HRSA
Health Resources & Services Administration
Health Systems Bureau/Division of Transplantation
5600 Fishers Lane
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President, Board of Directors
Organ Procurement and Transplantation Network
[redacted]

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Interim Executive Director
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Dear Dr. Formica and Ms. Wyse Morrissette:

The Health Resources and Services Administration (HRSA) has considered the Organ Procurement and Transplantation Network's (OPTN) recommendations in regard to organ procurement care provided by Network for Hope (OPTN code: KYDA), the organ procurement organization (OPO) serving Kentucky, southwest Ohio, and part of West Virginia. On October 18, 2024, HRSA directed the OPTN to undertake this special review based on authority granted by the final rule governing the operation of the OPTN (OPTN Final Rule) as described in 42 CFR 121.10(b)(3):

> *At the request of the Secretary, the OPTN shall conduct special reviews of OPOs and transplant programs, where the Secretary has reason to believe that such entities may not be in compliance with these rules or OPTN policies or may be acting in a manner which poses a risk to the health of patients or to public safety.*

In parallel with the OPTN's special review, HRSA has undertaken its own review of KYDA under the authority described in 42 CFR 121.10(a) (emphasis added):

> ***Review and evaluation by the Secretary.*** *The Secretary or her/his designee may perform any reviews and evaluations of member OPOs and transplant programs which the Secretary deems necessary to carry out her/his responsibilities under the Public Health Service Act and the Social Security Act.*

Background

The impetus for the OPTN and HRSA investigations was an allegation of potentially preventable harm to a neurologically injured patient in KYDA's donor service area (DSA) in 2021. The allegation was made in the form of a letter discussed at a Congressional hearing on September 11, 2024. On September 12, 2024 the OPTN Membership and Professional Standards Committee

(MPSC) sent a letter to KYDA requesting details of the case, including documents from the patient's electronic medical record (EMR) maintained by the OPO and results of any root cause analyses performed with regard to the case. KYDA replied to this request on September 20, 2024 with a letter clarifying that the case was not one involving brain death, but rather donation after circulatory death (DCD) procurement. The reply did not include the patient-level materials or administrative documents requested by the MPSC. On September 24, 2024, the MPSC closed the case without further action.

On October 1, HRSA directed the OPTN to reopen the investigation and reiterate the request for documents. On October 7, 2024, KYDA returned documents that had been requested by the OPTN in the September 12, 2024 letter. On the basis of these materials, HRSA directed the OPTN to request additional medical records from KYDA, with the period of review covering October 2021 through December 2024. Due to concerns regarding the MPSC's inadequate prior response, HRSA directed the OPTN to empanel an ad hoc review group to examine KYDA records provided[1] for the special review. On February 27 and March 3, 2025, the OPTN Board of Directors convened to discuss the findings of the special review.

Findings of the OPTN Special Review

The OPTN's report in response to the special review of KYDA is attached as Appendix I. The OPTN's final four page report stated, "[*O*]*verall, there were no major concerns or patterns identified. While no major issues were found, reviewers pointed out a few small areas of improvement*."[2] Specific points for improvement included a recommendation to improve surgical coverage to minimize alleged delays, and potentially premature contact with to patient families to request organs prior to assessment of the patient's suitability for donation. Following discussion of potential compliance options, the OPTN Board of Directors voted to make the following recommendation to the Secretary regarding KYDA:

> "*The OPTN recommends the Secretary (1) require KYDA to perform a root cause analysis of KYDA's failure to adhere to its own policies, including, but not limited to, failure to comply with the Five Minute Observation Rule, (2) require KYDA to develop and adhere to a KYDA policy that clarifies who is a suitable candidate as a DCD donor, and (3) require KYDA to develop a policy that allows any individual to stop progression of a donation if they identify a patient safety issue*."

