SENATE No. 1493

The Commonwealth of Massachusetts

PRESENTED BY:

Michael O. Moore

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act relative to source plasma donation centers.

PETITION OF:

NAME: DISTRICT/ADDRESS:

Michael O. Moore Second Worcester

SENATE No. 1493

By Mr. Moore, a petition (accompanied by bill, Senate, No. 1493) of Michael O. Moore for legislation relative to source plasma donation centers. Public Health.

[SIMILAR MATTER FILED IN PREVIOUS SESSION SEE SENATE, NO. 2871 OF 2019-2020.]

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Second General Court (2021-2022)

An Act relative to source plasma donation centers.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

- SECTION 1. The General Laws are hereby amended by inserting after chapter 1110 the
- 2 following chapter:-
- 3 Chapter 111P. SOURCE PLASMA DONATION CENTERS
- 4 SECTION 1. Definitions. As used in this chapter, the following words shall have the
- 5 following meanings:
- 6 "Department" means the Department of Public Health.
- 7 "Source plasma donation center" means a facility where source plasma is collected by
- 8 plasmapheresis but shall not include single donor plasma products intended for intravenous use.

"Source plasma" means the portion of human blood collected by plasmapheresis and intended source material for plasma protein therapies.

"Plasmapheresis" means a procedure in which, during a single visit to the facility, blood is removed from an individual, the source plasma separated from the formed elements, and at least the red blood cells are returned to the donor.

SECTION 2. Source plasma donation centers. A source plasma donation center may collect source plasma through plasmapheresis, and may employ a person to perform total protein tests using digital refractometers, if the source plasma donation center and such person comply with all the requirements of federal law and regulations governing the collection of source plasma, including, but not limited to laws governing staff supervision, training, and duties, including requirements for performing total protein tests using digital refractometers in a source plasma donation center.

SECTION 3. The Department shall establish requirements for registration of source plasma donation centers in the commonwealth that are consistent with federal requirements, including 42 CFR 493, 21 CFR 630 and 21 CFR 630, collect fees established for the registration, investigate complaints and take appropriate disciplinary action to protect the public health, safety and welfare.

The Department shall approve and issue certificates of registration and shall maintain a list of registered source plasma donation centers.

The Department shall promulgate such rules and regulations as it deems necessary to implement the provisions of this chapter including rules and regulations governing the registration of source plasma donation centers, including the establishment of registration fees.