

**OPTN Data Advisory Committee  
Meeting Summary  
July 8, 2024  
Conference Call**

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## **Introduction**

The Data Advisory Committee met via WebEx teleconference on 07/08/2024 to discuss the following agenda items:

1. Welcome, reminders, and agenda review
2. Introduce new members
3. Provide list of on-going Committee projects and prioritization and Members share their experience working with other Committees
4. Status update of Directive activities
5. Public forum
6. Closing remarks

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

### **1. Welcome, reminders, and agenda review**

An overview of the meeting's discussion topics was reviewed.

#### Summary of discussion:

No decisions were made as part of this agenda item.

OPTN contractor staff welcomed the members and reviewed the meeting agenda items.

#### Next steps:

Not applicable.

### **2. Introduce new members**

Three new Committee members started their terms on 07/01/2024. The Committee is in the process of filling a mid-term vacancy.

#### Summary of discussion:

No decisions were made as part of this agenda item.

Three new members joined the Committee on 07/01/2024. Two members joined the meeting and introduced themselves. One of the new members is associated with an organ procurement organization in OPTN Region 8.

Another of the new members is a patient and donor affairs representative. OPTN contractor staff reminded the members that all OPTN committees have at least two patient and donor affairs

representatives. It is the OPTN's intention that these members will elevate the patient and donor family voice in the policy development process. The Committee member shared their transplant journey story. Based on that experience, the member said that they wanted to participate in the OPTN to give back to the transplant system. The member stated that professionally, they work as a research statistician and are familiar with managing healthcare data.

Next steps:

The Committee continues working to fill the open representative position.

**3. Provide list of on-going Committee projects and prioritization and Members share their experience working with other Committees**

Members were directed to the spreadsheet on the Committee's SharePoint site where they can find information about DAC-led projects, other OPTN committees' projects that impact data collection, information about Committee members serving on other OPTN committee's workgroups, and information about Committee members' experience with OPTN data. Members were encouraged to ask questions about both the DAC-led projects and the other committees' projects. They were also told how they can share their ideas for Committee projects. Committee members were also informed that given DAC's role as data steward, other OPTN committee often request members to join workgroups and assist with developing data collection aspects of their projects.

Summary of discussion:

No decisions were made as part of this agenda item.

OPTN contractor staff shared with the Committee members that a spreadsheet is maintained on the Committee's SharePoint site identifying the DAC-led projects. The spreadsheet also identifies the projects with an expected data collection impact that are sponsored by other OPTN committees. These projects will need DAC review of the proposed data collection changes, so the spreadsheet serves to inform members of the projects they may review in the future.

Additionally, the spreadsheet identifies the DAC members who are volunteering on other OPTN committees' workgroups. Time is usually reserved during each Committee meeting for such volunteers to update the other DAC members about the activities of their workgroups. The spreadsheet also contains a worksheet for Committee members to share information about their experiences working with OPTN data. OPTN contractor staff use such information to identify potential volunteers to serve on other OPTN committees' workgroups and also to identify subject matter experts who can comment on data clarification-related activities the Committee performs.

The Chair shared with the members there are multiple projects DAC is involved with at different levels. There are projects salient to the Committee members' expertise with data collection that are instigated by other committees where DAC can add some feedback. And there are projects that simply request Committee feedback. And then there are DAC-sponsored projects, where the Committee initiated a project just as any other OPTN Committee can do. The Chair emphasized that for the latter, it is important to be inclusive and solicit members' ideas for DAC-sponsored projects. As a result, understanding what the Committee is already working on and sharing other ideas that members have from their relevant expertise is really important. The Chair continued that understanding DAC's responsibilities within the OPTN's data collection efforts can be challenging. The Chair reinforced to the members that if they have ideas, they should feel free to bring those forward. These might be ideas that would be a high priority for the Committee to either initiate or to work in partnership with another OPTN committee. The spreadsheet is intended as a resource to see all the moving parts.

Next steps:

The members were encouraged to share any project ideas with Committee leadership and the OPTN contractor. Members were also encouraged to review the list of projects from time-to-time, and to consider volunteering with other committees.

**4. Status update of Directive activities**

The Committee discussed the timelines for when the pre-waitlist and ventilated patient referral data elements would be shared with the OPTN community for feedback, and ultimately implementation. There was also discussion about how the proposed data collection will be implemented.

Summary of discussion:

No decisions were made as part of this agenda item.

