

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Office of Inspector General

3 Division of Health Care

4 (New Administrative Regulation)

5 902 KAR 20:019. Organ donation safety.

6 RELATES TO: KRS 13B, 311.1911, 311.1971

7 STATUTORY AUTHORITY: KRS 311.1971

8 NECESSITY, FUNCTION AND CONFORMITY: KRS 311.1971 requires the Cabinet for
9 Health and Family Services to promulgate administrative regulations establishing requirements
10 necessary for reporting, investigation, penalties and appeals processes related to the reporting of
11 pauses in procedure during organ donation in hospitals. This regulation establishes the cabinet
12 procedure for pauses in procedure during organ donation.

13 Section 1. Definitions.

14 (1) "Organ donation" is defined by KRS 311.1971(1)(f).

15 (2) "Organ procurement organization" is defined by KRS 311.1911(16).

16 (3) "Pauses in procedure" is defined by KRS 311.1971(1)(g).

17 Section 2. Reporting Requirements.

18 (1) All reports required by KRS 311.1971(5)(a) and any corrective action received from any
19 federal oversight authority shall be submitted by email to the Cabinet for Health and Family
20 Services, Office of Inspector General, Division of Health Care to
21 organdonationsafety@ky.gov on the same day the document is provided to, or received from,

1 the federal oversight authority.

2 (2) Any health care professional or employee of a hospital or an organ procurement
3 organization who has knowledge of violation of the duties imposed by KRS 311.1971 shall
4 report the failure to the Office of Inspector General pursuant to KRS 216B.165(1).

5 Section 3. Penalties and Appeal Procedure.

6 (1) Upon a determination that a health care facility or an organ procurement organization did
7 not comply with requirements of KRS 311.1971 the Office of the Inspector General shall:

8 a. Report all responsible individuals or entities to law enforcement, the appropriate
9 licensing or certification authorities;

10 b. Assess a civil penalty in an amount not to exceed \$500,000 for failures to comply
11 with a pause in procedure during organ donation protocols set forth in KRS
12 311.1971(3);

13 c. Assess a civil penalty in an amount not to exceed \$250,000 for retaliating against
14 any individual for requesting or initiating a pause in procedure during organ donation
15 procurement;

16 d. Assess a civil penalty in an amount not to exceed \$5,000 per instance of failing to
17 provide the reports or corrective action required by KRS 311.1971(5)(a); and

18 e. Order the facility or organ procurement organization to suspend any organ
19 donation recovery, preservation, or procurement activities.

20 (2) The amount of the civil penalty and the length of suspension shall be determined by the
21 Inspector General, upon considering all relevant factors, including the history of compliance

1 or noncompliance, the severity of the violation, the potential or actual harm caused to a
2 patient, the presence of internal compliance mechanisms, and efforts to
3 conceal or mitigate the violation.

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

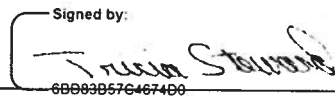
902 KAR 20:019

REVIEWED:

9/17/2026

Date

Signed by:



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Tricia Steward

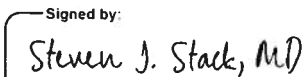
Inspector General, Office of Inspector General

APPROVED:

9/17/2026

Date

Signed by:



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Steven J. Stack, MD, MBA

Secretary, Cabinet for Health and Family Services

PUBLIC HEARING AND PUBLIC 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.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, KY 40621; Phone: 502-564-7476; Fax: 502-564-7091; CHFSrcgs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

902 KAR 20:019. Organ donation safety.

Agency Contact: Valerie Moore

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Subject Headings: Hospitals, Deaths, Physicians and Practitioners

(1) Provide a brief summary of:

(a) What this administrative regulation does: 26RS HB 510 codified as KRS 311.1971 required the cabinet to promulgate a regulation regarding pause in procedure during organ donations, requiring reports regarding this issue that are already being submitted by facilities and organ procurement organizations to the US Department of Health Services to additionally be sent to the Cabinet for Health and Family Services. Additionally, this legislation required the cabinet to assess penalties including but not limited to reporting to the appropriate licensure or certification board, suspension of program, and assessment of civil penalties for violation of statute regarding pauses in procedure during organ donation.

(b) The necessity of this administrative regulation: OIG is required by KRS 311.1971 to promulgate these regulations.

