

1 AN ACT relating to blood donation.

2 ***Be it enacted by the General Assembly of the Commonwealth of Kentucky:***

3 ➔Section 1. KRS 214.450 is amended to read as follows:

4 As used in KRS 214.452 to 214.466, unless the context otherwise requires:

- 5 (1) "Blood" means any blood, blood product, blood component, or blood derivative
6 including plasma;[]
- 7 (2) "Blood establishment" means a place of business under one (1) management at one
8 (1) general physical location which engages in the collection, preparation,
9 processing, labeling, packaging, and dispensing of blood to any health care facility,
10 health service, or health care provider and which is licensed by the United States
11 Food and Drug Administration. Blood establishment does not include autologous
12 blood donation programs permitted under KRS 214.456;[]
- 13 (3) "Blood-borne communicable disease" means any of those diseases which are
14 specifically so defined and set forth in administrative regulation promulgated by the
15 United States Food and Drug Administration;[]
- 16 (4) **"COVID-19 vaccine" or "mRNA vaccine" means any COVID-19 vaccination or**
17 **any other messenger ribonucleic acid (mRNA) vaccine components, including**
18 **evidence of lipid nanoparticles and spike protein from a vaccine for COVID-19**
19 **and COVID-19 antibodies;**
- 20 **(5) "Donor" means either a paid or volunteer donor of blood;**
- 21 [~~"Health facility" means any health facility set forth under KRS 216B.015 which~~
22 ~~provides for the transfusion of blood into a living human body.]~~
- 23 **(6) [(5)] "Health care provider" means any person licensed or certified under the laws**
24 **of the Commonwealth as a dentist, physician, osteopath, registered nurse, practical**
25 **nurse, paramedic, emergency medical technician, or physician assistant;[]**
- 26 **(7) "Health facility" means any health facility set forth under KRS 216B.015 which**
27 **provides for the transfusion of blood into a living human body;**

1 ~~(8)~~⁽⁶⁾ "Health service" means any health service as set forth under KRS 216B.015
2 and which provides for the transfusion of blood into a living human body; ~~[-]~~

3 ~~(9)~~⁽⁷⁾ "Transfuse" means to transfer blood from one (1) person to another; and ~~[-]~~

4 ~~(8)~~ "Donor" means either a paid or volunteer donor of blood; ~~[-]~~

5 ~~(10)~~⁽⁹⁾ "Untested blood" means blood that has not been tested or blood for which test
6 results have not yet been returned.

7 ➔Section 2. KRS 214.452 is amended to read as follows:

8 The following policies shall apply to blood establishments and to donors of blood:

9 (1) All blood establishments within the Commonwealth shall be licensed by the United
10 States Food and Drug Administration and remain in compliance with all applicable
11 federal regulations. The Cabinet for Health and Family Services shall, under
12 administrative regulations promulgated pursuant to KRS Chapter 13A, establish
13 fees necessary to cover the cost of and adhere to a schedule for regular inspection,
14 by the Office of the Inspector General of the Cabinet for Health and Family
15 Services, of all blood establishments within the Commonwealth to ascertain
16 whether each blood establishment is licensed and in compliance with KRS 214.450
17 to 214.464 and KRS 214.468; ~~[-]. The Office of the Inspector General shall~~
18 ~~commence its inspection program of blood establishments no later than September~~
19 ~~1, 1994.~~

20 (2) All blood establishments shall test blood for:

21 (a) The human immunodeficiency virus and for any known causative agent for
22 any blood-borne communicable disease, using tests approved and required,
23 for purposes of blood donation, by the United States Food and Drug
24 Administration; and

25 (b) COVID-19 antibodies, evidence of lipid nanoparticles, and spike protein; ~~[-]~~

26 (3) It shall be the duty of the administrator of any blood establishment which collects
27 blood for the purpose of distributing to another health service, health facility, or

1 health-care provider the blood for transfusion to:

2 (a) Secure donor consent and a signed written risk factor history and donor
3 consent form for each potential paid or volunteer donor for the purpose of
4 determining if the potential donor is at high risk for infection with the human
5 immunodeficiency virus, or has tested confirmatory positive for infection with
6 the human immunodeficiency virus; or has acquired immune deficiency
7 syndrome; or has tested confirmatory positive for infection with any causative
8 agent for acquired immune deficiency syndrome recognized by the United
9 States Centers for Disease Control; or has a blood-borne communicable
10 disease;

