

**May 2, 2018, Board of Directors Conference Call**  
**Indiana Donor Network (INOP)**  
**Staff Summary**

**Please note that this accompanying summary information, prepared by UNOS staff, is included only to supplement the original documentation and to assist the OPTN/UNOS Board of Directors in their thorough review of the source documentation provided on the designated SharePoint site.**

In December 2016, the Board of Directors placed Indiana Donor Network on Probation. Since then, the OPO submitted and implemented a plan for quality improvement, and the MPSC monitored the OPO's progress. At its meeting in December 2017, the MPSC recommended that the Board of Directors release the OPO from Probation.

According to the OPTN Bylaws, Appendix L.20.A, "A member may request restoration of membership privileges after it demonstrates to the satisfaction of the MPSC that:

1. The member is in compliance with OPTN Obligations.
2. The member has fully implemented any corrective action plan or a plan for quality improvement previously required by the MPSC.
3. The member has demonstrated that the underlying cause for the adverse action has been corrected, or eliminated.
4. The type of violation that resulted in the adverse action is not likely to recur.
5. There are no pending compliance issues that may lead to a potential violation or noncompliance that would require an Imminent Threat Review."

At its May 2, 2018, meeting, the Board will hear a brief presentation from the MPSC Vice Chair regarding the MPSC's recommendation. The Board will also have the opportunity to ask the MPSC Vice Chair questions. The member will not be present.

**Item for Consideration:**

- The Board of Directors must decide whether to affirm the Membership and Professional Standards Committee's recommendation to release Indiana Donor Network from Probation pursuant to Appendix L.20(A).

**Overview:**

UNOS conducted a routine site survey of INOP on August 30-31. During the record review, site surveyors identified potential missing elements of brain death pronouncement documentation in donor charts. On October 7, 2016, the MPSC Chair reviewed INOP's potential policy violations and the concerns and determined that the matter should proceed through the Expedited Review process, described in the Bylaws, Appendix L.13. The MPSC convened as an Expedited Review Committee on October 10, 2016, and considered recommending that the Board declare INOP a Member Not in Good Standing (MNGS) and refer the OPO to the Secretary of Health and Human Services for additional action. After an interview with INOP, the MPSC recommended that the Board of Directors place INOP on Probation. INOP waived its right to a hearing or to appear before the Board of Directors.

While on Probation, INOP submitted updates on its plan for quality improvement and all other documentation the MPSC requested. In December 2017, INOP requested release from

Probation. The MPSC commends INOP on its progress, and believes that INOP has corrected the underlying issue and demonstrated an ability to comply with OPTN obligations.

**Timeline of Events Prior to Probation:**

Date	Activities
8/30-31/2016	Routine OPO site survey <ul style="list-style-type: none"> <li>site surveyors identified potential missing elements of brain death pronouncement documentation in donor charts</li> </ul>
9/13/16	INOP received initial report with request for additional information on OPO policies relative to documentation of brain death and obtaining required source documents; pertinent staff training programs and documentation relative to assuring brain death has been properly declared and documented; quality policies, processes, and pertinent documentation for reviewing donor records to assure brain death declaration has been appropriately documented in the permanent donor record; and any policies for internal and external reporting of occurrences when issues are identified. In addition, INOP was required to conduct an audit reviewing and verifying brain death documentation on 100% of recovered brain dead donors for the last 12 months.
9/27/2016	INOP submitted response to report. Review of all donors showed additional discrepancies in documentation.
10/7/2016	MPSC Chair determined that issue should be reviewed under the Expedited Review pathway.
10/10/2016	MPSC convened to review results of the investigation. Considered recommending MNGS and requested additional information.
10/27/2016	INOP participated in an interview with the MPSC. MPSC acknowledged that the OPO reacted quickly and appeared to be taking this issue very seriously. The MPSC was concerned that staff at INOP may have additional procedures that were not being followed, and recommended Probation.
11/9/2016	INOP waived its right to a hearing and to appear before the Board of Directors and accepted the recommendation of Probation.

**Timeline of Events Post-Probation**

- October 2016: The MPSC approved the OPO's plan for quality improvement and requested that INOP submit updates for each MPSC meeting. The first submission included:
  - Continued monitoring of brain death declaration compliance
  - Demonstration of the QAPI process and ongoing monitoring of policies
  - A SWOT analysis of the process prior to and through brain death declaration for donors

- A description of what staff member has the responsibility to interact with physicians for the appropriate documentation of brain death, and who challenges the physician if they are not following the policy
  - Any activities in Hospital Development that relate to or include brain death declaration and testing information
  - An evaluation of the current process including examining the roles of the Organ Procurement Coordinator (OPC) and the Family Services Coordinator (FSC)
  - A review of job descriptions and expectations to ensure the appropriate qualifications are required
  - A plan for competency assessment of FSCs to make sure that staff are performing as they are trained to perform
  - An evaluation of the process for training Administrators on Call (AOC) and ongoing competency assessment of AOCs
  - A Hospital by hospital breakdown of institutions with ventilation capabilities, ICUs, and ORs
  - A plan for culture change, with the Board of Directors and Advisory Board as active participants
  - QAPI and Board meeting minutes
  - Consideration of including a quality consultant from outside AOPO.
- March 2017: The MPSC reviewed INOP's first submission from January. The OPO's submission included everything that the MPSC asked for in its resolution letter. The MPSC believed that the OPO was making progress, but was still early in their period of Probation. The work group recommended that the OPO continue to submit updates for each MPSC meeting, eliminating one time information.
- July 2017: The MPSC reviewed INOP's May submission. The MPSC felt that INOP reacted quickly and responded to the review well; and the MPSC appreciated that the OPO has taken this issue seriously. INOP has been very forthcoming with all information and addressing the issue appropriately. The MPSC requested that INOP continue to submit monitoring of brain death declaration compliance, an update on progress with or monitoring of the corrective action plan, any related policy changes or staff education, QAPI and Board meeting minutes, and any reports from quality consultants or plans based on those reports.
- October 2017: The MPSC reviewed INOP's September submission. The MPSC felt that INOP has been very forthcoming with all information, spreading its lessons learned in the community, and addressed the issue appropriately. The MPSC requested that INOP submit one final update of the same information along with its request for release.
- December 11, 2017: The MPSC reviewed INOP's December submission, as well as the OPO's request for release from Probation. The MPSC commended INOP for the substantial progress it made over the last year. The MPSC acknowledged the hard work and dedication that INOP has put forth by implementing additional quality assurance processes and monitoring and working with other OPOs to increase knowledge and inspire process improvements. The MPSC recommended that the Board of Directors release Indiana Donor Network from Probation and restore its membership privileges.

