

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.