

## **OPTN Network Operations Oversight Committee**

### **Meeting Summary**

**October 27, 2023**

**Webex**

**Daniel Yip, MD, Chair**

### **Introduction**

The Network Operations Oversight Committee (NOOC) met via Webex on 10/27/2023 to discuss the following agenda items:

1. Welcome
2. OPTN Member Security Project Updates
3. Third Party Organization Access and Security Requirements
4. Access to OPTN Data via the OPTN Computer System

The following is a summary of the committee's discussions.

#### **1. Welcome**

Dan Yip, Chair of the Network Operations Oversight Committee (NOOC), welcomed committee members and provided an overview of the agenda.

#### **2. OPTN Member Security Project Updates**

Courtney Jett, Policy Analyst, presented updates on the member security project. Ms. Jett presented on the OPTN required information security training that is required by the member security policy. She shared the OPTN's plans to implement the training by January 2024 and stated that the training was shared with the NOOC to review and provide feedback. Ms. Jett shared the feedback that has been received so far, including the suggestion to reduce the amount of specific incident response training to what an average user will see, and to increase the plain language. Ms. Jett explained that the NOOC will provide feedback, the draft of the training will be revised, and the training will be shared with the NOOC again to vote on.

Terry Doolittle, Member Security Program Manager, presented an update on the member security project. Mr. Doolittle shared that GuidePoint Security has been chosen as the vendor to assist the OPTN in implementing the member security project. He shared that analysts would assist in reviewing attestations from members, and training for these analysts is scheduled to begin November 6. Mr. Doolittle noted that the team is currently working to define the technical requirements for the security controls that are under development. Mr. Doolittle explained that members have been notified that attestations will begin November 20, and that communications have been sent to all members, even if they are not in the first group of members undergoing attestations.

Mr. Doolittle presented the member security project timeline. Mr. Doolittle explained that executing data calls in LogicGate and the review of member attestations are delayed because the OPTN is waiting to onboard staff to review attestations.

#### Summary of Discussion:

When discussing the OPTN required information security training, a committee advisor commented that the training was very well done but the training could be clearer on the discrepancy between the OPTN and the OPTN contractor. The committee advisor also recommended that the OPTN include a requirement for members to use a different login or password for the training from any other applications.

### **3. Third Party Organization Access and Security Requirements**

Courtney Jett, Policy Analyst, presented on third party organization access to the OPTN Computer System and security requirements. Ms. Jett shared that the goal of the conversation was to discuss the current state of third-party organizations in the system, limitations of third-party use, and to determine whether the NOOC recommends updates to OPTN policies and/or bylaws. Ms. Jett noted that this will go out for public comment because it will require a change to OPTN policy or OPTN bylaws. Draft language will be shared with the NOOC at a future meeting date.

Ms. Jett shared the background on why third-party access and security requirements are important for the NOOC to discuss. She shared that OPTN Member Security Policies/Programs currently only apply to transplant hospitals, OPOs, and histocompatibility labs. Currently, policies do not apply to organizations that are not in these three member types, even if they are OPTN members and access the OPTN Computer System. Ms. Jett shared that there are several third-party organizations that work on behalf of transplant hospitals, OPOs, and histocompatibility labs within the OPTN Computer System. Ms. Jett explained there are no accountability mechanisms for these third-party organizations that are not OPTN members. Ms. Jett noted that membership is not currently a condition of access to the OPTN Computer System. Ms. Jett reminded the committee that they began the conversations on third-party access to the OPTN Computer System in April 2023.

Ms. Jett shared that there are currently 32 third-party organizations accessing the OPTN Computer System that are not subject to the member security program policy. She noted that 10 of the 32 organizations are currently business members of the OPTN. Ms. Jett explained that the reason these organizations have access to the OPTN Computer System vary. A majority of these third-party users fulfill staff augmentation duties while performing tasks within transplantation, such as allocating organs, facilitating organ perfusion, or submitting data on behalf of members.

Ms. Jett shared current OPTN policy that addresses accessing the OPTN Computer System. OPTN Policy 3.1.D. *Non-member Access* notes that if a non-member is accessing the OPTN Computer System through another member organization, then the member must have a data use agreement (DUA) with the non-member. Ms. Jett also shared the limitations in the current OPTN Policy. She shared that the current policy challenges the scope of authority for the OPTN by permitting access to OPTN Computer Systems/Data for the placement of “organs for other purposes than transplantation”. Ms. Jett explained that because of this, there is no direct relationship or accountability between the OPTN contractor, HRSA, and these third-party users. The OPTN contractor and HRSA also do not have direct insight into what these members were hired to do. Ms. Jett asked the committee to consider who should grant access to third-party users of the OPTN Computer System. The limitations in the current policy include unclear rights and responsibilities, limitations on OPTN oversight for securing OPTN Computer System/Data, and that the OPTN Computer System was designed to meet the needs of OPTN members, not non-members or third-party users.

