HRSA
Health Resources & Services Administration

Health Systems Bureau
5600 Fishers Lane
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Dear Dr. Formica and Ms. Wyse Morrissette:

Thank you for the October 8, 2024 response from the Organ Procurement and Transplantation Network (OPTN) to the Health Resources and Services Administration (HRSA) regarding the critical comment about the practice of normothermic regional perfusion (NRP).

HRSA has considered the OPTN's response in light of the requirements of the National Organ Transplant Act (NOTA) of 1984, as amended, and the final rule governing the operation of the OPTN (OPTN Final Rule) as described in 42 U.S.C. 274(c); 42 CFR 121.4(d). Consistent with HRSA's oversight role, this letter directs the OPTN to submit a detailed plan by April 30, 2025 outlining:

1) Proposed OPTN policies, policy definitions, data collection, technical and quality standards, and standard practices that address patient safety for organ procurement organizations using NRP in patients from whom organs may be procured, and
2) Proposed OPTN data collection regarding the attempted and/or successful use of NRP in patients from whom organs may be procured.

The proposed plan should include key actions and timelines to develop and implement the policies, policy definitions, data collection, technical and quality standards, standard practices and data collection.

In addition to the OPTN's plan described above, HRSA requests additional information from the OPTN regarding NRP, as detailed in (A) – (D) below.

(A) The OPTN response to HRSA provided information regarding NRP as a practice. HRSA notes that the OPTN response included the following statement:

> *[The OPTN Board of Directors] determined it is imperative that the OPTN develop consistent and transparent protocols that all [organ procurement organizations (OPOs)] and transplant hospitals engaged in NRP recoveries must follow. Otherwise, there is a risk that the lack of standardized protocols will begin to cause distrust and could negatively impact people's willingness to agree to organ donation.*

In its response, the OPTN recognized a need for OPTN-developed NRP protocols and quality standards. HRSA would like additional information on actions relating to NRP that were taken by the OPTN to meet the OPTN's obligation, described at 42 U.S.C. 274(b)(2)(E), to adopt and use standards of quality for the acquisition of donated organs. HRSA requests that the OPTN provide information regarding the development of quality standards for NRP as considered by the OPTN prior to the September 27, 2024 critical comment.

1. Please provide the date, agenda, recordings, and discussion notes for each item at a Board of Directors meeting, OPTN Committee meeting, and/or OPTN regional meeting during the period from January 1, 2021 to September 27, 2024, specifically related to the need for and development of standards and policies related to the use of NRP.
2. The OPTN response describes a "*rise in NRP cases*" around January 2023 as noted by the Membership and Professional Standards Committee (MPSC). The OPTN notes that this "*rise*" led to a communication with OPTN members.[1]
    a. Please provide all records, including but not limited to dates, agendas, recordings, and discussion notes, related to the identification of this "*rise*" in NRP cases as identified by the MPSC.
    b. Please describe if, and when, the MPSC informed the OPTN board regarding the "*rise in NRP cases*," and all actions considered by the MPSC and/or OPTN board to address this "*rise*."

The OPTN response includes the following statement:

> *Therefore, on September 26, 2024 we took the following action:The OPTN Operations & Safety Committee is charged with establishing requirements for standardized practice in the use of NRP in organ procurement by both OPOs and transplant hospitals.*

HRSA seeks additional clarification regarding the OPTN's response to HRSA's request for: *"2. All OPTN Bylaw and Policy requirements related to use, monitoring, data reporting, and clinical setting for NRP in the care of potential organ donor patients."*

[1] See: "*An important message from the MPSC on donation after circulatory death (DCD) protocols and managing multiple organs*" accessible at: https://optn.transplant.hrsa.gov/news/an-important-message-from-the-mpsc-on-donation-after-circulatory-death-dcd-protocols-and-managing-multiple-organs/,

3. Please describe if, and when, the OPTN instructed any committee, workgroup, or task force to gather information when NRP is planned, attempted, or successfully performed in the clinical procurement of organs, including, but not limited to, any actions prior to September 26, 2024.

4. Please provide all records, including but not limited to dates, agendas, recordings, and discussion notes, related to the OPO Committee's proposed data collection tool for machine perfusion, including NRP, proposed on or around March 27, 2024.[2]

5. Please verify the OPO Committee's stated timeline of submitting a proposed machine perfusion data collection for public comment in July 2025,[3] and target for submission to OPTN Board for approval in December 2025.[4] Please specify at what target date the OPTN anticipates requiring such data collection if Board approval occurs in December 2025.[4]

6. Please describe if, and how, the OPO Committee's and/or Machine Perfusion Data Workgroup's proposed data collection fields address potential donor patient safety concerns or potential adverse events in NRP.

