

311.1971 Pause in procedure during organ donation -- Definitions for section -- Documentation -- Reports -- Failure to comply -- Administrative regulations.

(1) As used in this section:

- (a) "Death declaration" means the formal determination of death made by a hospital physician, in accordance with accepted medical standards and applicable state and federal law, based on either the irreversible cessation of:
 - 1. Circulatory and respiratory functions; or
 - 2. Functions of the entire brain, including the brain stem;
- (b) "Donation after brain death" or "DBD" means the organ recovery process that may occur following death by irreversible cessation of cerebral and brain stem function that is characterized by an absence of electrical activity in the brain, blood flow to the brain, and brain function, as determined by clinical assessment of responses;
- (c) "Donation after circulatory death" or "DCD" means the organ recovery process that may occur following death by irreversible cessation of circulatory and respiratory functions;
- (d) "Indication of life" includes but is not limited to:
 - 1. Spontaneous movement;
 - 2. Vocalization or attempts to vocalize;
 - 3. Purposeful or reflexive responses to stimuli;
 - 4. Observed respiratory effort by a patient-initiated attempt at breath;
 - 5. Changes in heart rate or blood pressure inconsistent with a death declaration; and
 - 6. Any neurological or physiological sign suggesting pain perception or neurological activity;
- (e) "Neurological status" means the clinical assessment of brain and nervous system function, including level of consciousness, reflexes, responsiveness, and indicators of pain perception;
- (f) "Organ donation" has the same meaning as "anatomical gift" in KRS 311.1911; and
- (g) "Pause in procedure" means the immediate suspension of any organ donation recovery, preservation, or procurement activity.

- (2) (a) During any organ donation recovery, preservation, or procurement activity for a DCD or DBD, a pause in procedure shall be initiated if any individual included in paragraph (b) of this subsection reports on any of the following:
 - 1. Observed or suspected change in neurological status;
 - 2. Observed or suspected indication of life; or
 - 3. Uncertainty regarding the accuracy or completeness of neurological status or death declaration assessments.
- (b) A pause in procedure may be requested or initiated by any individual involved or present, including but not limited to:

1. Hospital physicians, nurses, or clinical staff;
 2. Organ procurement organization personnel;
 3. Transplant center personnel;
 4. Members of the surgical or anesthesiology team; and
 5. The patient's spouse or legal representative.
- (c) An individual shall not be penalized, disciplined, or retaliated against for requesting or initiating a pause in procedure.
- (3) If a pause in procedure is initiated during any organ donation recovery, preservation, or procurement activity for a DCD or DBD:
 - (a) All organ donation recovery, preservation, or procurement activities shall cease;
 - (b) A comprehensive reassessment of the patient's neurological and physiological status shall be conducted by the hospital's clinical team;
 - (c) Organ donation recovery, preservation, or procurement activity shall not be resumed until the patient's neurological function is reassessed and a DCD or DBD is determined and deemed appropriate by a hospital physician;
 - (d) All determinations regarding patient status shall remain under the sole and exclusive authority of the treating hospital and physicians; and
 - (e) A patient shall not be denied appropriate comfort care, nutrition, hydration, or life-sustaining treatment solely for the purpose of facilitating organ donation.
- (4) Any pause in procedure shall be documented in the patient's medical record by the treating hospital and physician. The documentation shall include but not be limited to:
 - (a) The reason for the pause in procedure;
 - (b) Observations triggering the pause in procedure;
 - (c) Reassessment findings; and
 - (d) Final determinations.
- (5) (a) All pauses in procedure as described in this section shall be reported to:
 1. All applicable federal oversight entities in accordance with federal law; or
 2. Any entity directed by the United States Department of Health and Human Services, Health Resources and Services Administration (HRSA) to receive the pause in procedure report and any oversight and corrective guidelines.
 - (b) A copy of reports required under paragraph (a) of this subsection and any follow-up reporting shall be forwarded to the Cabinet for Health and Family Services.
- (6) The Cabinet for Health and Family Services shall, by October 1, 2026, and by October 1 of each year thereafter, submit a report to the Legislative Research Commission for referral to the Interim Joint Committee on Health Services that provides an overview of:
 - (a) Pause in procedure cases and outcomes; and

- (b) Any corrective actions related to pause and procedure cases issued by HRSA.
- (7) (a) Failure of a person or entity to comply with this section may result in administrative actions, including but not limited to:
 - 1. Reports to appropriate licensing or certification authorities;
 - 2. Suspension of organ donation recovery, preservation, or procurement activities in the Commonwealth; and
 - 3. Assessment of civil penalties.
- (b) The Cabinet for Health and Family Services shall promulgate administrative regulations in accordance with KRS Chapter 13A to implement and enforce this section.
- (c) A health care professional or any employee of a hospital who has knowledge of a failure to comply with the requirements of subsection (2) of this section shall immediately report the failure to the Cabinet for Health and Family Services.
- (8) This section shall not be construed to:
 - (a) Conflict with the determination of death under KRS 446.400;
 - (b) Discourage ethical organ donation;
 - (c) Interfere with independent end-of-life decision making;
 - (d) Conflict with the Revised Uniform Anatomical Gift Act; or
 - (e) Authorize the Commonwealth to suspend, revoke, or otherwise affect the federal certification, designation, or service area of an organ procurement organization, which shall remain under the exclusive authority of the United States Department of Health and Human Services.
- (9) If any provision of this section or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of the section that can be given effect without the invalid provisions or application, and to this end the provisions of this section are severable.

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