Ms. Jett reviewed the NOOC’s initial recommendation during the April 2023 meeting. In April 2023, the NOOC recommended requiring membership as a condition of access to the OPTN Computer System to have a consistent security requirement for every organization that accesses the OPTN Computer System,

and to hold third-party users to the same standards as members through clear rights and responsibilities in OPTN policies and bylaws.

Ms. Jett concluded the presentation by sharing the current OPTN business membership bylaw in OPTN Policy 1.7. She noted that the current bylaws pose potential restrictions to new businesses if the OPTN requires membership to access the OPTN Computer System. Ms. Jett noted that third-party organizations would not have voting privileges. Ms. Jett asked the committee if there were concerns about addressing current OPTN policy and bylaw limitations and whether the NOOC had recommendations on how to address them. She asked the NOOC if there were any additional changes they think should take place when addressing limitations.

#### Summary of Discussion:

The committee discussed how third-party members are granted access to the OPTN Computer System. Ms. Jett clarified that third-party members do not automatically have access to patient information because they have access to the OPTN Computer System. If they need specific permissions, they gain this access through an OPTN member for specific duties. A committee advisor asked if a list of the 32 third-party members accessing the OPTN Computer System could be shared with the NOOC for them to understand who these users are and what their purpose of accessing the OPTN Computer System is. The advisor also asked to clarify if any of these third-party members were granted access on behalf of the OPTN contractor or if all 32 third-party members were granted access through an OPTN member. Ms. Jett confirmed that none of the 32 third-party members were acting on behalf of the OPTN contractor and all were granted access from an OPTN member.

A representative from HRSA asked if the OPTN contractor reviews third-party users prior to granting them access to the OPTN Computer System. Ms. Jett explained that the OPTN Contractor does review requests prior to granting access and the OPTN contractor will review each third-party user on an annual basis. A representative from HRSA asked what the annual review of third-party members consisted of. Ms. Jett agreed to provide more information on the annual review at a later meeting. Ms. Jett asked the committee to consider and share if there is anything they would like to see included in the review process.

The committee agreed on the importance of having policy in place. The committee suggested having a data use agreement (DUA) in place for these third-party users. The committee discussed the need for members to have awareness on who they are granting access to and why these third-party users are using the OPTN Computer System. The committee chair asked the NOOC to consider whether there is value in categorizing these third-party users. They asked if categorizing third-party users will be beneficial in creating policy around their access.

A committee advisor commented that it is important that there is an agreement with these users and the OPTN contractor because these users are accessing the OPTN's data and systems. They also commented that there is no way for users to audit what these third-party users are accessing, so it would be beneficial to have that information available. The committee advisor suggested limiting these third-party users access to the system and limiting the information they may access. The committee advisor suggested that third-party users be categorized by the work they perform in the OPTN Computer System.

When discussing whether third-party users should have access to the OPTN Computer System for research purposes, a committee advisor commented that third-party users should have access to the OPTN Computer System for research purposes because that can enhance the field of transplantation.

A representative from HRSA suggested the OPTN contractor report to OPTN members who is accessing their system on a regular basis to understand why they are accessing the OPTN Computer System. Contractor staff explained that members are required to audit third-party users of the system three times a year and these audits are reviewed by members security administrators.

A committee advisor suggested that third-party users be held to the same standard as other members when accessing the OPTN Computer System. The committee advisor suggested that third-party users should likely be held to a higher standard than other members. They suggested that these third-party users have a DUA with the OPTN and have a DUA with the OPTN member they are contracted with to access the OPTN Computer System. The committee advisor also discussed that tailoring permission levels based on the needs of the third-party user should be discussed by the committee. A representative from HRSA agreed that having two DUAs for these third-party users is likely the best option, and that the NOOC should consider incorporating this requirement into OPTN policies and bylaws.

The committee discussed what the course of action should be if third-party users are accessing the OPTN Computer System and utilizing their permissions inappropriately. The committee discussed whether the decision to suspend access to the OPTN Computer System should be made by the NOOC or whether this decision should go to the Membership and Professional Standards Committee (MPSC).

The committee chair asked the NOOC if there should be better definitions on who members versus non-members of the OPTN are. Ms. Jett explained the different membership categories that are included in the OPTN bylaws. Ms. Jett noted that the NOOC should consider whether membership should be required in order to access the OPTN Computer System. Ms. Jett suggested that there needs to be more clarity in current policy for members who are not part of the three main membership groups, which are organ procurement organizations (OPOs), transplant hospitals, and histocompatibility labs. The committee chair asked if there should be a membership category that encompasses members that are not part of the main three categories of members. A committee member suggested that the current membership definitions stay the same but there is a delineation within membership types of who can access the OPTN Computer System. A representative from HRSA suggested adding a distinction to the membership category about who can access OPTN Data. Ms. Jett clarified who can and cannot access the OPTN Computer system. Ms. Jett shared OPOs, transplant hospitals, histocompatibility labs, some business members, and some third-party non-members may access the OPTN Computer System. Ms. Jett noted that there are no individual or general public members with access to the OPTN Computer System. The committee chair summarized that the gap in OPTN policy is around non-members and business members who have access to the OPTN Computer System.

