

214.452 Blood establishments to be federally licensed -- Inspection fees -- Donor conditions -- Forms -- Sign posting.

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

- (1) All blood establishments within the Commonwealth shall be licensed by the United States Food and Drug Administration and remain in compliance with all applicable federal regulations. The Cabinet for Health and Family Services shall, under administrative regulations promulgated pursuant to KRS Chapter 13A, establish fees necessary to cover the cost of and adhere to a schedule for regular inspection, by the Office of the Inspector General of the Cabinet for Health and Family Services, of all blood establishments within the Commonwealth to ascertain whether each blood establishment is licensed and in compliance with KRS 214.450 to 214.464 and KRS 214.468. The Office of the Inspector General shall commence its inspection program of blood establishments no later than September 1, 1994. The Office of the Inspector General of the Cabinet for Health and Family Services shall annually, by no later than September 1, submit a written report to the Interim Joint Committee on Health and Welfare on the compliance of blood establishments with KRS 214.450 to 214.464 and KRS 214.468.
- (2) All blood establishments shall test blood for the human immunodeficiency virus and for any known causative agent for any blood-borne communicable disease, using tests approved and required, for purposes of blood donation, by the United States Food and Drug Administration.
- (3) It shall be the duty of the administrator of any blood establishment which collects blood for the purpose of distributing to another health service, health facility, or health-care provider the blood for transfusion to:
 - (a) Secure donor consent and a signed written risk factor history and donor consent form for each potential paid or volunteer donor for the purpose of determining if the potential donor is at high risk for infection with the human immunodeficiency virus, or has tested confirmatory positive for infection with the human immunodeficiency virus; or has acquired immune deficiency syndrome; or has tested confirmatory positive for infection with any causative agent for acquired immune deficiency syndrome recognized by the United States Centers for Disease Control; or has a blood-borne communicable disease;
 - (b) Provide a means for a potential donor to self-elect not to donate blood;
 - (c) Refuse donation or sale of blood by persons at high risk for infection with the human immunodeficiency virus, or who have been medically diagnosed as having acquired immune deficiency syndrome, or who have tested confirmatory positive for infection with the human immunodeficiency virus, or who have a blood-borne communicable disease;
 - (d) Post a sign in the blood establishment which is visible to all potential donors and which states: "Persons with acquired immune deficiency syndrome (AIDS), or who have tested confirmatory positive for infection with the human immunodeficiency virus (HIV), or who have a blood-borne communicable disease or who have one (1) or more risk factors for the human immunodeficiency virus as determined by the United States

Centers for Disease Control, are prohibited by law from donating or selling blood. Persons violating the law are guilty of a Class D felony. ASK STAFF OF THIS BLOOD ESTABLISHMENT."

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

Effective: June 20, 2005

History: Amended 2005 Ky. Acts ch. 99, sec. 459, effective June 20, 2005. -- Amended 1998 Ky. Acts ch. 426, sec. 406, effective July 15, 1998. -- Amended 1994 Ky. Acts ch. 325, sec. 2, effective July 15, 1994. -- Created 1988 Ky. Acts ch. 76, sec. 2, effective July 15, 1988.

Legislative Research Commission Note. We have been advised by the U.S. Food and Drug Administration that it can only license those establishments engaged in interstate commerce.