11 (b) 1. Inquire on the donor history questionnaire whether a potential donor
12 has received a COVID-19 vaccine or any other mRNA vaccine during
13 the donor's lifetime; and
14 2. If the donor has received a COVID-19 vaccine, the donor shall
15 provide the manufacturer name of the COVID-19 vaccine the donor
16 received. If the donor fails to provide the manufacturer name of the
17 COVID-19 vaccine, the donor may be required to wait before donating
18 blood;

19 (c) Provide a means for a potential donor to self-elect not to donate blood;

20 (d)~~(e)~~ Refuse donation or sale of blood by persons at high risk for infection
21 with the human immunodeficiency virus, or who have been medically
22 diagnosed as having acquired immune deficiency syndrome, or who have
23 tested confirmatory positive for infection with the human immunodeficiency
24 virus, or who have a blood-borne communicable disease; and

25 (e)~~(d)~~ Post a sign in the blood establishment which is visible to all potential
26 donors and which states: "Persons with acquired immune deficiency
27 syndrome (AIDS), or who have tested confirmatory positive for infection with

1 the human immunodeficiency virus (HIV), or who have a blood-borne
 2 communicable disease or who have one (1) or more risk factors for the human
 3 immunodeficiency virus as determined by the United States Centers for
 4 Disease Control, are prohibited by law from donating or selling blood.
 5 Persons violating the law are guilty of a Class D felony. ASK STAFF OF
 6 THIS BLOOD ESTABLISHMENT.";

7 (4) (a) A donor shall wait at least two (2) weeks after having received a live
 8 attenuated COVID-19 vaccine before the donor may donate blood. If the
 9 donor does not know the manufacturer of the COVID-19 vaccine the donor
 10 received, the donor shall wait at least two (2) weeks from the day the donor
 11 received the vaccine before the donor may donate blood;

12 (b) A donor shall wait ten (10) days following a diagnosis of COVID-19 or
 13 displaying any signs and symptoms of COVID-19 before the donor may
 14 donate blood; and

15 (c) A donor who received an inactivated or mRNA based COVID-19 vaccine
 16 shall have no deferral requirements unless otherwise required by law; and

17 (5) The provisions of this section shall not be construed to impose requirements which
 18 are in conflict with donor eligibility requirements set out in United States Food and
 19 Drug Administration or American Association of Blood Banks standards.

20 ➔Section 3. KRS 214.458 is amended to read as follows:

21 (1) Each unit of blood collected by a blood establishment for transfusion shall be
 22 affixed with the United States Food and Drug Administration required label which
 23 includes a donor identification number through which the following information
 24 can be obtained:

- 25 (a) Date the blood was collected;
 26 (b) Name of blood establishment;
 27 (c) Nonidentifying code representing the name of the blood donor;

- 1 (d) A blood establishment serial number for the blood;
- 2 (e) The date of laboratory testing of the blood;
- 3 (f) The name of the person and laboratory testing the blood;
- 4 (g) The laboratory test results of testing required pursuant to subsection (2) of
5 Section 2 of this Act.

6 (2) Each unit of blood received by a blood establishment or health facility within the
7 Commonwealth from an out-of-state blood establishment shall contain a label in
8 accordance with the provisions of subsection (1) of this section and the blood
9 establishment or health facility shall either test the blood in accordance with the
10 requirements for blood establishments within the Commonwealth under the
11 provisions of KRS 214.452(2) or may accept documented evidence of the test
12 results as are required under subsection (1) of this section for blood collected within
13 the Commonwealth.

14 (3) Each laboratory testing blood for transfusion shall maintain for ten (10) years from
15 the date of testing, and each blood establishment shall maintain for ten (10) years
16 from the date of collection, a list containing the information set forth in subsection
17 (1) of this section.

18 (4) No blood may be transfused into any patient in any health facility or health service
19 or by any health care provider unless the unit of blood has affixed to it the label as
20 required under this section and the blood has tested negative for the human
21 immunodeficiency virus or any causative agent of AIDS, or any blood-borne
22 communicable disease as provided under KRS 214.452. When a unit of blood is
23 transfused, a label containing the donor identification number required under this
24 section shall be removed from the unit and affixed to the patient's medical chart or
25 the blood donor identification number for the unit of blood shall be recorded in the
26 patient's medical chart.

27 (5) Any unit of blood not containing the label required under this section shall be

- 1 destroyed by the health facility, health service, or health care provider.
- 2 (6) Any unit of blood testing confirmatory positive for an agent of a blood-borne
- 3 communicable disease and in the possession of a health facility, health service, or
- 4 health care provider may be donated to educational or scientific research
- 5 institutions for the purpose of scientific research only and not for transfusion.