McGuireWoods LLP
[redacted]
John S. Moran
[redacted]
McGUIREWOODS

VIA EMAIL
[redacted]

July 11, 2022

CONFIDENTIAL TREATMENT REQUESTED

Daniel Goshorn
Chief Investigative Counsel
United States Senate
Committee on Finance
Washington, DC 20510

Re: United Network for Organ Sharing – Response Subpoena and August 13, 2021 Correspondence from the Senate Committee on Finance, 117th Congress

Dear Dan:

On behalf of the United Network for Organ Sharing (UNOS), I write to address the Committee's follow up requests following the interviews conducted by the Committee in June 2022 and memorialized in emails dated June 3, 2022, June 15, 2022, and June 29, 2022. In addition to the responses included below, UNOS is today making a further production of 57 documents in response to these requests.

The materials included in today's production are produced in electronic format and Bates numbered: UNOS_9_000000001 - UNOS_9_000001024. The production file is password protected. We will provide instructions on accessing the production by separate email, and you should not hesitate to contact me should any issues arise.

You have asked about training materials for members and leadership of the MPSC. This production includes 2021–2022 orientation materials for new MPSC members that address the MPSC's review of OPO performance and compliance. These materials include general orientation presentations and agendas, trainings for compliance, membership, and performance cases, and performance monitoring project training. You will note redactions in this set of documents which appear as they do in the orientation.

You have asked about the criteria used by UNOS staff in referring cases to the MPSC. As we have discussed, and as UNOS witnesses have explained, upon intake of a complaint, staff evaluate how urgent the case is and what path it must take to get to the MPSC, based on "Wakefield

Criteria" and based on other criteria, such as whether the case is "exceptional". As explained during [redacted] interview, the "Wakefield criteria" play a role in UNOS staff's triage process, but they do not determine which cases do or do not get reviewed by the MPSC. The criteria were first articulated in a 2011 letter from then-HHS Secretary Mary Wakefield and have since been incorporated by reference into UNOS's contract with HRSA. The letter identified certain categories of cases in which UNOS staff would provide prompt *notice* to HRSA; in practice, UNOS leadership notifies MPSC leadership at the same time. Those categories largely overlap with cases that UNOS staff determines are "Exceptional." But a case that meets the Wakefield criteria would not necessarily qualify as "Exceptional" (*e.g.*, a living donor death that occurred more than two-years post-donation and did not involve any indicia of an error or ongoing patient-safety threat, such as death by a motor vehicle accident – the Wakefield criteria specify that UNOS must notify HRSA any time there is a living donor death, regardless of cause and regardless of how many years post-donation the death occurs, whereas OPTN policy only requires a transplant program to notify the OPTN of a living donor death within two years post-donation), and a case may qualify as "Exceptional" without necessarily meeting the Wakefield criteria (*e.g.*, an employee at an OPTN member institution inappropriately accessed donor records – there is no specific Wakefield criterion under which this would fall, but UNOS would consider the case to be "exceptional" because it poses a threat to the integrity of the transplant system.). UNOS processes require inclusion of HRSA on all notifications to MPSC leadership and UNOS staff provides prompt notice both to HRSA and to MPSC leadership whenever a matter arises that (a) meets the Wakefield criteria ***or*** (b) qualifies as an "Exceptional" case.

Apart from the Wakefield criteria, UNOS staff determines what cases to refer to the MPSC based on whether there is a substantiated issue that falls within the purview of the MPSC and whether there is an operational rule in place that governs how the issue should be handled. If the Member Quality staff learns of an issue but *does not* refer it to the MPSC, that would generally be because (a) the issues cannot be substantiated (*e.g.*, from an anonymous email account that will not provide supporting details) and staff have exhausted investigative efforts to substantiate the complaint; (b) the issue falls squarely outside the MPSC's purview (*e.g.*, a complaint about Medicare reimbursement); or (c) the issue is covered by an operational rule, developed in conjunction with the MPSC, that directs UNOS staff not to refer the matter to the MPSC (*e.g.*, a first-time issue involving improper vessel storage).

Today's production includes the most recent Operational Rules Manual with supporting materials; First-Time Non-Compliance (FTNC) Operational Guidelines for DTAC Late Reports; and Operational Guidelines related to Prohibited Vessel Storage. The documents provide guidance to UNOS staff regarding whether certain issues should be referred to the MPSC.

You have also asked about operational and training materials for UNOS Safety Analysts. Included in today's production are copies of UNOS' operational guidelines and training materials for Safety Analysts, including documents describing criteria to determine whether a matter qualifies as "Common" or "Exceptional." (Prior distinctions between "high," "medium," and "low" cases are no longer in use.) The current Member Quality Work Instruction on Incident Handling requires the Safety Analyst to categorize the issue as "Common" or "Exceptional" priority based on level of seriousness and time-sensitivity, and whether the presenting issue

involves: a patient safety or public health concern, a threat to the integrity of the OPTN, potential criminal activity, and/or the media. The instruction directs the analysts that "any questions or difficulties faced when completing this form should be addressed within the specified time period with the Manager of Committee Operations and Patient Safety." It is important to note that while these documents provide guidelines to follow, staff judgment is necessarily involved in the decision to refer a case to the MPSC and whether to treat a case as "Exceptional." These materials are intended to guide, rather than to supplant, staff judgment.