(c) How this administrative regulation conforms to the content of the authorizing statutes: 902 KAR 20:019 mandates that entities or facilities that participate in organ donation and submit reports on pauses in procedure during organ donation to the US Department of Health Services, additionally submit those reports to the cabinet. The cabinet is then further directed to compile a report of the data received in the reports and the corrective measures assessed by the federal government and submit that report annually to the legislature for their review. This administrative regulation provides details on how facilities/employees should submit reports to the cabinet, the regulation further details how reports of violations not previously reported can be submitted to the cabinet for investigation, additionally, this administration addresses penalties for violations of KRS 311.1971.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation details how employees, facilities or other entities that have information regarding pauses in procedure during organ donation or allegations of failure to pause procedures or to appropriately report pauses in procedure during organ donations occurring in Kentucky can report those for oversight and reporting purposes, and additionally lays out ways in which violations of statute are to be addressed.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This is a new administrative regulation.

(b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes: This is a new administrative regulation mandated by KRS Chapter 311.1971.

(d) How the amendment will assist in the effective administration of the statutes: This is a new administrative regulation mandated by KRS Chapter 311.1971.

(3) Does this administrative regulation or amendment implement legislation from the previous five years? Yes, 26RS HB 510, Acts Chapter 43.

(4) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Hospitals that participate in organ donation programs, employees of the affected facilities, organ procurement organizations, organ donors, families of organ donors. Per Network for Hope (the governing Organ Procurement Organization, approximately 112-125 hospitals in Kentucky participate. There are 2 main transplant centers in Kentucky. It is unknown how many employees at each facility participate in organ donation procurement and it is also unknown the number of family members who could potentially be affected by this regulation. There is 1 Organ Procurement Organization that operates in Kentucky (Network for Hope).

(5) Provide an analysis of how the entities identified in question (4) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (4) will have to take to comply with this administrative regulation or amendment: Hospitals or organ procurement organizations shall send a copy of any report detailing pauses in procedure during organ donation that are being sent to the US Department of Health Services to the Cabinet for Health and Family Services, Office of Inspector General. Facilities, staff or family members may report any failure to comply with laws regarding organ donation pauses to OIG for investigation and potential corrective action. Penalties for failure to comply with law are addressed in this administrative regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (4): No additional fiscal burden is anticipated.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (4): Compliance will ensure all safety measures and protocols are followed when procuring donated human organs.

(6) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: There is no anticipated additional cost from implementation of this administrative regulation.

(b) On a continuing basis: There is no additional cost expected as a result of this administrative regulation.

(7) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation or this amendment: No additional funding is necessary; however, if funding were to be used, it would come from state general funds.

(8) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: An increase in fees or funding will not be necessary in order to implement this administrative regulation.

(9) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish or increase any fees.

(10) TIERING: Is tiering applied? Tiering is not applied as this administrative regulation applies equally to all regulated parties impacted by it.

FISCAL IMPACT STATEMENT

902 KAR 20:019: Organ donation safety.

Contact Person: Valerie Moore

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Contact Person: Krista Quarles

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(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 311.1971

(2) Identify the promulgating agency and any other affected state units, parts, or divisions: Cabinet for Health and Family Services, Office of Inspector General, Division of Health Care

(a) Estimate the following for the first year:

Expenditures: OIG does not anticipate any additional expenditures from the implementation of this administrative regulation.

Revenues: Additional revenue is not anticipated as a result of this administrative regulation.

Cost Savings: Cost savings are not anticipated as a result of the implementation of this administrative regulation.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? No additional expenditures, revenues or cost savings are anticipated as a result of the implementation of this administrative regulation.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts): No local entities are anticipated to be affected by this administrative regulation.

(a) Estimate the following for the first year:

Expenditures: OIG does not anticipate any additional expenditures from the implementation of this administrative regulation.

Revenues: Additional revenue is not anticipated as a result of this administrative regulation.

Cost Savings: Cost savings are not anticipated as a result of the implementation of this administrative regulation.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? OIG does not anticipate additional expenditures/revenue/cost savings as a result of this administrative regulation.

(4) Identify additional regulated entities not listed in questions (2) or (3): Hospitals that participate in organ donation programs and organ procurement organizations.

(a) Estimate the following for the first year:

Expenditures: No additional expenditures are anticipated as a result of this administrative regulation.

Revenues: No additional revenues are expected as a result of this administrative regulation.

Cost Savings: No additional cost savings are expected as a result of this administrative regulation.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? OIG does not anticipate additional expenditures/revenues or cost savings as a result of implementation of this administrative regulation.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation: There is no anticipated fiscal impact as a result of this administrative regulation.

(b) Methodology and resources used to determine the fiscal impact: There is no anticipated fiscal impact from implementation of this administrative regulation.

(6) Explain:

(a) Whether this administrative regulation will have an overall negative or adverse major economic impact to the entities identified in questions (2) - (4). (\$500,000 or more, in aggregate) There is no anticipated economic impact as a result of this administrative regulation.

(b) The methodology and resources used to reach this conclusion: There is no additional fiscal impact anticipated as a result of this administrative regulation.