HRSA also seeks information regarding the number of OPTN business members that may hold third party contracts with OPOs or transplant centers to provide NRP services.

7. Please provide, for each OPTN business member, confirmation if the business member has provided third-party NRP services under contract or other agreement with an OPO or transplant center since January 1, 2021, a description of those services, and identification of the OPOs and transplant centers to which such business member provided those services and timeframe during which they were provided.

(B) HRSA has reviewed the documents gathered by the OPTN contractor from OPOs per the September 27, 2024 request. Commentators have suggested that non-standard OPO protocols, which are not currently subject to OPTN policy requirements regarding NRP may contribute both to widely variable conditions under which patients may undergo NRP protocols in the attempt to procure organs, as well as variable processes under which NRP

[2] See: "*They noted that NRP is going to be important to allocation, but all of that information is collectible by the OPO.*" March 27, 2024 OPTN OPO Committee meeting minutes accessible at: https://optn.transplant.hrsa.gov/media/jzklj4rk/20240327_optn-opo-meeting-summary_final.pdf

[3] See: Machine Perfusion Workgroup meeting recording, September 25, 2024, in which an OPTN volunteer stated: "*But I feel like within our NRP, because the data sources is relatively well contained and the procedures or the machine variability is less. I suspect that we could probably bang out NRP in, you know, a meeting or two and, come up with a reasonable solution to it*."

[4] See: Agenda item "*OPO Committee, Machine Perfusion Project first check in*" presentation slides, noted in August 12, 2024 OPTN Data Advisory Committee meeting minutes accessible at: https://optn.transplant.hrsa.gov/media/30xmxdre/20240812_dac_committee-meeting-summary.pdf

may be administered.[5,6] Therefore, HRSA requests the following information from the OPTN to further HRSA's review of NRP use in patients by OPOs to date:

1. For each OPO, please collect every patient record since January 1, 2021 for patients with attempted or actual recovery as donation after cardiac death (DCD) donor patients, including UNet DonorID and the OPO's unique patient identifier.
    a. For each patient record, please specify whether each patient had NRP:
        i. planned,
        ii. attempted (i.e., unsuccessful cannulation or initiation of circuit perfusion),[7]
        iii. perfused and halted (i.e., perfusion for less than one hour or less than the preoperatively planned timeframe before cross-clamp[8,9]), or
        iv. successfully performed.
    b. For each patient record, please specify:
        i. Cannula placement location: aortic, iliac, or femoral.
        ii. If femoral venous and/or arterial access was made pre-mortem,[10] either for diagnostic purposes or to aid in post-mortem cannulation, please note for each line attempt:
            1. The source of consent
            2. The location of the procedure (intensive care unit (ICU), operating room (OR))
            3. The personnel performing the procedure (hospital, OPO, transplant center, other)

[5] See: Sellers, M. T., Philip, J. L., Brubaker, A. L., Cauwels, R. L., Croome, K. P., Hoffman, J. R., Neidlinger, N. A., Reynolds, A. M., Wall, A. E., & Edwards, J. M. (2024). Normothermic Regional Perfusion Experience of Organ Procurement Organizations in the US. *JAMA Network Open*, *7*(10), e2440130. https://doi.org/10.1001/jamanetworkopen.2024.40130

[6] As noted in a conversation between OPTN contractor staff and MPSC chair in an MPSC leadership meeting on February 18, 2025, "*the member is responsible for parties that they contract with and the actions that [contracted parties] take*."

[7] See: November 20, 2024 OPTN Machine Perfusion Data Workgroup meeting, in which a volunteer stated that "*intention*" of NRP was relevant to data collection, as in "*getting an understanding of when we try and fail to get [potential donor patients] on the circuit, akin to how surgeons document surgical damage in a regular donor.*" Meeting minutes accessible at: https://optn.transplant.hrsa.gov/media/g5el5ie3/20241120_opo_machine-profusion-data-collection-workgroup_meeting-summary.pdf

[8] See: "*Based on currently available evidence, a minimal duration of 1 hour and maximal duration of 4 hours should be considered for organ evaluation*." Croome, K., Bababekov, Y., Brubaker, A., Montenovo, M., Mao, S., Sellers, M., Foley, D., Pomfret, E., & Abt, P. (2024). American Society of Transplant Surgeons Normothermic Regional Perfusion Standards: Abdominal. *Transplantation*, *108*(8), 1660–1668. https://doi.org/10.1097/TP.0000000000005114

