PRINTER'S NO. 584

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 575 Session of 2023

INTRODUCED BY J. WARD, COLLETT, FONTANA, BARTOLOTTA, DILLON, SCHWANK, CAPPELLETTI, ROTHMAN, BREWSTER AND COSTA, APRIL 13, 2023

REFERRED TO HEALTH AND HUMAN SERVICES, APRIL 13, 2023

AN ACT

Amending the act of December 6, 1972 (P.L.1614, No.335), entitled "An act defining blood banks, serum exchanges, blood bank depositories; blood fractionization and blood products operation; regulating the operations of same; requiring such organizations to obtain licenses to engage in these activities; requiring minimal standards of operation and qualifications of supervising personnel; imposing certain duties upon the Department of Health; establishing a blood bank advisory committee and providing penalties," providing for source plasma donation centers.

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

Section 1. The act of December 6, 1972 (P.L.1614, No.335), known as the Pennsylvania Blood Bank Act, is amended by adding a section to read:

Section 14.2. Source Plasma Donation Centers.--

Notwithstanding any other law, a source plasma donation center may collect source plasma through plasmapheresis if the source plasma donation center complies with all the requirements governing the collection of source plasma and operation of a clinical laboratory, including laws governing donor screening

and monitoring, staff qualifications, responsibilities, supervision, training and duties, in a source plasma donation center and clinical laboratory. The source plasma donation center must be in compliance with all of the following as of the effective date of this section:

(1) 21 CFR Pt. 600 (relating to biological products: general).

(2) 21 CFR Pt. 601 (relating to licensing).

(3) 21 CFR Pt. 606 (relating to current good manufacturing practice for blood and blood components).

(4) 21 CFR Pt. 607 (relating to establishment registration and product listing for manufacturers of human blood and blood products and licensed devices).

(5) 21 CFR Pt. 610 (relating to general biological products standards).

(6) 21 CFR Pt. 630 (relating to requirements for blood and blood components intended for transfusion or for further manufacturing use).

(7) 21 CFR Pt. 640 (relating to additional standards for human blood and blood products).

(8) 42 CFR Pt. 493 (relating to laboratory requirements).

Section 2. This act shall take effect in 60 days.