

1 AN ACT relating to organ donation safety.

2 WHEREAS, an organ donation is a remarkable and life-saving gift that allows
3 thousands of individuals each year to receive life-sustaining transplants and offers hope
4 to patients and families awaiting organs; and

5 WHEREAS, the success of the organ donation and transplant system depends upon
6 public trust, transparency, and strict adherence to ethical and clinical standards that
7 prioritize patient safety and human dignity; and

8 WHEREAS, the United States Department of Health and Human Services through
9 the Health Resources and Services Administration has announced major reforms to
10 strengthen oversight of the national organ procurement system; and

11 WHEREAS, donation after circulatory death, which occurs following the
12 withdrawal of life-sustaining treatment and declaration of death based on circulatory and
13 respiratory criteria, presents unique clinical risks requiring procedural safeguards; and

14 WHEREAS, existing Kentucky law defines the determination of death but does not
15 expressly require a mandatory pause in organ procurement when new neurological
16 information or indications of life arise; and

17 WHEREAS, it is in the interest of the Commonwealth to ensure that patients,
18 families, and health care professionals have clear, enforceable protocols for organ
19 procurement;

20 NOW, THEREFORE,

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

22 ➔SECTION 1. A NEW SECTION OF KRS CHAPTER 311 IS CREATED TO
23 READ AS FOLLOWS:

24 **(1) As used in this section:**

25 **(a) "Death declaration" means the formal determination of death made by a**
26 **hospital physician, in accordance with accepted medical standards and**
27 **applicable state and federal law, based on either the irreversible cessation**

1 of:

2 1. Circulatory and respiratory functions; or

3 2. Functions of the entire brain, including the brain stem;

4 (b) "Donation after brain death" or "DBD" means the organ recovery process
5 that may occur following death by irreversible cessation of cerebral and
6 brain stem function that is characterized by an absence of electrical activity
7 in the brain, blood flow to the brain, and brain function, as determined by
8 clinical assessment of responses;

9 (c) "Donation after circulatory death" or "DCD" means the organ recovery
10 process that may occur following death by irreversible cessation of
11 circulatory and respiratory functions;

12 (d) "Indication of life" includes but is not limited to:

13 1. Spontaneous movement;

14 2. Vocalization or attempts to vocalize;

15 3. Purposeful or reflexive responses to stimuli;

16 4. Observed respiratory effort by a patient-initiated attempt at breath;

17 5. Changes in heart rate or blood pressure inconsistent with a death
18 declaration; and

19 6. Any neurological or physiological sign suggesting pain perception or
20 neurological activity;

21 (e) "Neurological status" means the clinical assessment of brain and nervous
22 system function, including level of consciousness, reflexes, responsiveness,
23 and indicators of pain perception;

24 (f) "Organ donation" has the same meaning as anatomical gift in KRS
25 311.1911; and

26 (g) "Pause in procedure" means the immediate suspension of any organ
27 donation recovery, preservation, or procurement activity.

1 (2) (a) During any organ donation recovery, preservation, or procurement activity
2 for a DCD or DBD, a pause in procedure shall be initiated if any individual
3 included in paragraph (b) of this subsection reports on any of the following:

4 1. Observed or suspected change in neurological status;

5 2. Observed or suspected indication of life; or

6 3. Uncertainty regarding the accuracy or completeness of neurological
7 status or death declaration assessments.

8 (b) A pause in procedure may be requested or initiated by any individual
9 involved or present, including but not limited to:

10 1. Hospital physicians, nurses, or clinical staff;

11 2. Organ procurement organization personnel;

12 3. Transplant center personnel;

13 4. Members of the surgical or anesthesiology team; and

14 5. The patient's spouse or legal representative.

15 (c) An individual shall not be penalized, disciplined, or retaliated against for
16 requesting or initiating a pause in procedure.

17 (3) If a pause in procedure is initiated during any organ donation recovery,
18 preservation, or procurement activity for a DCD or DBD:

19 (a) All organ donation recovery, preservation, or procurement activities shall
20 cease;

21 (b) A comprehensive reassessment of the patient's neurological and
22 physiological status shall be conducted by the hospital's clinical team;

23 (c) Organ donation recovery, preservation, or procurement activity shall not be
24 resumed until the patient's neurological function is reassessed and a DCD
25 or DBD is determined and deemed appropriate by a hospital physician;

26 (d) All determinations regarding patient status shall remain under the sole and
27 exclusive authority of the treating hospital and physicians; and

1 (e) A patient shall not be denied appropriate comfort care, nutrition, hydration,
2 or life-sustaining treatment solely for the purpose of facilitating organ
3 donation.

4 (4) Any pause in procedure shall be documented in the patient's medical record by
5 the treating hospital and physician. The documentation shall include but not be
6 limited to:

7 (a) The reason for the pause in procedure;

8 (b) Observations triggering the pause in procedure;

9 (c) Reassessment findings; and

10 (d) Final determinations.

11 (5) (a) All pauses in procedure as described in this section shall be reported to:

12 1. All applicable federal oversight entities in accordance with federal
13 law; or

14 2. Any entity directed by the United States Department of Health and
15 Human Services, Health Resources and Services Administration
16 (HRSA) to receive the pause in procedure report and any oversight
17 and corrective guidelines.

18 (b) A copy of reports required under paragraph (a) of this subsection and any
19 follow-up reporting shall be forwarded to the Cabinet for Health and
20 Family Services.

21 (6) The Cabinet for Health and Family Services shall, by October 1, 2026, and by
22 October 1 of each year thereafter, submit a report to the Legislative Research
23 Commission for referral to the Interim Joint Committee on Health Services that
24 provides an overview of:

25 (a) Pause in procedure cases and outcomes; and

26 (b) Any corrective actions related to pause and procedure cases issued by
27 HRSA.

1 (7) (a) Failure of a person or entity to comply with this section may result in
2 administrative actions, including but not limited to:

3 1. Reports to appropriate licensing or certification authorities;

4 2. Suspension of organ donation recovery, preservation, or procurement
5 activities in the Commonwealth; and

6 3. Assessment of civil penalties.

7 (b) The Cabinet for Health and Family Services shall promulgate
8 administrative regulations in accordance with KRS Chapter 13A to
9 implement and enforce this section.

10 (c) A health care professional or any employee of a hospital who has
11 knowledge of a failure to comply with the requirements of subsection (2) of
12 this section shall immediately report the failure to the Cabinet for Health
13 and Family Services.

14 (8) This section shall not be construed to:

15 (a) Conflict with the determination death under KRS 446.400;

16 (b) Discourage ethical organ donation;

17 (c) Interfere with independent end-of-life decision making;

18 (d) Conflict with the Revised Uniform Anatomical Gift Act; or

19 (e) Authorize the Commonwealth to suspend, revoke, or otherwise affect the
20 federal certification, designation, or service area of an organ procurement
21 organization, which shall remain under the exclusive authority of the
22 United States Department of Health and Human Services.

23 (9) If any provision of this section or the application thereof to any person or
24 circumstance is held invalid, the invalidity shall not affect other provisions or
25 applications of the section that can be given effect without the invalid provisions
26 or application, and to this end the provisions of this section are severable.