OPTN contractor staff stated that they have been working with HRSA staff to create a page on the OPTN website containing information about the two workgroup's past activities and the recommendations that were made. The site will allow for more information to be published as events continue to evolve with the Directive for both data collection efforts. If HRSA approves creation of the webpage, it can be used to communicate to workgroup members, as well as the broader community, about the status of Directive-related activities and next steps. OPTN contractor staff said that establishing the webpage is important.

From a project update perspective, OPTN contractor staff said there have been a few meetings with HRSA staff regarding the pre-waitlist solution ideas. Contractor staff added that the plan is to use an upcoming weekly meeting with HRSA to provide additional details. Then, HRSA will review those ideas in order to make decisions on how to direct the OPTN contractor on next steps for pre waitlist. As discussed, it is anticipated that DAC members' programs will be involved with piloting early adoption, and those activities are forthcoming. For ventilated patient data collection, HRSA staff are working with feedback that they received from the OPOs. Specifically, the MPSC workgroup chair provided some information to HRSA staff, who will share it with CMS, and the next steps will be determined.

Contractor staff previously talked with HRSA about the need to revise the Directive to add specifics clarifying the submission timelines. Because the Directive is different than a policy project, the OPTN needs the Directive to be very clear about how OPTN Policy 18 would change to add new data collection forms and when those forms would be due. Also, clarifications are needed regarding targeted or official start dates for data collection. It is anticipated that the ventilated patient data collection will also result in changing some of the existing data collection forms and that also needs to be very clear in the Directive language. Clarifying the Directive in these ways permits the OPTN to take all of those actions without having to go through its normal public comment processes, because that would take additional time. The OPTN anticipates a revision of the Directive as part of the work moving forward.

OPTN contractor staff also updated the Committee on the projected timeframes. The OPTN has been anticipating submitting an official response after the 60-day Federal Register notice is posted. However, there is no set time frame for when the 60-day window will open. It was pointed out that the timeline has continued moving farther into the future as a result of trying to work through the details associated with the ventilated patient data collection forms. OPTN contractor staff added that there are other OPTN Board-approved projects waiting to be published on the Federal Register as part of the 60-day window and that still need OMB approval before they can be implemented. The pre-waitlist data collection has been set for a long time. HRSA, CMS, and the OPTN are still working through the details on the ventilated patient side. Once the 60-day window opens, the OPTN will work with the pre-waitlist

workgroup chairs and the MPSC workgroup chair on the official OPTN response. The official OPTN response will be shared with the OPTN Presidents, and other OPTN Committees as needed, before it is actually posted on the Federal Register.

At that stage, HRSA will be collecting the feedback received regarding the package. Concurrently, the OPTN will be developing and capturing the burden estimates on any new forms from the OPO Committee and the Transplant Administrators Committee (TAC), and maybe the Transplant Coordinators Committee (TCC) as well.

Following the 60-day posting, there will be a 30-day posting also on the Federal Register. Once the 30-day posting is available it is anticipated that all of the requirements will be considered final. It is then, probably, when HRSA will direct the OPTN contractor to begin any development of solutions. Moreover, it is HRSA's decision on what IT solutioning information can be shared with the OPTN community and when it can be shared.

A member asked what estimated burden information the OPO and TAC committees are reacting to because it is not clear that something has already been proposed, and there have also been conversations about a secondary solution that does not include the batch process the workgroup identified or includes another type of submission process? OPTN contractor staff responded that the data collection forms will be new regardless of the IT solution. Determining the burden estimate is independent from any IT solutioning. The OMB package requires an estimate of collection burden. In the past, the OPTN contractor has used historical queries to determine such estimates. This has been performed by gathering TAC input and sometimes feedback from other committees whose members are most likely to complete the forms. The contractor uses queries of history to identify the volume and then the estimated burden is calculated. For the new data collection forms, the contractor is looking at how to determine the best estimates. As a result, it is important to capture all the activity to get something like the best estimate for inclusion with the OMB package because that is what will go in the 30-day response.

The member responded that they think DAC would want to be involved with the discussions about the burden estimate. The member stated their belief that the burden estimate is going to be different from previous estimates, such as those involving the Transplant Candidate Registration (TCR) form, because this does not involve manual data extraction. Rather, this involves data that exists in discrete data reports that should lend itself to automated data reporting. The information that is presented to the OPO and TAC has to be done so in way that describes how the data elements were designed along with the intent and frequency of collection. The member also said that the community is very interested in any proposed solutioning because there may be impacts around how much time is needed to collect the data before it can be analyzed and how the data are included in and extracted from Electronic Medical Records (EMR). OPTN contractor staff acknowledged the offer of help and added that the solutioning is being directed by HRSA and it is their decision about what can be shared with the community. HRSA staff said that no decisions have been made.

