

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1795 Session of 2023

INTRODUCED BY GERGELY, BRIGGS, MADDEN, FRANKEL, SANCHEZ,
BRENNAN, GIRAL, HILL-EVANS, ROZZI, DALEY AND DONAHUE,
OCTOBER 25, 2023

REFERRED TO COMMITTEE ON HEALTH, OCTOBER 25, 2023

AN ACT

1 Amending the act of September 26, 1951 (P.L.1539, No.389),
2 entitled "An act defining clinical laboratory; regulating the
3 operation of the same; requiring such laboratories to obtain
4 permits, and to be operated under the direct supervision of
5 qualified persons; imposing certain duties upon the
6 Department of Health; and providing penalties," further
7 providing for definitions and for exemptions.

8 The General Assembly of the Commonwealth of Pennsylvania
9 hereby enacts as follows:

10 Section 1. Section 2 of the act of September 26, 1951
11 (P.L.1539, No.389), known as The Clinical Laboratory Act, is
12 amended by adding definitions to read:

13 Section 2. Definitions.--The following words and phrases
14 when used in this act shall have the meanings given to them in
15 this section unless the context clearly indicates otherwise:

16 * * *

17 "Plasma." The fluid portion of human blood.

18 "Plasmapheresis." A procedure in which, during a single
19 visit to a facility, blood is removed from an individual, the
20 source plasma is separated from the formed elements and at least

1 the red blood cells are returned to the donor.

2 "Source plasma donation center." A facility where plasma is
3 collected by plasmapheresis and used as a source material for
4 further manufacturing use. The term does not include single
5 donor plasma products intended for intravenous use.

6 * * *

7 Section 2. Section 13 of the act is amended to read:

8 Section 13. Exemptions.--This act shall not include nor
9 apply to [any]:

10 (1) Any laboratory or laboratories maintained and
11 operated by the Federal government[; nor to any].

12 (2) Any laboratory or laboratories maintained and
13 operated purely for research or teaching purposes.

14 (3) Any source plasma donation center that performs only
15 hematocrit and total protein donor eligibility tests.

16 Section 3. This act shall take effect in 60 days.