CABINET FOR HEALTH AND FAMILY SERVICES
Office of Inspector General
Division of Health Care
(New Administrative Regulation)

902 KAR 20:019. Organ donation safety.

RELATES TO: KRS 13B, 311.1911, 311.1971
STATUTORY AUTHORITY: KRS 311.1971
CERTIFICATION STATEMENT:
NECESSITY, FUNCTION, AND CONFORMITY: KRS 311.1971 requires the Cabinet for Health and Family Services to promulgate administrative regulations establishing requirements necessary for reporting, investigation, penalties and appeals processes related to the reporting of pauses in procedure during organ donation in hospitals. This regulation establishes the cabinet procedure for pauses in procedure during organ donation.

Section 1. Definitions.
(1) "Organ donation" is defined by KRS 311.1971(1)(f).
(2) "Organ procurement organization" is defined by KRS 311.1911(16).
(3) "Pauses in procedure" is defined by KRS 311.1971(1)(g).

Section 2. Reporting Requirements.
(1) All reports required by KRS 311.1971(5)(a) and any corrective action received from any federal oversight authority shall be submitted by email to the Cabinet for Health and Family Services, Office of Inspector General, Division of Health Care to organdonationsafety@ky.gov on the same day the document is provided to, or received from, the federal oversight authority.
(2) Any health care professional or employee of a hospital or an organ procurement organization who has knowledge of violation of the duties imposed by KRS 311.1971 shall report the failure to the Office of Inspector General pursuant to KRS 216B.165(1).

Section 3. Penalties and Appeal Procedure.
(1) Upon a determination that a health care facility or an organ procurement organization did not comply with requirements of KRS 311.1971 the Office of the Inspector General shall:
(a) Report all responsible individuals or entities to law enforcement, the appropriate licensing or certification authorities;
(b) Assess a civil penalty in an amount not to exceed $500,000 for failures to comply with a pause in procedure during organ donation protocols set forth in KRS 311.1971(3);
(c) Assess a civil penalty in an amount not to exceed $250,000 for retaliating against any individual for requesting or initiating a pause in procedure during organ donation procurement;
(d) Assess a civil penalty in an amount not to exceed $5,000 per instance of failing to provide the reports or corrective action required by KRS 311.1971(5)(a); and
(e) Order the facility or organ procurement organization to suspend any organ donation recovery, preservation, or procurement activities.
(2) The amount of the civil penalty and the length of suspension shall be determined by the Inspector General, upon considering all relevant factors, including the history of compliance or noncompliance, the severity of the violation, the potential or actual harm caused to a patient, the presence of internal compliance mechanisms, and efforts to conceal or mitigate the violation.

(3) The facility or organ procurement organization may appeal a suspension or civil penalty by submitting a written notice of appeal to the Inspector General within thirty (30) calendar days from the day notice of the penalty is provided. The notice of appeal shall include a statement setting forth the particular facts or law that constitute the grounds for appeal. The hearing shall be conducted by the Office of Administrative Hearings within the Department of Law in accordance with KRS Chapter 13B.

COMPILER'S NOTE: 2025 RS HB 6, enacted by the General Assembly on March 27, 2025, altered the information to be provided at the time an administrative regulation is filed. Aside from formatting changes necessary to upload the regulation into the LRC's publication application, this regulation has been published as submitted by the agency.

TRICIA STEWARD, Inspector General
STEVEN J. STACK, MD, MBA, Secretary

APPROVED BY AGENCY: September 17, 2026
FILED WITH LRC: October 14, 2026 AT 2:00 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on December 21, 2026, at 9:00 a.m., Eastern Time / 8:00 a.m. Central Time, using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by December 14, 2026, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation through December 31, 2026. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

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