

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2368 Session of  
2024

INTRODUCED BY ORTITAY AND JAMES, JUNE 3, 2024

REFERRED TO COMMITTEE ON HEALTH, JUNE 3, 2024

AN ACT

1 Amending Title 35 (Health and Safety) of the Pennsylvania  
2 Consolidated Statutes, in Commonwealth services, providing  
3 for emergency stockpiles and medical countermeasures.

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

6 Section 1. Chapter 73 of Title 35 of the Pennsylvania  
7 Consolidated Statutes is amended by adding a subchapter to read:

8 SUBCHAPTER G

9 EMERGENCY STOCKPILES AND MEDICAL COUNTERMEASURES

10 Sec.

11 7391. Definitions.

12 7392. Duties of department.

13 7393. Qualifications to administer program.

14 7394. Administration of program by third parties.

15 7395. Regulations.

16 § 7391. Definitions.

17 The following words and phrases when used in this subchapter  
18 shall have the meanings given to them in this section unless the  
19 context clearly indicates otherwise:

1 "Department." The Department of Health of the Commonwealth.  
2 "Emergency stockpile." A stock of biological products,  
3 drugs, medical devices, vaccines and other supplies in such  
4 numbers, types and amounts as appropriate to provide for and  
5 optimize public health and safety, including the health and  
6 safety of children and other vulnerable populations, in the  
7 event of a declared disaster emergency.

8 "Medical countermeasures." Medical supplies and medicines  
9 used to diagnose, prevent or treat diseases related to chemical,  
10 biological, radiological or nuclear threats, including  
11 antibodies, antimicrobial and antiviral drugs, blood products,  
12 diagnostic tests, personal protective equipment and vaccines.

13 "Program." The program established under section 7392(1)  
14 (relating to duties of department).

15 § 7392. Duties of department.

16 No later than 90 days after the effective date of this  
17 section, the department shall, in consultation with the agency,  
18 do all of the following:

19 (1) Establish a program for the creation of an  
20 emergency stockpile and the procurement of medical  
21 countermeasures.

22 (2) Issue requests for proposals to administer the  
23 program.

24 (3) Contract with a third party to administer the  
25 program.

26 § 7393. Qualifications to administer program.

27 (a) Responses to requests for proposals.--In a response to  
28 an invitation to a request for proposal from the department  
29 under section 7392(2) (relating to duties of department), a  
30 third party shall include an assessment or description of the

1 planned stockpile and countermeasures inventory and methods for  
2 all of the following:

3 (1) Properly disposing spoiled or expired emergency  
4 stockpile items and medical countermeasures.

5 (2) Renewing expired emergency stockpile items and  
6 medical countermeasures.

7 (3) Selling unnecessary emergency stockpile items and  
8 medical countermeasures.

9 (4) Placing emergency stockpile items and medical  
10 countermeasures into an inventory and quality management  
11 system.

12 (5) Relocating as needed emergency stockpile items and  
13 medical countermeasures into the appropriate environment.

14 (6) Retrofitting the warehouse specified under  
15 subsection (d) as necessary to provide for the storage and  
16 management of an emergency stockpile and medical  
17 countermeasures as well as food and water and other supplies  
18 in accordance with the following:

19 (i) In the correct environment with appropriate  
20 security, temperature and humidity controls.

21 (ii) In compliance with industry licensing and  
22 regulatory standards, including the United States Food  
23 and Drug Administration's current good manufacturing  
24 practice regulations under 21 CFR Ch. I Subch C. Pt. 211  
25 (relating to current good manufacturing practice for  
26 finished pharmaceuticals).

27 (iii) With warehouse space and surface lot area  
28 sufficient to access, maintain, inventory and distribute  
29 the supplies.

30 (7) Establishing a staffing plan that meets all of the

1 following criteria:

2 (i) Ensures that staff for the warehouse specified  
3 under subsection (d) have appropriate knowledge, skills  
4 and training to maintain, organize, identify and package  
5 medical countermeasures and other supplies.

6 (ii) Demonstrates how staff will utilize the  
7 inventory and quality management system in day-to-day  
8 operations to support the program.

9 (iii) Identifies the number of staff necessary to  
10 operate the warehouse specified under subsection (d) at  
11 the direction of the department under the program.

12 (8) Establishing an inventory and quality management  
13 system that meets all of the following criteria:

14 (i) Tracks and traces, in real time, the  
15 Commonwealth's emergency stockpile and medical  
16 countermeasures, including by number, type, location and  
17 expiration date.

18 (ii) Facilitates the regular testing, maintenance  
19 and rotation of the emergency stockpile and medical  
20 countermeasures.