[9] See: Hoffman, J. R. H., Hartwig, M. G., Cain, M. T., Rove, J. Y., Siddique, A., Urban, M., Mulligan, M. S., Bush, E. L., Balsara, K., Demarest, C. T., Silvestry, S. C., Wilkey, B., Trahanas, J. M., Pretorius, V. G., Shah, A. S., Moazami, N., Pomfret, E. A., Catarino, P. A., & In collaboration with members from The American Society of Transplant Surgeons (ASTS), The International Society of Heart and Lung Transplantation (ISHLT), The Society of Thoracic Surgeons (STS), and The American Association for Thoracic Surgery (AATS) (2024). Consensus Statement: Technical Standards for Thoracoabdominal Normothermic Regional Perfusion. *Transplantation*, *108*(8), 1669–1680. https://doi.org/10.1097/TP.0000000000005101

[10] HRSA notes that six of the submitted OPO protocols explicitly permit or reference pre-mortem cannulation ([redacted], [redacted]). One OPO ([redacted]) expressly prohibits pre-mortem cannulation. Twenty-three OPO protocols were silent on pre-mortem cannulation in documents provided to the OPTN.

4. Whether local anesthetic was used[11]
5. Whether sedation was given or adjusted
6. Whether cannulae placed pre-mortem became dislodged
7. Whether any complications were noted (hemorrhagic, embolic, ischemic, or infectious)
8. Whether a clinical note was entered into the patient's hospital chart
9. For patients who did not expire within the OPO's timeframe for DCD organ recovery, note whether femoral access was removed, and if so, by what personnel and at what time point (in OR, in ICU).[12]

c. For each of these patient records, please specify if, and which of the following procedures[13,14,15] were used to limit extent of arterial blood flow:
   i. Clamping of brachiocephalic vessels with a single clamp
   ii. Clamping of brachiocephalic vessels individually
   iii. Suture or staple ligation of brachiocephalic vessels
   iv. Clamping of the descending aorta
   v. Suture or staple ligation of descending aorta
   vi. Balloon occlusion of the descending aorta, with indication of this as temporary or definitive control.

   For each case, please specify if the artery was divided above the level of vascular control, and if so, whether it was left open to either atmosphere or to a return line for the NRP circuit.[5] For cases where a clamp was used, please specify whether a single or double clamp was applied.
d. For each of these patient records, please specify how adequacy of cerebral blood flow interruption was assessed,[9,15,16,17] including:

[11] See: [redacted] response, *"Cannulation of the femoral artery and vein access under local anesthetic will be completed if necessary and as approved by patient, NOK [next of kin] authorization, or appropriate surrogate authorization."*
[12] HRSA notes that only two OPOs [redacted]) of six that permit pre-mortem cannulation specify removal of cannula in patients who do not progress to cardiac death.
[13] See: Domínguez-Gil, B., Miñambres, E., Pérez-Blanco, A., Coll, E., & Royo-Villanova, M. (2025). Sustained Absence of Perfusion to the Brain Must Be Ensured During Thoracoabdominal Normothermic Regional Perfusion. *Transplantation*, *109*(1), e78. https://doi.org/10.1097/TP.0000000000005230
[14] See: Manara, A., Shemie, S. D., Large, S., Healey, A., Baker, A., Badiwala, M., Berman, M., Butler, A. J., Chaudhury, P., Dark, J., Forsythe, J., Freed, D. H., Gardiner, D., Harvey, D., Hornby, L., MacLean, J., Messer, S., Oniscu, G. C., Simpson, C., Teitelbaum, J., … Watson, C. J. E. (2020). Maintaining the permanence principle for death during in situ normothermic regional perfusion for donation after circulatory death organ recovery: A United Kingdom and Canadian proposal. *American Journal of Transplantation, 20*(8), 2017–2025. https://doi.org/10.1111/ajt.15775
[15] See: Wall, A. E., Merani, S., Batten, J., Lonze, B., Mekeel, K., Nurok, M., Prinz, J., Gil, J., Pomfret, E. A., & Guarrera, J. V. (2024). American Society of Transplant Surgeons Normothermic Regional Perfusion Standards: Ethical, Legal, and Operational Conformance. *Transplantation*, *108*(8), 1655–1659. https://doi.org/10.1097/TP.0000000000005115
[16] See: Perez-Villares, J. M., Rubio, J. J., Del Río, F., & Miñambres, E. (2017). Validation of a new proposal to avoid donor resuscitation in controlled donation after circulatory death with normothermic regional perfusion. *Resuscitation*, *117*, 46–49. https://doi.org/10.1016/j.resuscitation.2017.05.030
[17] See: Gardiner, D., McGee, A., Kareem Al Obaidli, A. A., Cooper, M., Lentine, K. L., Miñambres, E., Nagral, S., Opdam, H., Procaccio, F., Shemie, S. D., Spiro, M., Torres, M., Thomson, D., Waterman, A. D., Domínguez-Gil, B., & Delmonico, F. L. (2025). Developing and Expanding Deceased Organ Donation to Its Maximum Therapeutic Potential: An Actionable Global Challenge From the 2023 Santander Summit. *Transplantation*, *109*(1), 10–21. https://doi.org/10.1097/TP.0000000000005234

