant~~  
22 ~~or outpatient infant under the health care provider's care~~  
23 ~~receives medically necessary PDHM when any of the following~~  
24 ~~apply:~~

25 ~~(1) The infant's mother is medically or physically~~  
26 ~~unable to produce maternal breast milk.~~

27 ~~(2) The infant's mother is medically or physically~~  
28 ~~unable to produce maternal breast milk in sufficient~~  
29 ~~quantities to meet the infant's needs.~~

30 ~~(3) The infant's mother's maternal breast milk is~~



1 ~~contraindicated.~~

2 Section ~~5~~ 4. Duties of department. <--

3 (a) Public information campaign.--The department, in  
4 collaboration with the Department of Human Services, shall  
5 conduct a public information campaign to inform parents and  
6 health care providers of the availability of PDHM in this  
7 Commonwealth to treat inpatient infants and outpatient infants,  
8 including the availability of ~~health insurance coverage~~ COVERAGE <--  
9 BY INSURERS AND GOVERNMENT PROGRAMS with reimbursement in  
10 accordance with section ~~6~~ 5. <--

11 (b) Educational materials.--In conducting the public  
12 information campaign under subsection (a), the department, in  
13 collaboration with the Department of Human Services, shall  
14 develop culturally and linguistically appropriate educational  
15 materials regarding PDHM, including the availability of PDHM,  
16 the importance of the use of PDHM in medically necessary  
17 circumstances to prevent NEC and treat NAS and the requirements  
18 of this act. The department shall make the educational materials  
19 under this subsection publicly accessible at no cost and shall  
20 develop the educational materials for specific audiences,  
21 including parents, medical assistance recipients and health care  
22 providers.

23 Section ~~6~~ 5. Pasteurized donor human milk coverage AND <--  
24 REIMBURSEMENT.

25 (a) Coverage.--A health insurance policy or government  
26 program covered under this section shall provide coverage with  
27 reimbursement for PDHM prescribed for an inpatient infant or  
28 outpatient infant ~~when~~ IF any of the following apply: <--

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

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

4 (3) The infant's mother's maternal breast milk is  
5 contraindicated.

6 (b) Copayments, deductibles and coinsurance.--The coverage  
7 with reimbursement provided under this section shall be subject  
8 to copayment, deductible and coinsurance provisions and any  
9 other general exclusions or limitations of a health insurance  
10 policy or government program to the same extent as other medical  
11 services covered by the policy or program are subject to these  
12 provisions.

13 ~~(c) Reimbursement.~~ BILLING AND REIMBURSEMENT.--A HEALTH <--  
14 CARE PROVIDER SHALL BILL SEPARATELY FOR PDHM AND ITS  
15 REIMBURSEMENT. A health insurance policy or government program  
16 covered under this section shall provide reimbursement for PDHM  
17 separately from the health care provider payment for inpatient  
18 services. REIMBURSEMENT FOR PDHM SHALL NOT BE INCLUDED IN AN <--  
19 ALL-INCLUSIVE BUNDLED PAYMENT.

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

23 ~~(e) Applicability.~~ <--

24 ~~(1) This section shall apply to any individual or group~~  
25 ~~health insurance policy, contract or plan that provides~~  
26 ~~medical or health care coverage on an expense incurred~~  
27 ~~service or prepaid basis, that is offered, issued or renewed~~  
28 ~~in this Commonwealth on or after the effective date of this~~  
29 ~~section and that is offered by or governed under any of the~~  
30 ~~following:~~

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

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

6           ~~(iii) The act of December 29, 1972 (P.L.1701,~~  
7 ~~No.364), known as the Health Maintenance Organization~~  
8 ~~Act.~~

9           ~~(iv) The act of May 18, 1976 (P.L.123, No.54), known~~  
10 ~~as the Individual Accident and Sickness Insurance Minimum~~  
11 ~~Standards Act.~~

12           ~~(v) A nonprofit corporation subject to 40 Pa.C.S.~~  
13 ~~Ch. 61 (relating to hospital plan corporations) or 63~~  
14 ~~(relating to professional health services plan~~  
15 ~~corporations).~~

16           ~~(2) This section shall not apply to any of the following~~  
17 ~~policies:~~

18           ~~(i) An accident only policy.~~

19           ~~(ii) A credit only policy.~~

20           ~~(iii) A long term care or disability income policy.~~

21           ~~(iv) A specified disease policy.~~

22           ~~(v) A Medicare supplement policy.~~

23           ~~(vi) A Civilian Health and Medical Program of the~~  
24 ~~Uniformed Services (CHAMPUS) supplement policy.~~

25           ~~(vii) A fixed indemnity policy.~~

26           ~~(viii) A dental only policy.~~

27           ~~(ix) A vision only policy.~~

28           ~~(x) A workers' compensation policy.~~

29           ~~(xi) An automobile medical payment policy.~~

30           ~~(xii) A hospital indemnity policy.~~

1           ~~(xiii) Another similar policy providing for limited~~  
2           ~~benefits.~~

3           (E) SCOPE.--THIS SECTION SHALL APPLY TO COVERAGE AND           <--  
4 REIMBURSEMENT UNDER ALL OF THE FOLLOWING:

5           (1) AN INDIVIDUAL HEALTH INSURANCE POLICY.

6           (2) A GROUP HEALTH INSURANCE POLICY.

7           (3) A GOVERNMENT PROGRAM.

8 Section 7 6. Applicability of policies.           <--

9           For a health insurance policy for which a form or rate is  
10 required to be filed with the Insurance Department or the  
11 Federal Government, section 6 5 shall apply to a policy for           <--  
12 which a form or rate is first filed on or after the effective  
13 date of this section. For a health insurance policy for which a  
14 form or rate is not required to be filed with the Insurance  
15 Department or the Federal Government, section 6 5 shall apply to <--  
16 a policy issued or renewed on or after 90 days after the  
17 effective date of this section.

18 SECTION 7. ADDITIONAL PROTECTIONS.           <--

19           NO PERSON MAY SELL OF OFFER TO SELL HUMAN MILK OVER THE  
20 INTERNET TO ANOTHER PERSON DIRECTLY OR THROUGH A CLASSIFIED  
21 ADVERTISEMENT.

22 Section 8. Effective date.

23           This act shall take effect in 60 days.