21 (iii) Provides reporting to assist in the  
22 Commonwealth's emergency response and recovery.

23 (9) Calculating the one-time and ongoing costs  
24 associated with retrofitting or renovations, utilities,  
25 inventory assessment and relocation, software, product  
26 maintenance or rotation staffing, as appropriate.

27 (b) Qualifications.--In order to be qualified to contract  
28 with the department to administer the program, a third party  
29 shall meet all of the following requirements:

30 (1) Have submitted to the department, following an

1 invitation to a request for proposal from the department  
2 under section 7392(2), a response that meets the requirements  
3 under this subsection.

4 (2) Have at least three years of experience  
5 establishing, procuring, maintaining and managing emergency  
6 stockpiles and medical countermeasures for the Federal  
7 Government.

8 (3) Manage at least 1,000,000 square feet of combine  
9 warehousing for emergency stockpile items and medical  
10 countermeasures.

11 (4) Hold an appropriate license or other  
12 authorization authorizing the third party to obtain, possess  
13 and have custody and control of any part of an emergency  
14 stockpile.

15 (c) Review.--The department shall review each response  
16 submitted by a third party to an invitation to a request for  
17 proposal from the department under section 7392(2) to determine  
18 if the requirements under subsections (a) and (b) have been met.  
19 The department shall only contract with a third party that meets  
20 the requirements under subsections (a) and (b) to administer  
21 the program.

22 (d) Lease of warehouse.--In addition to a contract between  
23 the department and a third party to administer the program, the  
24 department and the third party shall enter into an agreement for  
25 which the third party leases from the department or other  
26 authorized Commonwealth agency space in a central warehouse that  
27 is owned by the department or other authorized Commonwealth  
28 agency and located in this Commonwealth. The third party shall  
29 use the leased space under the agreement to administer the  
30 program, which may necessitate retrofitting the space as

1 specified under subsection (a) (6).

2 (e) Notice.--After entering into a contract with a third  
3 party to administer the program, the department shall provide  
4 written notice to all of the following:

5 (1) The Majority Leader and the Minority Leader of the  
6 Senate.

7 (2) The Majority Leader and the Minority Leader of the  
8 House of Representatives.

9 (3) The chairperson and minority chairperson of the  
10 Health and Human Services Committee of the Senate.

11 (4) The chairperson and minority chairperson of the  
12 Health Committee of the House of Representatives.

13 § 7394. Administration of program by third parties.

14 A third party shall engage in all of the following activities  
15 under a contract to administer the program:

16 (1) Obtain all of the following for the program's  
17 emergency stockpile and medical countermeasures:

18 (i) Antibodies.

19 (ii) Biological products.

20 (iii) Blood products.

21 (iv) Diagnostic tests.

22 (v) Drugs, including antimicrobials and antivirals.

23 (vi) Medical devices.

24 (vii) Medical and other supplies.

25 (viii) Medicines.

26 (ix) Personal protective equipment.

27 (x) Vaccines, including vaccines recommended by the  
28 United States Food and Drug Administration.

29 (2) Manage the program's emergency stockpile and medical  
30 countermeasures, including ensuring their storage at

1 appropriate temperatures and humidity levels and tracking  
2 supplies in real time.

3 (3) Monitor expiration dates to ensure that the  
4 program's emergency stockpile items and medical  
5 countermeasures remain safe and effective.

6 (4) Secure the emergency stockpile and  
7 medical countermeasures in the warehouse specified under  
8 section 7393(d) (relating to qualifications to administer  
9 program).

10 (5) Replace the program's emergency stockpile items and  
11 medical countermeasures that have expired with emergency  
12 stockpile items and medical countermeasures that have not yet  
13 expired.

14 (6) Ensure that the program's emergency stockpile items  
15 and medical countermeasures remain ready for deployment in  
16 the event of a declared disaster emergency.

17 (7) Comply with 21 U.S.C. Ch. 9 (relating to Federal  
18 Food, Drug, and Cosmetic Act) and the Pandemic and All-  
19 Hazards Preparedness Reauthorization Act of 2013 (Public Law  
20 113-5, 42 U.S.C. § 201 et. seq.).

21 (8) Establish a reporting system to notify the  
22 department during a disaster emergency of the availability of  
23 specific emergency stockpile items and medical  
24 countermeasures and whether the emergency stockpile items and  
25 medical countermeasures are near expiration or require  
26 maintenance.

27 § 7395. Regulations.

28 The department may promulgate regulations as necessary to  
29 implement this subchapter.

30 Section 2. This act shall take effect in 90 days.