The Committee Chair asked if HRSA could clarify whether the data elements that the pre-waitlist workgroup proposed are likely to be what appears on the Federal Register when the 60-day window opens or does the potential exist that the data elements could be changed? HRSA staff responded that there have been no discussions about changing any of the data elements proposed by the pre-waitlist workgroup. The Chair also said that there needs to be very clear messaging to the OPTN committees about what this data collection effort involves. The Chair added that if the messaging is unclear, then programs are going to respond to the burden question as they have in the past without considering that this involves a different approach. The Chair also asked if the pre-waitlist data collection effort could be separated from the ventilated patient data collection effort so as to avoid any further delays? The Chair

added that if the pre-waitlist data collection is fairly set in stone, then moving forward as quickly as possible with that side of the effort makes sense. HRSA staff responded that as of now the two data collection efforts will remain together as far as the OMB process is concerned.

OPTN contractor staff said there is an opportunity to use the upcoming regional meetings to increase the OPTN members' awareness of the Directive and the actions performed to date. It is expected that HRSA and the OPTN contractor will use a future meeting to determine what kind of message should be provided to the community during the regional meetings describing the status of the Directive effort and next steps.

Next steps:

The OPTN contractor will continue sharing information about the timeline and other aspects of the process as it becomes available.

**5. Public forum**

There were no requests to speak during the public forum period.

**6. Closing remarks**

Information about the upcoming public comment period and regional meetings was shared with the members. Members were also reminded to book their travel to the Committee's in-person meeting scheduled for 09/10/2024 in Detroit, Michigan. They were also encouraged to share any project ideas with Committee leadership and/or OPTN contractor staff.

Summary of discussion:

No decisions were made as part of this agenda item.
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The OPTN contractor informed the Committee members about the upcoming regional meetings that start on 08/06/2024 and continue through 09/20/2024. Members were told there are options to attend in-person or virtually. Members were encouraged to register for a regional meeting on the OPTN website.

Contractor staff also stated that the OPTN public comment period starts 07/31/2024 and is open through 09/24/2024. A list of the public comment proposals was shared with the members, along with a description of how to access the proposals on the OPTN website. Members were asked to let Committee leadership or OPTN contractor staff know if they are interested in receiving a presentation associated with one of the public comment proposals. For example, the OPTN Network Operations Oversight Committee (NOOC) submitted its proposal "Revise Conditions for Access to the OPTN Computer System" for public comment. During the Committee's 03/22/2024 in-person meeting, the NOOC Chair provided an overview of the items the proposal would address, which included information about ownership of OPTN data and potential data use agreements. At that time, Committee members shared concerns with the NOOC Chair about the proposal's attempt to define ownership of OPTN data. In particular, DAC members raised questions about when does data ownership revert back to the OPTN member if the data is consumed in their data system? And how does that impact the data use agreement NOOC was considering submitting for public comment? As part of the 07/08/2024 Committee meeting, a member asked if the current public comment proposal reflected the Committee's earlier recommendations and was told it did. It was mentioned that HRSA staff had shared DAC's feedback from the 03/22/2024 meeting with HRSA legal staff and that they are working on a resolution. HRSA staff on the call agreed with the characterization of events. They added that additional clarity is needed about what actually reflects a change in ownership or a recognition that HIPAA protections provided through Electronic

Medical Records are adequate for protecting those data. HRSA staff confirmed that they did not want to delay the NOOC public comment proposal but at the same time they continue exploring clarifications.

Next steps:

OPTN contractor staff said they would inform the Committee members when the public comment proposals were available on the OPTN website.

**Upcoming Meetings**

- August 12, 2024
- September 10, 2024 – In-person meeting, Detroit, MI

## Attendance

- **Committee Members**
  - Jesse Schold
  - Kate Giles
  - Cassie Hertert
  - Michael Ison
  - Paul MacLennan
  - Michael Marvin
  - Christine Maxmeister
  - Nancy McMillan
  - Sumit Mohan
  - Jennifer Peattie
  - Julie Prigoff
  - Meghan Schaub
  - Allen Wagner
- **HRSA Representatives**
  - Steve Keenan
  - Chris McLaughlin
- **SRTR Staff**
  - Avery Cook
  - Ajay Israni
  - Jon Snyder
- **UNOS Staff**
  - Brooke Chenault
  - Jonathan Chiep
  - Sevgin Hunt
  - Morgan Jupe
  - Eric Messick
  - Nadine Rogers
  - Laura Schmitt
  - Divya Yalgoori
  - Anne Zehner
- **Other Attendees**
  - Andrew Kao