

By Senator Pizzo

37-01625-26

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A bill to be entitled

An act relating to patient-directed blood donations; amending s. 381.0601, F.S.; providing a short title; defining terms; requiring blood banks to comply with a licensed physician's order for an autologous or directed blood donation for a named patient, subject to certain conditions; requiring hospitals that facilitate blood donations or contract with blood banks to allow patients to provide autologous or directed donations under certain circumstances; authorizing blood banks and hospitals to charge a reasonable and necessary fee to cover administrative costs; providing requirements for the fee structure; providing construction; requiring that all autologous and directed donations be collected, tested, stored, and transfused in accordance with certain laws and standards; requiring that a unit of blood or blood component collected for an autologous or directed donation for a specific patient be reserved for that patient; providing exceptions; providing for the reversion of a reserved unit of blood or blood component to general inventory to be used for other patients under certain circumstances; authorizing the use of a reserved unit of blood or blood component in certain emergency circumstances; authorizing the Department of Health to adopt rules; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

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Section 1. Section 381.0601, Florida Statutes, is amended to read:

(Substantial rewording of section. See s. 381.0601, F.S., for present text.)

381.0601 Patient-directed blood donations.—

(1) SHORT TITLE.—This section may be cited as the “Patient-Directed Blood Donation Act.”

(2) DEFINITIONS.—As used in this section, the term:

(a) “Autologous donation” means the collection and storage of blood or blood components from an individual for transfusion back to the same individual.

(b) “Blood bank” means any entity licensed under state or federal law to collect, process, store, or distribute human blood or blood components.

(c) “Directed donation” means the collection and storage of blood or blood components from a specific donor for transfusion to a specifically identified patient, ordered by a licensed physician.

(d) “Hospital” has the same meaning as in s. 395.002.

(3) COMPLIANCE WITH PHYSICIAN ORDERS; DUTIES OF BLOOD BANKS AND HOSPITALS.—

(a) A blood bank shall comply with a licensed physician’s order for an autologous or directed blood donation for a named patient, subject to applicable medical suitability criteria and the availability of services at that facility.

(b) A hospital that facilitates blood donations or contracts with a blood bank shall allow a patient who is scheduled for a medical procedure to provide autologous or

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59 directed donations if ordered by the patient's licensed  
60 physician, to the extent that such donations are medically  
61 appropriate and logistically feasible.

62 (4) ADMINISTRATIVE FEES.—

63 (a) A blood bank or hospital may charge a fee that is  
64 reasonable and necessary to cover the administrative costs of  
65 facilitating autologous and directed donations, including  
66 collection, processing, testing, storage, and distribution.

67 (b) Fees authorized under this subsection may not be  
68 structured in a manner that unreasonably deters medically  
69 appropriate autologous or directed donations as ordered by a  
70 licensed physician.

71 (5) SAFETY AND REGULATORY COMPLIANCE.—This section does not  
72 alter or diminish any requirement under federal or state law  
73 regarding donor eligibility, screening, testing, labeling,  
74 storage, recordkeeping, or compatibility of blood and blood  
75 components, including requirements of the United States Food and  
76 Drug Administration and applicable accreditation standards. All  
77 autologous and directed donations must be collected, tested,  
78 stored, and transfused in accordance with such laws and  
79 standards.

80 (6) REVERSION TO GENERAL INVENTORY; EMERGENCY EXCEPTION.—

81 (a) A unit of blood or blood component collected as an  
82 autologous or directed donation for a specific patient must be  
83 reserved for that patient, consistent with medical and  
84 regulatory requirements, until one of the following occurs:

- 85 1. The patient no longer requires the unit; or  
86 2. The unit is no longer medically appropriate for  
87 transfusion to that patient.

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88       (b) When a reserved unit is no longer needed or medically  
89 appropriate for the designated patient, and remains suitable for  
90 transfusion, the unit may revert to general inventory and be  
91 used for other patients in accordance with applicable laws and  
92 standards.

93       (c) In a documented emergency in which an immediate  
94 transfusion is necessary to prevent serious harm or death and no  
95 suitable alternative unit is available, a reserved unit may be  
96 released for emergency use in another patient, consistent with  
97 federal and state requirements and hospital policies.

98       (7) RULEMAKING.—The Department of Health may adopt rules to  
99 implement this section, including to provide guidance on  
100 reasonable and necessary fees and any reporting or documentation  
101 needed to demonstrate compliance with this section.

102       Section 2. This act shall take effect July 1, 2026.