Ms. Jett summarized that the takeaways of the discussion were a request from the committee to update OPTN policies and bylaws to require membership in order for individuals to gain access to the OPTN Computer System, and to make clear additional requirements on what they need to do to gain and maintain this access if they are not an OPO, transplant hospitals or histocompatibility lab.

Next steps:

Contractor staff will draft and present a DUA for third-party users at a future meeting. Contractor staff will also take the NOOC's recommendations and draft policy and bylaw language for the NOOC to review at a future meeting. The committee asked Ms. Jett to provide a list of the 32 third-party users who can access the OPTN Computer System and what role they serve for the organization that are contracted through.

#### **4. Access to OPTN Data via the OPTN Computer System**

Ms. Jett presented that the goals of the presentation were to discuss the current state of accessing OPTN data through the OPTN Computer System and the limitations associated with this, and for the NOOC to determine recommendations to update related policies.

Ms. Jett started the presentation by asking the NOOC to consider why non-members are permitted to access data within the OPTN Computer System. Ms. Jett explained that the OPTN responds to requests from the general public and OPTN members for OPTN data. Data can be provided so that requesters can perform their own analysis in datasets or in static reports. Ms. Jett shared different types of data requests, including: STAR files, Custom Limited Datasets, Patient-Identified Datasets, and Aggregated Data. Ms. Jett noted that all requests for patient identifiable information require a data use agreement (DUA), security plan, research plan, and an approved IRB to be submitted to HRSA for approval.

Ms. Jett shared OPTN Policy 3.1.D. that details access to the system. Ms. Jett shared that the limitations in the current policy for members are that the policy does not cover restrictions on member access to the system for research or other non-clinical and non-data submission purposes. This includes no restrictions for business members that are third parties acting on behalf of other members. Current policy also does not cover restrictions on member use of OPTN data accessed through the OPTN Computer System, and members do not have a DUA with the OPTN. Ms. Jett shared related HRSA information security findings relevant to the conversation.

Ms. Jett informed the NOOC that they are the appropriate committee to sponsor policy changes related to DUAs between the OPTN and its members. Ms. Jett asked the NOOC if there were any additional changes they would like to include when clarifying these policies.

#### Summary of Discussion:

The committee discussed that if membership is a requirement to access the OPTN Computer System, it would simplify oversight and enforcement of member access.

The committee chair suggested that before members contract with other entities and make them third-party users of the system, that these entities become members of the OPTN on their own before they are granted access to the OPTN Computer System. If these contractors are members of their own, it will allow for more oversight and accountability for their access to the OPTN Computer System, as they are no longer granted access to the OPTN Computer System on behalf of another member. Multiple committee advisor agreed that this would be a more effective and efficient route so there is not a gap, and the OPTN contractor can work straight with the third-party user, if they are a member. They commented that there should be a DUA between the third-party user and the OPTN contractor to allow the OPTN contractor to work directly with the third-party user.

A representative from HRSA asked if it would be cumbersome for members to require third-party users to gain membership. A committee advisor commented that they were unsure how long it would take to gain membership to the OPTN, but that this would improve the process and members would then know accessing the data was done correctly. The committee chair commented that this may take some responsibility off members because the OPTN contractor would now be assisting in holding these third-party users accountable.

#### Next Steps:

Contractor staff will take the NOOC recommendations to draft policy language for the committee to review at a future meeting.

### **Upcoming Meetings**

- November 6, 2023
- November 20, 2023

## Attendance

- **Committee Members and Advisors**
  - Bruno Mastroianni
  - Colleen McCarthy
  - Daniel Yip
  - James Pittman
  - Kelley Hitchman
  - Melissa McQueen
  - Paul Connelly
  - Willscott Naugler
- **HRSA Representatives**
  - Adriane Burton
  - Christopher McLaughlin
  - Cle Diggins
  - Cliff Myers
  - Manjot Singh
  - Nick Lewis
  - Vinay Vuyyuru
- **UNOS Staff**
  - Amy Putnam
  - Anna Messmer
  - Bonnie Felice
  - James Jobes
  - Jerry DeSanto
  - Kristine Althaus
  - Marty Crenlon
  - Michael Ferguson
  - Michael Ghaffari
  - Morgan Jupe
  - Rob McTier
  - Robert Emerson
  - Roger Vacovsky
  - Steve Mohring
  - Terry Doolittle
  - Tiwan Nicholson
  - Tony Ponsiglione
  - Tynisha Smith