i. If continuous arterial blood pressure monitoring was performed above the level of the clamp, and at what anatomic point.
ii. Which individual roles, either hospital staff, OPO staff, contractor staff, or operative team staff, had designated responsibility to monitor for evidence of cerebral perfusion and/or neurologic activity on the part of the donor patient.
iii. How use of paralytic agent in the perfusate may impact monitoring for evidence of neurologic reanimation.
iv. The protocol response to concerns of cerebral perfusion and/or neurologic reanimation during NRP.

e. For each record, please specify whether the patient:
   i. had organs procured (and list procured organs),
   ii. expired in the operating room but had no organs procured, or
   iii. did not expire in the operating room.
f. For each patient record, please specify the terminal point of the OPO's record, including cardiac time of death (whether in operating room or on the floor) and/or discharge.
   i. For each patient with pre-mortem arterial access without a cardiac time of death, please specify if the OPO examined the patient for an ischemic injury at the cannulation site.
   ii. For each patient with pre-mortem arterial access without a cardiac time of death, please specify if the OPO noted an ischemic injury at the cannulation site.

2. For each OPO, please provide each patient record for all cases in which there was concern for neurologic perfusion and/or neurologic activity after the initiation of NRP.
   a. For each patient, provide a description of which modality of monitoring or activity detected this concern, including whether it was observed by hospital, OPO, transplant center, third party procurement, or other staff.
   b. For each patient, describe the response on the part of staff in the categories described in (B)(6)(a) above, including whether NRP was continued or aborted, and whether organs were recovered from the donor patient.
   c. For each patient, provide all post-case actions and/or education undertaken by OPO which were conducted to prevent reoccurrence of neurologic perfusion.

3. For each OPO, please specify if the NRP protocol permits drapes to be stapled to potential donation after cardiac death (DCD) donor patients procured in the operative environment.[18]
   a. Each OPO should specify if this policy applies to all DCD potential donor patients, or only those undergoing NRP.

[18] See: [redacted] response, *"The patient is prepped and draped for the surgical procedure in normal fashion by hospital staff. Care will be taken not to attach the towel clamps or staples to the patient."*

4. For each OPO, please specify whether the NRP protocol includes direction regarding methods[9,16] of vascular control, as in (B)(1)(c) above, including any, some, or all of the following actions to be taken with cranial aspects of occluded vessel(s):
    a. Clamped,
    b. Cut,
    c. Vented externally,
    d. Aspirated from the surgical field, and/or
    e. Returned to the circuit.

5. For each OPO, please specify whether the NRP protocol does or does not include a notification or reminder to the operative team that the patient may have intact hearing or perception.[19]
    a. If the OPO NRP protocol does not specify this notification, please include if the OPO protocol for DCD potential donor patients includes a reminder to the operative team that the patient may have intact hearing or perception.

6. For each OPO, please specify whether the NRP protocol includes methods to limit donor patients' auditory or visual awareness of surroundings during transport to the operating room and/or withdrawal of life-sustaining therapy.
    a. If the OPO NRP protocol does not specify such methods, please include if the OPO protocol for DCD potential donor patients includes methods to limit donor patients' auditory or visual awareness of surroundings during transport to the operating room and/or withdrawal of life-sustaining therapy.