Findings of the HRSA Review

Between December 1, 2024 and February 28, 2025, HRSA reviewed the complete set of OPO EMR documents for 351 unique patients for whom organ donation was attempted by KYDA but from whom organs were not procured (generally referred to by the organ procurement industry as "authorized not recovered" or ANR patients). In addition, HRSA reviewed documents regarding hospital development and corrective action reports in response to KYDA-identified

[1] HRSA notes that the empaneled committee did not complete review of 47 (13% of total) cases.
[2] "Findings of the HRSA-Directed Investigation of Network for Hope," report to OPTN Board of Directors, 3/4/2025.

adverse events. In contrast to the OPTN report of its special review, HRSA found a concerning pattern of risk to neurologically injured patients in KYDA's DSA stemming from KYDA staff practices. These included:

1. Inconsistent assessment and re-assessment of patient neurologic function to detect changes that could be inconsistent with or unfavorable to DCD organ recovery. *Multiple patients were documented as evincing pain or discomfort during peri-procurement events after OPO staff had either failed to adequately assess neurologic function in the setting of sedation or chemical paralysis, or had documented findings inconsistent with successful DCD recovery without change to the plan for procurement.*

2. Inconsistent coordination of care with patients' primary medical teams, including a lack of clarity in the roles of OPO staff and healthcare teams in patient care. *OPO records document instances of OPO staff preempting healthcare teams' concerns about planned care.*

3. Inconsistent attention to independent decision-making authority of legal next of kin. *OPO records document OPO staff approaching potential donors' family members that they believed to be under the influence of illicit substances or lacking cognitive capacity to understand their role in the decision to donate..*

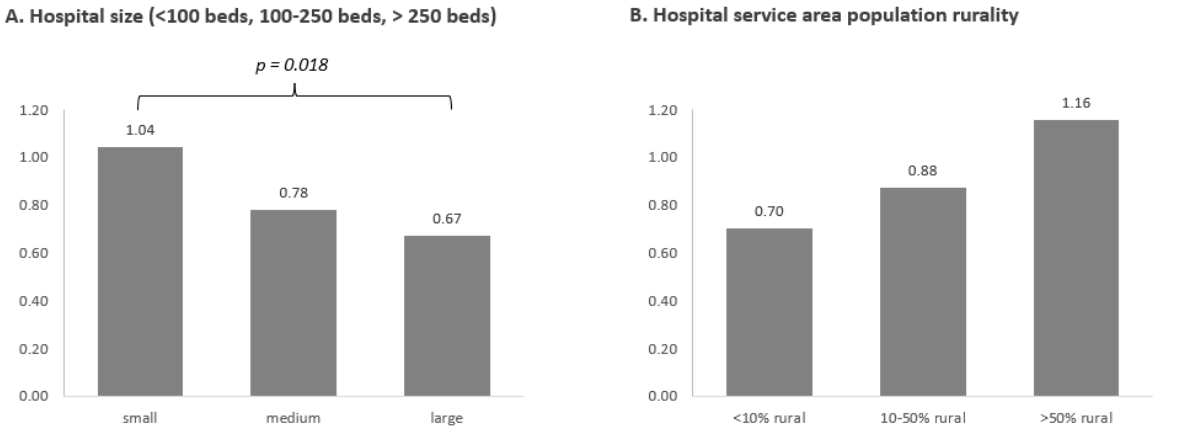
4. Inconsistent collection and coding of patients' medical data, as outlined in OPTN policies,[3] professional best practices[4] as well as internal policies and guidelines. *A high proportion of patients for whom the OPO's records show evidence of drug overdose or intoxication were described as having mechanisms of death other than drug-related.*

HRSA's review found 103 ANR cases (29.3%) with concerning features, including 73 patients (20.8%) for whom either the initial or subsequent neurologic status showed features not conducive to DCD procurement. At least 28 (8.0%) patients had no cardiac time of death noted, suggesting potential survival to hospital discharge.[5]

The records HRSA reviewed suggest that patients may experience variable care from KYDA depending on the hospital in which they are seen. There was a higher frequency of ANR cases relative to total DCD procurements at smaller hospitals and hospitals serving more rural populations (Figure 1).