**Case Documents available on SharePoint:**

The member submitted four reports on the status of its plan from December 2016 through December 2017 for the MPSC's review during its Probation.

Each submission included the following:

- Monitoring of brain death declaration compliance
- An update on progress with or monitoring of the corrective action plan
- Any related policy changes or staff education
- QAPI and Board meeting minutes
- Any reports from quality consultants or plans based on those reports.

The attached case packet includes the member's corrective action plan and copies of all formal correspondence from the MPSC to the member during the Probationary period. Staff encourage you to use the bookmarks provided to navigate through the documents, and to focus on the December 2017 submission including the OPO's most recent information. All documents in the member's file prior to Probation are available in the "Additional Documentation" Folder on SharePoint if you would like to review any of that information in additional detail. Please contact [REDACTED], Board Liaison if you have any questions.



*Working together. Saving lives.*

CONFIDENTIAL MEDICAL PEER REVIEW

December 8, 2016

**VIA SECURE EMAIL**

[REDACTED]  
Chief Executive Officer  
Indiana Donor Network

[REDACTED]  
Medical Director  
Indiana Donor Network

Dear [REDACTED]:

As President of the Organ Procurement and Transplantation Network (OPTN) and United Network for Organ Sharing (UNOS), I am writing to inform you of an adverse action taken by the OPTN/UNOS Board of Directors in response to its review of Indiana Donor Network (INOP).

At its meeting on December 5-6, 2016, the Board of Directors placed INOP on Probation. The Board adopted the following resolution:

RESOLVED, that the Board of Directors places Indiana Donor Network on Probation based violation of Policy 2.2 (OPO Responsibilities), effective December 6, 2016.

The Board approved this resolution by a vote of 34 For, 0 Against, and 0 Abstentions.

This action was based on information and data reviewed by the Membership and Professional Standards Committee (MPSC), and information and data presented by INOP. As provided by the OPTN Bylaws, INOP was offered due process steps including an interview conducted on October 27, 2016, and a hearing with the MPSC, which INOP waived.

Being placed on Probation by the OPTN does not affect the ability of INOP to continue to function as an organ procurement organization. Probation is described in Appendix L.15(E)(1) of the Bylaws. Also pursuant to the Bylaws, UNOS will provide formal notification to all OPTN members and the general public that INOP has been placed on Probation.

In addition, INOP is required to notify within 30 days all hospitals in INOPs donation service area that have a contractual agreement with INOP. In advance of notifying the appropriate

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hospitals, INOP should submit a copy of a representative notification letter and a list of those hospitals that will receive the letter to [REDACTED]@unos.org.

**Restoration**

The Bylaws, Appendix L.20 outlines the process for restoration of membership privileges after a member has been placed on Probation and includes:

- A) Request for Restoration of Membership Privileges.  
A Member may request restoration of membership privileges after it demonstrates to the satisfaction of the MPSC that:
1. The Member is in compliance with OPTN obligations.
  2. The Member has fully implemented any corrective action plan or plan for quality improvement previously required by the MPSC.
  3. The Member has demonstrated that the underlying cause for the adverse action has been corrected, or eliminated.
  4. The type of violation that resulted in the adverse action is not likely to recur.
  5. There are no pending compliance issues that may lead to a potential violation or non-compliance that would require an Imminent Threat Review.

The burden is on the Member at all times to demonstrate that restoration of membership privileges is appropriate.

- B) Minimum Requirements to Request Restoration of Membership Privileges  
The MPSC will only consider requests for restoration of membership privileges during its regularly scheduled meetings and the member may not request restoration of membership privileges until *both* occur:

At least twelve months have passed since the approval and implementation of the MPSC prescribed corrective action plan.

At least twelve months have passed since the approval of the final action by the Board of Directors or the Secretary of HHS.

If the MPSC denies the member's request for restoration of membership privileges, the member may renew its request 6 months from the date the MPSC denied the request.

- C) Additional Requirements.  
At its discretion, the MPSC may require any of the following before it considers a request for restoration of privileges:
1. An unannounced OPTN Contractor on-site review.
  2. An unannounced peer on-site review.
  3. Data and document review.
  4. A presentation to the MPSC by the member.

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Section 21 of Appendix L further provides that in response to the Member request for restoration of the unrestricted membership, the MPSC may recommend to the Board a trial reinstatement period.

This matter was conducted as confidential medical peer review. Therefore, only a limited amount of information regarding the details of the matter may be made public. I refer you to the OPTN website for additional information on the details of the matter that have been made public.

If you have any further questions or concerns regarding this resolution or need any additional information, please contact [REDACTED]  
[REDACTED]

Sincerely,

[REDACTED]

[REDACTED]

President, OPTN/UNOS Board of Directors

[REDACTED]

cc: Brian M. Shepard, Executive Director and CEO, UNOS