7. For each OPO, please specify whether the NRP protocol permits a perfusionist or other member of the organ recovery team to remain in the patient room prior to declaration of death to manage patient movement or perform maintenance of any cannula placed pre-mortem.[20]

8. For each OPO, please specify what, if any, OPO protocols, policies, guidelines, or third-party contractual agreements describe or otherwise elaborate on potential ethical considerations that may arise in the use of NRP.[21]
    a. Please provide all policies, guidelines, and/or educational materials provided by OPOs to hospitals regarding the use of NRP in patients in organ procurement.
    b. Please provide all agreements between OPOs and hospitals that describe, permit, or otherwise discuss the use of NRP in patients, including permission or limitations on pre-mortem femoral access for the purpose of NRP.[22]

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[19] See: [redacted] response, NRP "huddle" process: *"As a reminder, this patient is alive and therefore has potential to still hear speech until cardiac death occurs. We ask that all discussion be respectful and kind."*
[20] See: [redacted] response, *"We may need to have a perfusionist to stay scrubbed and available to assist with cannula management if the patient is moving significantly."*
[21] See: [redacted] response, *"[Regional Perfusion Services] RPS General Performance Expectations operational needs [include] refusal of services in the event of ethical considerations."*
[22] See: "*An important message from the MPSC on donation after circulatory death (DCD) protocols and managing multiple*

9. For each OPO, please specify the process by which the OPO verifies or otherwise documents the appropriate licensure and training of operative staff performing NRP procedures.[23]
    a. Please provide the method by which the OPO verifies the credentialing of procuring surgeons using NRP in the OR.
        i. If the OPO specifies the Association of Organ Procurement Organization (AOPO) Credentials Information Network (ACIN), please provide a list of each ACIN data field that includes NRP information.
    b. For each OPO, please specify whether the NRP protocol permits non-licensed practitioners[24] to participate in any component of clinical care related to NRP, including but not limited to: pre-mortem cannulation, placement of clamps for head vessel occlusion, and/or venting of the descending thoracic aorta.
        i. If the OPO contracts with a third-party procurement service,[25] please specify if the contracted agreement permits non-licensed practitioners to participate in any, and if so, which, components of clinical care related to NRP, including but not limited to: pre-mortem cannulation, placement of clamps for head vessel occlusion, and/or venting of the descending thoracic aorta.

10. For each OPO, please specify what, if any, thresholds for neurological status exist in protocol for patient eligibility for NRP.
    a. If the OPO protocol does specify a neurological status threshold, please include the OPO rationale for this determination.

11. For each OPO, please specify what, if any, thresholds for age exist in protocol for the eligibility for patient for NRP.

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organs" accessible at: https://optn.transplant.hrsa.gov/news/an-important-message-from-the-mpsc-on-donation-after-circulatory-death-dcd-protocols-and-managing-multiple-organs/, which states: *"OPOs should ensure that their donor hospitals protocols and practices reflect current donation practices to include new technologies and procedures."*

[23] See: [redacted] response, "[redacted] *expects the accepting OPTN Member Transplant Center to ensure their staff performing normothermic regional perfusion are appropriately licensed and trained to perform these procedures. There is not a regulatory standard nor system currently to allow the OPO to verify licensure for NRP procedures.*

[24] See: [redacted] response: *"In situations where practitioners without a valid U.S. medical license are the only option for timely organ procurement, the non-licensed practitioners must have completed surgical training of greater than 2 years and should have 25, but no fewer than 10, proctored multi-organ procurements. […] For DCD donors, the non-licensed practitioners must have completed complete 5 proctored DCD procurements."*

[25] See: "*One member suggested that if there is an NRP workgroup, this project would fall under their work. A member agreed, emphasizing that if one of these outside entities has a bad outcome, how will that be tracked? Currently, OPOs email each other if there is an issue with an outside entity, but that isn't necessarily the best practice, and going forward, having a centralized method would be useful. The Chair mentioned that at previous external discussions, a centralized method was brought up, but it can cause legal actions from companies, however, they voiced their support for some way of identifying what is important and how to appropriately share that information.*" March 27, 2024 OPTN OPO Committee meeting minutes accessible at: https://optn.transplant.hrsa.gov/media/jzklj4rk/20240327_optn-opo-meeting-summary_final.pdf

a. If the OPO protocol does specify an age threshold, please include the OPO rationale for this determination.[26]
b. If the OPO protocol does not specify age restrictions, please document the number of pediatric donor patients recovered via NRP by age <1, 1-5, 6-10, and 11-17 since January 1, 2021.

12. Please describe if, and how, the OPO Committee's and/or Machine Perfusion Data Workgroup's proposed data collection fields address information requested for each item described in (B) (2-11).