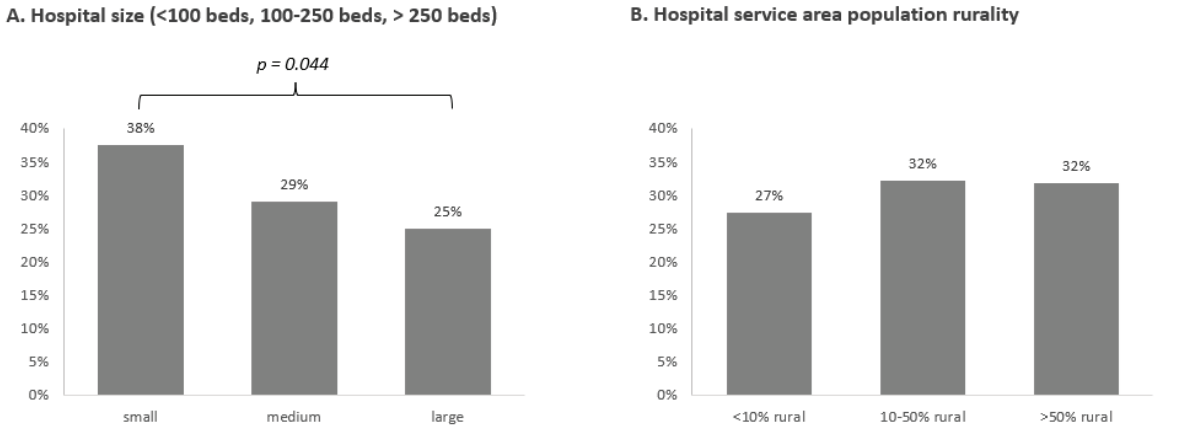
[3] See: OPTN Policies 2.3, 2.11.
[4] Association of Organ Procurement Organizations (AOPO) Standards & Interpretive Guidelines, 2020, CL-4B.
[5] See: 42 CFR 486.328(a) *Condition: Reporting of Data* for requirements regarding the "number of deaths" and "data related to the non-recovery of organs" for which cardiac time of death would generally be collected and noted by the OPO for authorized, but not procured, patients.

Figure 1: Authorized, not recovered (ANR) cases per DCD donor, by hospital characteristic within KYDA DSA 2021-2024



The fraction of ANR cases with concerning clinical features also varied by hospital size and patient population (Figure 2).

Figure 2: Fraction of ANR cases with concerning features by hospital characteristic with KYDA DSA, 2021-2024



Cases submitted by KYDA consistently misreported the role of illicit drug use in patient histories. Among the 351 cases reviewed by HRSA, 28 (8.0%) were reported as having drug intoxication as their mechanism of death. Review of material entered by KYDA staff into their EMR shows that OPO staff had information showing that 98 (27.9%) of ANR cases showed the terminal admission and neurologic insult to be related to active use of opioids, amphetamines, or cocaine at the time of their injury.[6] Stated another way, KYDA did not document drug overdose

[6] This is a conservative estimate, as it is based on documentation in OPO staff notes, patient toxicology reports, and family reporting of active drug use at the time of the patient's presentation. Records provided to HRSA trended toward lesser inclusion of these chart elements in 2023 and 2024, so the fraction of cases with missed drug intoxication as a cause may be higher than reported.

as the mechanism of death in approximately three out of four patients with evidence of drug intoxication from the sample HRSA reviewed.

The miscoding or lack of recognition of drug intoxication is of relevance because patients in a DCD pathway may be at higher risk of their neurologic condition being masked by ongoing psychoactive effects of drug intoxication. As opposed to brain dead donors, in which physiologic or chemical confounders of suppressed mental status must be ruled out prior to establishing a brain death diagnosis, there is no such standard for DCD evaluation.[7] The risk for potential-DCD patients is that depressed mental status may be ascribed to a permanent and irreversible injury, rather than slow clearance of the effects of chemical intoxication. Twenty of the ANR cases reviewed by HRSA, including that of the index patient, involved failure to recognize high neurologic function in a victim of drug intoxication. In 15 (75%) of those cases, the OPO's documented mechanism of death did not reflect overdose as the inciting event for the neurologic injury. As above, these numbers and rates are conservative estimates given the incomplete nature of the OPO charts.[6]

The prevalence of these patient-level issues suggests systemic concerns regarding the treatment of potential DCD donor patients by KYDA staff. HRSA's review indicates the potential for ongoing risk of harm to patients in KYDA's DSA, as cases similar to the 2021 index case were found to have occurred as recently as December 2024.