Today's production also includes templates for the Staff Summary documents. Summary documents are used to provide a synopsis of information that might be relevant to MPSC review and are used in various occasions. Staff summaries are supplemental to the case packets provided to the MPSC; the MPSC receives all evidence gathered during the investigation period, and the Staff Summary simply helps to synthesize the case file.

In the interview with [redacted], you asked about [redacted]

We would also like to provide some clarification on certain terms and numbers in UNOS_1_000000253 (Tab 11 of [redacted] interview binder), which may aid the Committee in its understanding of the Member Quality process. In addition to the explanation below, today's production includes reports that provide some of the source data for this presentation.

- **Clarification on Certain Terms**: For the purposes of this presentation, there is no formal distinction between "investigations" and "events." Incident Handling typically uses the word "event" to describe a report that comes to it. Not all events turn into cases or "investigations." However, it would not be unusual for someone within UNOS to refer to an "event" as an "investigation" since Incident Handling still conducts some level of preliminary investigation, even if only a discussion, when an event is reported.

- **Slide 10 – 2018 Patient Safety Investigations (PSI)**: This slide is based on events reported by members through the Safety Situation section of the Improving Patient Safety Portal. A new search of 2018 events in the Portal itself shows 179, rather than the 156 on the slide. We have not determined a definitive explanation for the discrepancy but believe that two factors likely explain it: (a) the same event may have been reported by multiple members but were de-duplicated in the 156 figure (*e.g.,* an OPO might have reported its own labeling error, and the transplant program that received the organ with the labeling error might also report the same incident); and (b) events that should have been reported through the Living Donor Event or Disease Transmission Event sections of the Portal may instead have been reported through the Safety Situation section but were manually removed from the data set used to arrive at the 156 figure.

- **Slide 11 – Patient Safety Events by Mode of Receipt**: This slide reflects data from trends and patterns in Patient Safety Cases reported to the OPTN from January 1, 2016, through December 31, 2018. Specifically, this slide shows the number of events reported by members through the Safety Situation section of the Portal, as well as events reported to Patient Safety staff through other monitoring mechanisms, such as reports generated by the UNOS Research Department to flag certain scenarios.

- **Slide 13 – OPO Patient Safety System Events (in 2018):** The figure of 164 Total Patient Safety Reports is a typo and should be 156. As indicated, there were 98 reports about OPOs submitted by non-OPOs plus 58 reports about OPOs submitted by OPOs, for a total of 156 reports.

You have also asked about transportation data. Today's production includes the Strategic Plan Report provided to the OPTN Board this June, as well as the Organ Center's transportation data from January 2021 – March 2022. Recall that Organ Center transportation data is limited only to those organs that the Organ Center assisted in placing, and of those, the subset that experienced some sort of transportation issue. For reasons explained in February 2020 when we provided the first batch of Organ Center transportation data, these data should not be understood as representative of the entire donation and transplantation community's processes. We would also like to provide the Committee with additional context for [redacted] description of the transportation data. Her statements were based on the following data points for the timeframe of January 1, 2016 through December 31, 2020, which she reviewed in anticipation of her interview:

Total Cases.....1,479

Transportation Event, Total 37

Transportation Event, Air, Commercial.....14
Transportation Event, Air, Charter/Private.....7
Transportation Event, Ground 16

Transportation Event, Organ Discard 13

This reporting of 37 transportation events out of 1,479 total events in the five-year period served as the basis for [redacted] statement that they constituted about 2% of cases (more precisely, about 2.5%). Of those 37 cases, 14 were classified as involving commercial air transportation, 7 were classified as involving private or chartered air transportation, and 16 were classified as involving ground transportation. Of the same 37 transportation events, 13 involved an organ discard.

Another data question arose during [redacted] interview. We can confirm that the data presented to the Ops & Safety Committee in the April 2021 report that [redacted] identified were also provided to HRSA.

Finally, you have identified documents related to several individual incidents and asked whether any additional documents from UNOS's production are relevant to the Committee's understanding of those incidents. We expect that the materials produced today, including training materials for UNOS's Member Quality staff and details on the OPTN's operational rules, may further assist the Committee in understanding how those incidents were reviewed and handled by UNOS staff. If the Committee continues to have questions about these matters after reviewing the materials from today's production, we would be happy to try to address them.

* * * * *

Today's production and our related correspondence also include confidential and proprietary UNOS business information, as well as, in some instances, sensitive personal information. We respectfully request that these materials, including this letter and our other correspondence with the Committee and its staff, be treated as confidential Committee records in accordance with Standing Rule of the Senate XXIX, clause 5; that they be afforded the fullest protection available by law and policy; and that they be treated as confidential and exempt from disclosure beyond the Committee. Accordingly, we have stamped each page of this production as "Confidential." The production of any privileged or otherwise protected information which is not responsive to the Subpoena is unintentional, and we request the prompt return of any such information if identified or upon our request. We further request that confidential treatment be accorded to any notes, memoranda, or other records created by or at the direction of the Committee or employees that reflect, refer, or relate to this letter or to any portion of the enclosed productions.

Please promptly inform me, at the address and phone number listed above, of any request seeking access to the documents or any of the above-mentioned records, including this letter, to enable us to substantiate the grounds for confidential treatment, unless the Committee intends to deny such request for access. At the conclusion of the Committee's review of the enclosed documents, we request that all copies be returned to me at the address above.

If you have any questions regarding the enclosed materials or any issues relating to this matter, please do not hesitate to contact me.

Respectfully submitted,

John S. Moran

John Moran

Counsel to United Network for Organ Sharing

Cc: [redacted]