(C) HRSA requests the following information from the OPTN to provide a more complete picture of the authorization or consent process under which OPOs inform the patient's family (commonly referred to by OPOs as the "legal next of kin" (LNOK)) about the use of NRP in a patient. Specifically, HRSA seeks additional information from the OPTN regarding educational materials provided by OPOs to the families of patients related to the following:

1. For each OPO, please provide all educational materials provided to family (or LNOK) regarding NRP practice.
    a. If the OPO protocol permits NRP in pediatric patients, please specify if the OPO provides different or supplementary information regarding NRP to family (LNOK) of pediatric potential donor patients.
    b. If the OPO protocol permits NRP in high neurological status patients, please specify if the OPO provides different or supplementary information regarding NRP to family (LNOK) of high neurological status potential donor patients.

2. For each OPO, please provide the form under which a family (or LNOK) provides authorization or consent to NRP.
    a. For each OPO, please specify if, and if so, where, information about pre-mortem cannulation is provided to family (or LNOK) in the process of authorization.
    b. For each OPO, please specify if, and if so, where, OPOs provide information to family (or LNOK) regarding risks of injury from pre-mortem cannulation if the patient survives extubation.

3. For each OPO, please collect and provide all hospital- and/or family (LNOK)-initiated complaints or concerns made since January 1, 2021 for patients that were consented for NRP.
    a. Please provide the OPO's documentation of the complaint or concern, any investigative findings, and any root cause analysis completed.

[26] See: [redacted] response, "*What about pediatrics? Two big issues with pediatric NRP. Cerebral physiology and blood flow. There is potential for collateral flow to the brain even if the vessels are occluded. Pediatric brain stem is more resilient and may gain some neuronal activity in a very low flow state such as collateral flow. Suggest moving forward when COD is significant brain injury. Kids cannot make decisions for themselves.*"

   b. Please indicate if the complaint or concern was reported to the OPTN under the requirement of OPTN Bylaw 1.1.G. If not, please provide the OPO's rationale for not reporting the complaint or concern to the OPTN.

4. For each OPO, please collect and provide all hospital- and/or family (LNOK)-initiated complaints or concerns made since January 1, 2021 for patients that underwent NRP.
   a. Please provide the OPO's documentation of the complaint or concern, any investigative findings, and any root cause analysis completed.
   b. Please indicate if the complaint or concern was reported to the OPTN under the requirement of OPTN Bylaw 1.1.G.
      i. If not, please provide the OPO's rationale for not reporting the complaint or concern to the OPTN.

5. Please describe if, and how, the OPO Committee's and/or Machine Perfusion Data Workgroup's proposed data collection fields address information requested for each item described in (C) (1-4).

(D) HRSA understands that the OPTN Operations & Safety Committee has been charged with establishing requirements for standardized practice in the use of NRP in organ procurement by both OPOs and transplant hospitals, and that the Committee was expected to provide a progress report to the OPTN Board in November 2024.

1. Please indicate how the OPTN plans to use the specific information HRSA requests in (B)(1)(a)-(f), above, to develop new NRP policies, policy definitions and data collection, including quality standards and standardized practices, that address patient safety. If not, explain why the OPTN has chosen to develop NRP policies in the absence of patient-level data regarding safety and outcomes.

2. Please indicate how the OPTN plans to use the specific information HRSA requests in (B)(2)-(11), above, to develop new NRP policies, policy definitions, data collection and standards for monitoring processes for patient safety relating to NRP. If not, please explain how the OPTN will develop new NRP policies, definitions, data collection, and monitoring processes in the absence of member-level information regarding adverse events, potential adverse events, complaints, concerns from stakeholders, and/or current protocols and quality assurance processes.

3. Please indicate how the OPTN plans to use the specific information HRSA requests in (C)(1)-(4) to develop new NRP policies, policy definitions, and data collection.

Please send your response to me by April 30, 2025. Given that my role as HRSA's Health Systems Bureau Associate Administrator includes oversight of the OPTN, on behalf of the Secretary, I will review the OPTN's response considering the requirements of NOTA and the OPTN Final Rule.

To ensure that the national organ procurement and transplant system continues to serve patients and families safely, and with transparency, efficiency, and effectiveness, HRSA stands ready to work with the OPTN and the community on addressing this important matter.

Sincerely,

/Suma Nair/

Suma Nair, PhD, MS, RD
Associate Administrator