Corrective actions

Action to address care by KYDA that presents potential risk to public health and patient safety and provide objective and transparent oversight of all OPOs is central to HRSA's regulatory role and the aims of the OPTN Modernization Initiative, as it serves to measurably improve accountability, fairness, and performance within the national organ procurement and transplant system.[8] HRSA has considered the OPTN's report of its special review of KYDA, in conjunction with HRSA's findings of its own review of KYDA records. As per the OPTN Final Rule:

> *"[t]he Board of Directors shall advise the Secretary of the results of any reviews and evaluations conducted under . . . paragraph(b)(3) of this section [relating to Secretary-directed OPTN special reviews] which, in the opinion of the Board, indicate noncompliance with these rules or OPTN policies, or indicate a risk to the health of patients or to the public safety, and shall provide any recommendations for appropriate action by the Secretary*"; and *"[u]pon the Secretary's review of the Board of Directors' recommendations, the Secretary may . . . take such other action as the Secretary deems necessary*."[9]

Pursuant to these authorities, this letter directs the OPTN to take the following actions:

[7] Greer DM, Kirschen MP, Lewis A, et al. (2023) Neurology 101(24):1112-1132.
[8] HRSA OPTN Modernization Initiative announcement, 3/22/2023.
[9] See: 42 CFR 121.10 (c).

(A) Within 30 days, develop and implement a 12-month OPTN MPSC monitoring plan for KYDA to address the concerns identified in the OPTN and HRSA reviews, including improved documentation of patient neurologic status. Reliability, completeness, and timing of neurologic assessment by KYDA should be the highest priority. At a minimum, the monitoring plan should address the following areas:

1. Just-in-time pre-procurement education with hospital operating room staff about anticipated possible outcomes from DCD procurements with patient-specific information including accurate neurologic status.

2. Neurologic assessments at a minimum frequency of every twelve hours from initial assessment until case end, either by organ recovery, cardiac time of death without organ recovery, or case closure. Assessments should include:
    a. Total and component (eye, motor, verbal) Glascow Coma Scale (GCS)
    b. Brain stem reflexes (cough, gag, corneal, pupillary)
    c. Respiratory effort, including ventilator settings and mandatory and patient-initiated breath rates
    d. Patient sedative history, including current infusions and injections of narcotic, sedative, or other psychoactive medications in the six hours preceding exam
    e. Presence or absence of pathologic or pharmacologic paralysis
    f. Evidence or suspicion of reversible encephalopathy from infection, uremia, drug withdrawal or metabolic source

3. Consultation with the primary healthcare team regarding any potential risk or concern that the patient has not metabolically cleared any illicit psychoactive drugs, and document such assessment.

4. Documentation for all paralytic and psychoactive medications administered in conjunction with withdrawal of life support, with documentation beginning six hours prior to extubation or other withdrawal of support through either cardiac time of death or termination of the procurement attempt.

Failure to comply with corrective action requirements as described above will prompt review by the Secretary for further actions to protect patient safety and public health in the KYDA DSA.

Since the review of KYDA was initiated, HRSA has received reports of similar patterns of high risk DCD procurement practices at multiple other OPOs. While reviews of these individual events and OPOs are ongoing, the high frequency of DCD procurement and concern for variation in the quality and safety of care across the country merit immediate development of minimum safety standards for the protection of neurologically injured patients being assessed as potential DCD donors. Therefore, the Secretary directs the OPTN to:

(B) Within 180 days, propose policies for public comment to improve safeguards for potential DCD patients in the organ procurement process and increase information shared with patient

families regarding DCD organ procurement. At a minimum, the proposed policies should address:

1. The process by which a "pause" in procurement efforts can be undertaken if there is concern for unrecognized neurological improvement or potential for a patient to experience pain in the act of procuring organs, including:
    a. A process for informing all stakeholders, including patient family, hospital staff, transplant center staff, and third party procurement and preservation staff that they empowered to call for a pause on procurement efforts if they believe the patient is experiencing increased neurological function or is at risk of experiencing pain during a procurement attempt.
    b. Any automatic triggers for a pause in procurement efforts if the patient shows objective signs of improving neurologic status. Potential triggers could include changes in brain stem reflexes, change or minimum threshold for GCS, or planned DCD procurement in the setting of self-determined withdrawal of care.
    c. Requirements for informing legal next of kin (LNOK), primary healthcare team, hospital leadership team, and any transplant centers with provisional acceptances if a pause in DCD organ procurement is triggered or requested.
    d. In cases where a pause is triggered or requested, requirements for the OPO to fulfill prior to resuming procurement efforts, such as convening with LNOK and primary healthcare team to discuss the patient's suitability for continued procurement efforts.
    e. In cases where procurement efforts are resumed after a pause has been triggered and discussed, the OPO must:
        1. Obtain acknowledgement from all transplant teams and their contracted representatives (i.e. procurement and preservation contractors) that they are aware of the pause and its resolution prior to the surgical procedure
        2. Inform the OPTN and HRSA of the case's resumption and subsequently provide further medical records to document case outcome.
    f. Data that should be collected regarding any "pauses" in procurement attempts. Data should be captured in the OPTN Deceased Donor Registration (DDR) Form or OMB-approved DDR replacement instrument. Each proposed field for data collection should be named and defined.
    g. A requirement for the OPTN to be informed within 24 hours of any requested or triggered pause, including specific data elements or records that should be included in the notification. MPSC will review the cadence and outcome of pauses during regular monthly meetings.

2. Requirements for family information about DCD organ procurement to be provided at the time of organ donation authorization. This education should include descriptions of any actions to be taken by the hospital and OPO should the patient not expire within the operative time limit or if organ procurement attempts are aborted in the operating room. HRSA understands this education is prevalent among OPOs, but the content and scope of

this education is variable and not defined in policy.[10] The OPTN should define what elements must be included in this education, and should involve the OPO, Ethics, and Patient Affairs Committees and donor, family, and patient representatives from the community to ensure the patient views are central to the proposed policy requirements.

3. An addition to OPTN Policy 2.2 that describes the OPO's responsibility to ensure that the patient family, hospital staff, transplant center staff, and third party procurement and preservation staff are empowered to call for a "pause" on procurement efforts if they believe the patient is experiencing increased neurological function or is at risk of experiencing pain during a procurement attempt to comport with the proposed policy described in this letter at (B)(1)(a), above.

4. An addition to OPTN Policy 2.2 that describes the OPO's responsibility to ensure accuracy in neurological assessment and appropriate neurological re-assessments to comport with the proposed policy described in this letter at (B)(1)(b), above.

5. For the policies proposed in (B)(1)–(4), above, the OPTN should include language that will solicit public comment regarding whether the proposed OPTN policies should be approved by the Secretary and made enforceable by HHS, in accordance with the process outlined in the OPTN regulations at 42 CFR 121.4(b)(2) and (c).

HRSA appreciates the work of the OPTN on behalf of patients, and we look forward to a collaborative relationship in enacting these needed safety reforms. If the OPTN has questions about the directives contained in this letter, HRSA staff are available for discussion and support. Please send the OPTN's response to the directives in parts A and B, above, by the dates indicated. Given that my role as HRSA's Health Systems Bureau Associate Administrator is one of oversight, on behalf of the Secretary, I will review the OPTN's response considering the requirements of NOTA and the OPTN Final Rule.

Sincerely,

Suma Nair -S Digitally signed by Suma Nair -S Date: 2025.05.28 11:25:01 -04'00'

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[10] See Association of Organ Procurement Organization (AOPO) Standards and Interpretive Guidelines, January 2020, sections CL 11.2-11.3. https://aopo.org/wp-content/uploads/AOPO-Standards-Interpretive-Guidlines_January-2020_Final.pdf